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Manual of Operations and Standard Operating Procedures

NRG Oncology

Biospecimen Bank- San Francisco

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MOO Table of Contents

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- 1. Background:**
 - 1.1 Mission Statement
 - 1.2 History of the Biospecimen Bank
 - 1.3 Biospecimens in the Legacy RTOG Biospecimen Bank
 - 1.4 Patient Consent and Confidentiality
 - 1.5 Data in the Biospecimen Bank & Custodianship of Biospecimens
- 2. Organization of the NRG Oncology Biospecimen Banks**
 - 2.1 Biospecimen Bank Participants
 - 2.2 GBC Steering Committee and Subcommittee Participation
 - 2.3 Research Evaluation Panels
 - 2.4 The Data Centers
- 3. Personnel-NRGBB-SF Bank**
 - 3.1 Training
 - 3.2 Key Personnel and Duties
- 4. NRG Facilities- NRGBB-SF Bank.**
 - 4.1 Facilities:
 - 4.2 Equipment
 - 4.3 Monitoring
- 5. NRG Safety Requirements- NRGBB-SF Bank**
- 6. NRG Oncology Specimen Collection- NRGBB-SF Bank**

- 7. Utilization of NRG Oncology Materials- NRGBB-SF Bank**
 - 8. Quality Assurance and Quality Control- NRGBB-SF Bank**
 - 9. Informatics: Data Management and Security for the NRG Biospecimen Bank- SF**
 - 10. Human Subjects**
 - 10.1 Policies and Procedures for Protecting Human Research Subjects**
 - 10.2 Informed Consent**
 - 10.3 Guidance Regarding Patients Who Refuse to Consent**
 - 10.4 Policy for IRB Approval of Research Projects**
 - 10.5 HIPAA Requirements in Disclosure or Use of Protected Health Information**
 - 10.6 Transfer of Specimens to Third Parties**
 - 10.7 Certificates of Confidentiality**
 - 11. Disaster Plan, Emergency Procedures and Biorepository Safety SOPs**
 - **SA-1 BioSafety**
 - **SA-2 Fire and Evacuation Plan**
 - **SA-3 Employee Training and Orientation**
 - **SA-4 Prevention of Ergonomic/ Repetitive Motion Injuries**
 - **SA-5 Chemical Hygiene Plan**
 - **SA-6 Electrical Safety**
 - 12. Standard Operating Procedures**

SOP-NRGBB-SF-01	Pathology Specimen Processing and Receiving
SOP-NRGBB-SF-02	Fresh Tissue Processing
SOP-NRGBB-SF-03	Blood Processing/Receiving
SOP-NRGBB-SF-04	Storage of Pathology Materials
-

SOP-NRGBB-SF-05	Return Requests
SOP-NRGBB-SF-06	Pathology QA review
SOP-NRGBB-SF-07	Central Review
SOP-NRGBB-SF-08	TRP Outgoing Requests
SOP-NRGBB-SF-09	TMA Creation
SOP-NRGBB-SF-10	Specimen Tracking IT
SOP-NRGBB-SF-11	Emergency Action Plan
SOP-NRGBB-SF-12	Kit Requests
SOP-NRGBB-SF-13	Aperio Slide Scanner and Scanscope

13. Appendices

A1: NRG Oncology MTA form

A2: NRG Oncology Specimen Transmittal Form

A3: NRG Oncology Material Log Sheet

A4: UCSF Committee for Human Research Approval Letter

A5: NRG Oncology UCSF STARS Database Entry

A6: Notification of Materials Received Document

1. Background:

1.1 Mission Statement

The NRG Oncology Biospecimen Bank- San Francisco (NRGBB-SF) is located in the department of Radiation Oncology at the University of California San Francisco. The bank is one of three NRG central repositories of biospecimens collected from cancer patients enrolled in new NRG and legacy RTOG clinical trials. The mission of the NRG Biospecimen Banks is to receive and store biospecimens in a standardized manner such as to maximize the potential use of the material for current and potential research studies and to do so within the NCI Best Practices for Biospecimen Banks. Samples, including stained and unstained slides, tissue blocks, frozen and fresh tissue and fluids like plasma or serum from various disease sites are stored at the NRG Biospecimen Bank. Extensive clinical follow-up data exist on the patients through the NRG Oncology Statistical Group. The aim of the Biospecimen Bank is to provide annotated patient samples to qualified investigators who have significant research hypotheses that require the use of such specimens. De-identified samples are distributed to qualified outside researchers who comply with Biospecimen Bank access policies and are funded to carry out projects.

1.2 History of the Biospecimen Bank

NRG Oncology is a newly constituted National Clinical Trials Network (NCTN) Group created through the coordinated efforts of the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Radiation Therapy Oncology Group (RTOG), and the Gynecologic Oncology Group (GOG). These 3 legacy cancer cooperative groups (CCG) have over 150 years cumulative experience in the conduct of practice-defining, multi-institutional, Phase II and Phase III trials supported primarily by the National Cancer Institute (NCI). The new NCTN group, **NRG Oncology** (NRG), leverages the unique capabilities and experience of NSABP, GOG, and RTOG as a foundation for innovative late-stage clinical trials and translational science (TS) across 7 major cancer disease sites, including gender-specific, rare, and under-studied cancers. Specifically, NRG creates a synergy greater than the sum of the 3 legacy groups to improve the lives of adult cancer patients burdened with localized or locally advanced disease through the conduct of practice-defining clinical trials. Each legacy group has been supported by comprehensive biospecimen banking operations that have close operational links with the group statistics and data management center (SDMC) and the TS program. In April 2015 the 3 legacy biospecimen banks merged into the new NRG Oncology Biospecimen Bank based in San Francisco CA, Columbus OH and Pittsburgh PA. The legacy RTOG bank has been housed at UCSF since 2008 and under the direction of Dr Richard Jordan since 2011. Prior to 2008 the bank was housed at LDS Hospital under the direction of Liz Hammond. The bank has tripled in size since 2008 primarily due to increased numbers of patients enrolling in RTOG and NRG trials but also due to a significant effort to optimized biospecimen collection in the clinical trial protocols.

1.3 Biospecimens in the Legacy RTOG Biospecimen Bank

Biospecimens in the legacy RTOG tissue bank consist of tumor tissue from formalin fixed paraffin embedded (FFPE) tumors as well as frozen biospecimens collected primarily from patients at pre-treatment as well as some timepoints during and post treatment. The frozen biospecimens are

primarily Plasma, Serum, Whole Blood or Buffy Coat. A vast inventory of Urine samples have also been collected primarily from GU and Brain patients.

As of March 31st, 2015 there are 93,943 specimens from 34,394 cases with a total of 514,261 biospecimens being housed in the San Francisco Bank.

1.4 Patient Consent and Confidentiality

All biospecimens received by the NRG Oncology Biospecimen Bank are de-identified of all patient health identifiers and are enrolled in an approved NRG Oncology study. Each patient being enrolled by an institution has to qualify and consent to be part of the study before being assigned a case and study ID by the NRG Oncology Statistical Center. The enrolling institute identifies the patient using only the study and case ID when submitting specimens to the Biospecimen Bank. Individual patient consent forms are maintained and stored by the enrolling institution and there is no requirement for the Biospecimen Bank to receive these forms. However, all specimens received by the Biospecimen Bank must have had patient consent to tissue banking. No information containing specific patient health identifiers is maintained by the bank's STARS database which is primarily an inventory and tracking system. The specimen transmittal form also includes the Study # and Case #. If this information is missing then the Biospecimen Bank contacts the submitting institute to correct this before the specimens can be entered into the database and stored by the Biospecimen Bank. The procedure for returning specimens should the patient withdraw consent is outlined below in Section 3.

1.6 Data in the Biospecimen Bank & Custodianship of Biospecimens

All specimens received by the Biospecimen Bank must have had patient consent to tissue banking. No information containing specific patient health identifiers is maintained by the Biospecimen Bank STARS database which is primarily an inventory and tracking system.

- **Storage and Returning of Specimens:**
The NRG Oncology Biospecimen Bank- SF is located at University of California San Francisco, at 2340 Sutter Street rm S341, San Francisco, CA 94115. UCSF is accredited by the College of American Pathologists (CAP) and The Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The Biospecimen Bank is located in a secure building at the UCSF Mt Zion Campus with access limited to Biospecimen Bank personnel. The specimens are stored in a cool, dry environment using normal specimen storing techniques.
- The NRG Oncology Biospecimen Bank- SF is supported by the National Cancer Institute to collect, store, and distribute these specimens. The specimens will be stored for an indefinite period of time.
- If at any time the patient withdraws consent to store and use their specimens, they will be returned to the institution that submitted them, provided any specimen are left in storage. The specimen also will be returned within 24-48 hours if needed for patient, physician, or legal reasons. Patients should contact the institution that enrolled them on

the clinical trial. The institution will supply the study and case numbers, which will allow retrieval of the specimens. These requests should be sent by email (NRGBB@UCSF.edu) or by fax (415-476-5271) to the NRG Biospecimen Bank Manager at UCSF.

- **Accessibility to Specimens:**

The Biospecimen Bank will permit the study of cases entered on NRG oncology clinical trials by any qualified investigator making an application to the group or to the Biospecimen Bank via an Intergroup. The NRG Oncology Translational Research Committee, which decides whether specimens can be allocated for the project proposed, reviews all applications. All applicants will eventually be required to request samples through the NCI funded Navigator Project.

In the years to come, there may be development of new technology that will help us to learn more about cancer. Therefore, specimens are retained for future unspecified projects. As part of the consent process, patients can agree whether they would permit such use or whether they would like to be contacted before such use occurs. When a new technology or test is performed, only those cases having appropriate permission will be utilized.

- **Biospecimen Data Accessibility**

The only data released from the Biospecimen Bank is the number of specimens available for aggregated cases on each clinical trial. No case specific information is released except to the NRG Oncology central office, where all other information about each patient is stored and maintained. NRG Oncology maintains specific security measures approved by the National Cancer Institute for protection of patient-specific information. There is never a name or any other identifier given with this information and no clinical information is available for release.

The patient will NOT experience a medical benefit from this research. The Biospecimen Banks allow research to be performed on clinically standardized patient populations that may give us important information about prognostic factors, treatment selection factors, and biologic behavior. Cancer patients in general may benefit because the results of research may change treatment for cancer patients in the future.

2. Organization of the NRG Oncology Biospecimen Banks

2.1 Biospecimen Bank Participants

NRG Oncology is a newly constituted National Clinical Trials Network (NCTN) group created through the coordinated efforts of the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Radiation Therapy Oncology Group, and the Gynecologic Oncology Group (GOG). These three legacy cancer cooperative groups have over 150 years of cumulative experience in the conduct of practice-defining, multi-institutional phase II and phase III trials supported primarily by the National Cancer Institute (NCI). The three banks will be responsible for banking the tissue specific samples based on their expertise and legacy banks. The San Francisco Bank will be banking CNS, GI (non-colorectal), GU, Head and Neck and Lung tumors. The Pittsburgh bank will be banking Breast and Colo-rectal GI tumors and the Columbus bank will be banking Gynecological tumors.

2.2 GBC Steering Committee and Subcommittee Participation

All NRG Oncology Biospecimen Bank directors participate on the GBC Steering Committee and attend the semi-annual face to face meetings. The GBC Subcommittees include the Best Practices and Operations, Informatics, Access and Marketing and Regulatory.

All NRG directors, Biospecimen Bank managers and IT managers participate on selected subcommittees.

2.3 Research Evaluation Panels- Described in Chapter 7 of MOO

2.4 The Data Centers

NRG Oncology biospecimen data is stored in the NRG Oncology STARS informatics system. The NRG oncology statistical and data management center is able to link patient information to the STARS data. The Biospecimen Bank has no direct access to the data center.

3. Personnel-UCSF Bank

3.1 Training

As described in the NRG Oncology MOO all members of the SF Biospecimen Bank are required to read and sign off the Emergency Action Plan (SOP-11) and all of the safety training (SA 1-6) in its MOO. In addition, each of the NRGBB-SF SOPs (1-13) have a separate section covering protocol specific safety precautions listed in the GBC MOO.

UCSF has online training that is update annually or bi-annually. The Biospecimen Bank Manager is responsible for making sure all staff are up to date on their required training.

3.2 Key Personnel and Duties

3.2.1 Director of Biospecimen Bank Operations

The Director is responsible for administration and operation of the NRG Oncology Biospecimen Bank- San Francisco. The Director's role will include organization and oversight to ensure that acquisition, storage, processing, and disbursement of tissues occurs without loss or waste, that there is immediate and central computerization of the tissue and that concept development includes consideration of pathologic/histologic issues and methodology. The Director will be available for discipline pathology review to determine tissue adequacy and to guide methodology such as block trimming or micro-dissection.

3.2.2 Biospecimen Bank Operations Manager

The Supervisor/Manager is responsible for day-to-day operation of the Biospecimen Bank, as well as supervision and training of the tissue bank staff. The Supervisor/Manager is responsible for overall management of the specimen collection and data entry, preparation of fixed and frozen tissues, and processing of blood and body fluids, cells, and intercellular products. The Supervisor/Manager assists in development of protocol, SOPs, MOO, and policies in implementation of scientific worksopes, and review of scientific proposals intending to use materials from such biorepository.

The Supervisor/Manager also assists in overall quality assessment and assurance processes, works closely with the Director, and participates in designated/assigned CGB Committees.

3.2.3 Senior Research Technologist/Pathology Coordinator

The Research Technologist should have extensive experience with histology, digital image technology and familiarity with online clinical trials operation and databases. The Technologist provides laboratory maintenance and support, maintains records, maintains attention to regulatory requirements, apply molecular biology laboratory techniques and procedures, train technicians, assist in development and implementation of SOPs and MOO, and perform other duties as assigned. They also will be available to help the manager with responding to various inquiries relating to protocol activities, entering data into appropriate databases, and other assigned duties.

3.2.4 Lab Assistants

The Biospecimen Bank Lab Assistants perform routine and semi-complex processing of blood and other fluid, following procedures outlined in the applicable SOPs and MOO, enter data into databases, help with outgoing kits and outgoing biospecimens.

3.2.5 Informatics Support

The Biospecimen Bank is supported by the UCSF Translation Informative Director and one Informatics and database specialist. STARS support is provided by the NRG Oncology STARS team at Columbus.

4. NRG Facilities- UCSF Bank.

4.1 Facilities

The NRG Oncology Biospecimen Bank- SF is located in the Department of Radiation Oncology at University of California San Francisco, at 2340 Sutter Street rm S341, and at 1657 Scott Street, San Francisco, CA 94115. The Biospecimen Bank is located in secure buildings at the UCSF Mt Zion Campus with access limited to Biospecimen Bank personnel.

4.2 Equipment

The UCSF Biospecimen Bank storage capabilities includes an Aperio Digital scanner, Fourteen -80°C Freezers, six 4°C Refrigerators, one -20°C freezer, one fridge/freezer, two cabinets for saliva samples, 30 racks for stained slides, and 18 Racks for blocks.

The Biospecimen Bank has a tissue micro array machine, biological hood, fume hood, staining area and full access to histology services in the UCSF Cancer Center Tissue and IHC cores.

4.2.1 Back up Equipment

One backup -80°C freezer is available to the Biospecimen Bank with additional units in other departments in the same building.

4.2.2 Maintenance

Daily inspection of all equipment is performed and documented. Annual maintenance contracts are in place for all -80°C Freezers. All repairs are documented.

4.3 Monitoring

The NRG Oncology Biospecimen bank has protocols for biospecimen storage conditions (SOP-04) and an emergency backup plan (SOP-11) which covers back-up power requirements. All -80°C Freezers are monitored using a wireless "Accsense" system which is accessed over the web. This system also acts as an alarm when issues arise such as loss of power or equipment malfunction or alarm set points are reached. The system also records the temperature of the freezers and the data is exported monthly for record keeping.

Trained personnel are available 24 hours per day, 7 days per week to take corrective action. Emergency contact information for other key personnel is available and is posted on the -80°C Freezers.

4.3.3. Power Failure

In the event of power failure the UCSF backup generator is activated. In the event the generator fails Twelve of the -80°C Freezers are backed up by a LN2 tank. Two freezers containing Urine are backed up with CO2 tanks. All personnel are trained in processes and techniques for rapidly transferring material to backup units when necessary.

5. NRG Safety Requirements- UCSF Bank

UCSF Environmental Health and Safety (EH&S) oversees the safety requirements for the Biospecimen Bank. An EH&S designated safety officer oversees and inspects the lab and maintains compliance. The Biospecimen Bank manager is responsible for the day to day general safety in the bank.

All employees are required to take Blood-borne Pathogen, Chemical, Fire, General Lab Safety, BSL2 and safe shipping training annually or every two years as indicated by UCSF. Records are kept electronically and are monitored by EH&S for compliance.

All staff members are encouraged to be vaccinated against hepatitis. A copy of the vaccination record or notice of declination is kept for an extended time (30 years) by the University.

5.1 Biological Safety

All biospecimens derived from humans whether fresh, frozen, fixed, paraffin-embedded, or freeze-dried should be considered as biohazardous. Thus, all human specimens independent of their state should be treated with universal precautions, i.e., should be handled as if infected with agents that may be pathogenic to humans.

Universal precautions involve the use of protective barriers such as gloves, gowns, aprons, masks, or protective eyewear, which can reduce the risk of exposure of the health care worker's skin or mucous membranes to potentially infective materials. In addition, under universal precautions, it is recommended that all workers take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices.

The US regulation 29 CFR Part 1910.1030 "Occupational Exposure to Blood-Borne Pathogens" addresses requirements for organizations to protect against one type of biohazard. Any

organization which deals with human biospecimens must meet the requirements of this regulation. The UCSF biological safety program is outlined below:

- Implement and maintain an overall safety program and training programs related to biohazards.
- Identified risks include biological fluids and blood borne pathogens. All work involving this is performed in an approved location.
- Review annually the biological use authorization for the Biospecimen Bank.
- Review all incidents and modify the safety plan to prevent similar incidents from occurring in the future.
- Implement the UCSF training program with the major focus of biosafety and maintenance of employee training records.
- Preventative vaccinations against hepatitis B are available
- UCSF Needlestick program is available for all employees exposed to blood-borne pathogens.

5.2 Chemical Safety & Chemical Hygiene Plan- See SOP SA5 in chapter 11

The UCSF BB has limited access to chemical exposure. A full chemical inventory with MSDS sheets is on file with the UCSF EH&S and is available to all employees. All employees are required to read MSDS before using a new chemical. Written SOPs for use of potentially hazardous chemicals as identified by UCSF EH&S are in place. Emergency plans for spills are listed in SOP "Emergency Action Plan". All employees have access to personalized PPE as mandated by the University of the President. This includes barrier and regular lab coats, gloves, safety glasses and goggles, safety shields and cold temperature protective gloves

5.3 Electrical Safety- See SOP SA-6 in chapter 11.

5.4 Fire Safety- See SOP SA-2 in chapter 11

5.5 Physical Safety- See SA-4 "Prevention of Ergonomic/ Repetitive Motion Injuries" in chapter 11

5.6 International Air Transportation Association (IATA) Shipping

All UCSF employees are trained in Safe Shipping of hazardous materials and are retrained every 2 years.

Regulations governing the transport of dangerous goods in the US are found in 49 Code of Federal Regulations (49CFR). The US Department of Transportation (DOT) has the responsibility of developing and refining hazardous materials regulations (HMR). Many International Civil Aviation Organization (ICAO) Technical Instructions have been incorporated into US law. Dangerous goods shipments involve certain risks with the potential for both criminal and civil liabilities. Proper training and compliant shipping can greatly reduce the risk of incurring very high fines and civil suits with no upper limit. Dangerous goods regulations require that a test be completed. SAFTPAK™ offers current compliance training and a competency exam.

6. NRG Oncology Specimen Collection- SF Bank

These are listed in Chapter 12: SOPs 1-13.

7. Utilization of NRG Oncology Materials- SF Bank

All utilization of material has to be approved. The regulations for the SF bank are listed in Chapter 12: SOP-8

8. Quality Assurance and Quality Control- SF Bank

As described in the GBC MOO, the NRG Oncology Biospecimen Bank- SF trains all personnel how to process and handle incoming specimens to preserve them in the best possible method as listed in NRGBB_SF SOPs 1, 2, 3, 4, 12. Quality control and assurance is routinely performed for pathology materials as outlined in SOP 6. In addition, each of the NRGBB_SF SOPs (1-13) include separate quality control sections, each of which is protocol specific.

9. Informatics: Data Management and Security for the NRG Oncology Biospecimen Bank- SF

Data management, tracking and network security issues and precautions are included in the NRGBB-SF MOO Chapters 4 and 5 and 12: SOP-10 and as outlined below.

9.1 Security:

The CCRC Informatics Core oversees access to the STARS database and the NRG Biospecimen bank network data storage. This access is controlled and is limited to authorized users. User logons and access rights are requested by the NRG biospecimen bank- SF manager, who makes requests that users are added and removed from access for the database and network shares. Access to the main STARS specimen database is secured using a separate logon than the logon used to access the workstations. The security for the NRGBB-SF STARS database is accomplished by the use of username/passwords and roles. A username/password combination is assigned to each user of the system. A role is then assigned to each user giving them privileges to perform certain operations on the system. All users must be fully trained for HIPPA compliance by an institutionally mandated training program.

9.2 Data Protection:

All biospecimen bank data is stored and accessed through a dedicated server maintained by the CCRC Informatics Core. Data is backed up on a daily basis, and is stored on redundant (RAID) hard drives. Secured offsite storage of backup media is used (Iron Mountain) With a 3 week rotational period, with 2 weeks of media stored in a secured location offsite at all times. Disaster recovery plans are currently being rewritten for the CCRC Informatics service as we have recently relocated

9.3 Database Location:

The NRGBB-SF Stars server is located in a locked and secured data rack in the CCRC Informatics core. Appropriate physical and network measures are employed to ensure security of both the server itself and the data it holds. Access to the equipment room is

limited and auditable and is restricted to support staff only. All system maintenance and troubleshooting is handled by the CCRC informatics core.

9.4 Data Access Controls:

Access to the specimen tracking system is controlled by HIPPA-compliant user logins administered by the CCRC Informatics Core. Passwords must use 2 of the 3 special character categories, capital letters, numbers, and symbols, and cannot use parts of the user's name, and must be changed every 90 days as per institutional HIPPA rules. Only the technicians and Investigators authorized have system access. Any users that use the specimen tracking system must be approved by the NRG Biospecimen Bank- SF Manager and then access will be granted by the CCRC Informatics Core.

The Biospecimen Bank's STARS system is not accessible to outside users over the internet.

9.5 Data Sharing:

No data is accessible to outside users and there is no patient personal health information stored in our database other than that allowed by our local IRB. This may include patient initials and pathology accession numbers.

9.6 HIPPA protection:

All HIPAA security procedures for data/servers are maintained by the informatics core personnel. There is no personal health information stored in our database.

9.7 STARS Data Entry Procedures

Entering Specimens in STARS- See Appendix V

STARS protocol for removal of biospecimens from Inventory- See Appendix V

10. Human Subjects

10.1 Policies and Procedures for Protecting Human Research Subjects

The Cooperative Group Banks (CGBs) established operating policies and procedures that protect participating patients from whom specimens are obtained. These policies and procedures are consistent with current regulations and guidance for United States (US) and Canadian biorepositories from the Office of Human Research Protections (OHRP) in the Department of Human and Health Services (DHHS, www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm). The following policies and procedures govern collection of specimens and their distribution to research investigators:

- Specimens are normally derived from material removed as part of routine medical care. All specimens are collected in accordance with state and local laws. The majority of tissues are collected as part of a clinical diagnostic procedure, although in some instances, such as in frozen tissue, residual material not needed for patient care is collected for research.
- NRG Oncology Biospecimen Bank-SF has UCSF IRB approval for collections and storage of samples collected from NRG trials. A copy of the IRB letter is located in Appendix A4.

- Specimens are assigned unique codes and all NRGBB-SF employees have signed an agreement to protect patient privacy and confidentiality. Each Biospecimen Bank employee is trained in human subjects, IRB/REB, and Health Insurance Portability and Accountability Act (HIPAA) issues and regulations.

NRGBB-SF actively participates in national discussions of the legal and ethical issues relating to the research use of human specimens. NRGBB-SF will continue to review procedures for compliance with applicable regulations and for consistency with any emerging consensus about the ethical collection and use of specimens for research.

10.2 Informed Consent

NRG Oncology requires a signed informed consent document for the receipt and research use of specimens. Specimens and information from patients who decline to have their specimens used in research are not so used. In addition, a patient who consents to have specimens used in research may change his/her mind at any time. In such a case, if specified by the patient specimens still held by the NRGBB-SF will be destroyed or returned to the institution and not used in research; however, specimens already distributed to researchers will not be recalled.

Uniform CGB Consent Form

The Group Banking Committee (GBC) Regulatory Subcommittee has developed a uniform CGB consent form, CGB Informed Consent to Participate in Specimen Banking and Human Specimen Research. The CGB Patient Information Brochure was developed by the GBC Regulatory Subcommittee to be used by the patient as a guide and explanation to the Informed Consent Document. The GBC Regulatory Subcommittee has developed the CGB IRB Information Sheet explaining the CGB common Informed Consent for institutional IRBs.

The OHRP has determined that coded specimens and information with signed agreements by the investigators and an inability to contact the patient do not constitute human subject research (August 10, 2004 guidance). However because of undefined future research, the GBC Steering Committee has made a collective decision to require informed consent from individual patients. Access and use guidelines have also been produced, and include IRB/REB review and approval of proposed research to ensure that it fits the selected preferences of each individual. The intent is to respect our patients, and allow a degree of autonomy through their ability to generally choose how their specimens may be used.

10.3 Guidance Regarding Patients Who Refuse to Consent

If a patient refuses consent for their specimens to be used in future research, this refusal applies to all specimens and associated information in the CGB and no specimens or information should be used for future research. This also applies to diagnostic blocks, and the NRGBB-SF will return the blocks when requested by the site.

10.4 Policy for IRB Approval of Research Projects

Any researcher who intends to use specimens from a CGB must submit an application to NRG Oncology and then to CTEP. Every application is carefully reviewed by expert scientific committees, and if approved, by the researcher's IRB/EC. The IRB/EC ensures that patient's rights are protected.

10.4.1 Material Use Agreement

Specimens and associated data are only released to researchers whose studies have been approved by CTEP and reviewed by the researcher's IRB/REB. Additionally, any researcher receiving specimens from NRG oncology must sign a written Material Use Agreement (MUA) developed by the GBC. The MUA is signed with the Cooperative Group and acknowledges that the recipient agrees to comply fully with all regulations, use the specimens in accordance with the conditions stipulated by the bank's IRB/REB, and to promptly report to the bank any proposed changes in the research project and any unanticipated problems involving risks to subjects or others.

10.4.2 Requirements for Material Use Agreement

The DHHS issued the HIPAA Privacy Rule on August 14, 2002 (www.hhs.gov/ocr/). The Canadian equivalent of the Common Rule is known as the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. The Privacy Rule is a federal regulation that governs protection of individually identifiable health information. The Rule was enacted to increase the privacy and confidentiality of health information on identified individuals, and to regulate known and unanticipated risks to privacy that may accompany the use and disclosure of such information. The Privacy Rule does not apply to specimens per se, but does apply to some of the health information that may be provided with the specimen. NRG oncology protects the identity of patients from whom specimens are obtained. However, the Privacy Rule imposes new requirements on the use of information associated with the specimens.

In order to meet the requirements of the Privacy Rule, NRG oncology requires that each researcher signs a MUA in order to receive specimens with associated data. NRGBB-SF follows all HIPAA and UCSF institutional policies.

The MUA permits researchers to receive specimens and associated specimen information from NRG Oncology. Researchers who require patient information beyond that which is routinely provided or clinical outcome data shall work with the NRG oncology statistical and data center. The NRGBB-SF does not maintain or provide patient clinical information.

10.5 HIPAA Requirements in Disclosure or Use of Protected Health Information

Any plan to meet HIPAA requirements must consider the implications of the HIPAA accounting requirements regarding patient data exchange in the CGB operations. The exchange of information between NRG Oncology and the specimen recipient of the information is possible because of a Limited Data Set. The MUA does not require patient authorization or a waiver of authorization. The Limited Data Set and the MUA do not require records of disclosure. NRGBB-SF will use the Limited Data Set and MUA to distribute specimens and information on consented and HIPAA authorized patients.

10.6 Transfer of Specimens to Third Parties

NRG specimens are intended to be utilized by laboratory and/or personnel that fall under the supervision of the researcher listed in the application. The researcher and his/her institution shall sign the NRG Oncology MUA. Any transfer of specimens or aliquots to personnel or laboratories that are not under the supervision of the indicated researcher requires the following:

- An explanation of the need to transfer the specimens and benefit to the researcher's research
- A copy of the enclosed NRG agreement page signed by the collaborator

- A copy of the collaborator's IRB, approval unless the collaborator is covered under the IRB approval granted for the project proposed in this application.

10.7 Certificates of Confidentiality

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure (<http://grants1.nih.gov/grants/policy/coc/index.htm>). They allow the investigator and others with access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting research investigators and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants.

The National Cancer Institute contact for information pertaining to Certificates of Confidentiality can be reached at www.mj62n@nih.gov. NIH institutes have been delegated the authority to grant Certificates of Confidentiality. The certificates apply to any data collected from the time of issuance onward and are valid indefinitely. Even after the certificate is expired, data will continue to be protected. All patients covered by Certificates of Confidentiality must have the conditions of the Certificate of Confidentiality explained to them

11. Disaster Plan, Emergency Procedures and Biorepository Safety

NRG Biospecimen Bank- SF understands the importance for a complete disaster plan, and this is included in Chapter 12: SOP 11: Emergency Action Plan. Each member of the Biospecimen Bank reads and signs the EAP.

11.1 NRGBB-SF Safety SOPs are included following this page

SA-1: NRG BB-SF- LABORATORY BIOSAFETY

SOP Number: NRG BB-SF-SA-1
Author(s): Sandy DeVries

Version: 7.0
Effective Date: 4/1/15

PRINCIPLE/PURPOSE

To delineate the key principles of processing and working safely with hazardous biospecimens. The purpose is for all employees to understand the risks, and to minimize exposure to these hazards.

PROCEDURE

A. Responsibilities

1. Employees must
 - a) Complete UCSF online training courses: BSL2-training and Bloodborne Pathogen training, and update training annually.
 - b) Be alert in recognizing hazards of working with biospecimens
 - c) Assume all biospecimens are potentially infectious and biohazardous
 - d) Have access to Hepatitis B Vaccine
 - e) Understand the importance of calling the Needle Stick Hot line in the event of an exposure.
 - f) Process all unfixed biospecimens according to UCSF BSL-2 handling protocols including:
 - Wear all PPE- gloves, lab coat, eye goggles.
 - Only receive and process specimens in the BSL2 room- #E220
 - Report any leaks or spills to the manager to discuss correct cleanup/disposal
 - Work in the Biological safety cabinet when at all possible, or if there is risk for splashing.
 - Wash hands frequently and before exiting room.
 2. Supervisor or senior employee on duty responsibilities
 - a. See that the procedures delineated in this plan are followed.
 - b. Ensure employees have access to Hepatitis vaccine
 - c. Maintain copies of training records
 - d. Follow up on all exposure events
-

B. Spill Procedures

In the event of a biohazardous spill the following serves as a guideline how to proceed

- a) Notify supervisor of spill to decide if Environmental Health and Safety is needed to help with clean up or if it is a contained spill that Biospecimen Bank staff can take care of
- b) Make sure all PPE is being worn, and double glove.
- c) Soak up liquids using absorbent paper.
- d) Discard all packing material and clean up material in biohazardous waste.
- e) Dispose of all broken sharps in hard sided Red Sharps containers
- f) Wipe down area of spill with a 10% bleach solution or use 100% ethanol in stainless steel Biosafety cabinets.

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPATH		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

NRG BB-SF LABORATORY FIRE AND EVACUATION PLAN

SOP Number: NRG BB-SF-SA-2
Author(s): Sandy DeVries

Version: 7.0
Effective Date: 4/1/15

PRINCIPLE/PURPOSE

To delineate the fire and evacuation response plan for the laboratory and address specific employee responsibilities and expected actions in the event of a fire and/or need for evacuation in their work area.

PROCEDURE

A. Responsibilities

1. Employees must
 - a. Be alert in recognizing fire hazards and practicing fire prevention.
 - b. Keep passageways and work areas around fire extinguishers and exit doors clear at all times.
 - c. Report extinguishers that appear to have expired, been used, or been tampered with, to facilities department.
 - d. Know the location of fire equipment; evacuation plans for the work area, emergency phone numbers and department emergency action plan.
 - e. Know how to use all fire equipment.
 - f. Know the specifics for their role as outlined within this plan.
 - g. Complete mandatory fire and evacuation testing.
 - h. Attend hands on fire extinguisher training.
 - i. Participate in a fire drill.
2. Supervisor or senior employee on duty responsibilities
 - a. See that the procedures delineated in this plan are followed.
 - b. Check all areas of the lab before evacuating the lab and provide assistance for people with disabilities when necessary.

B. When the fire alarm system in your area is activated.

1. Do not pull alarm station.
 2. Check area smoke detectors to find one that has been activated.
 3. When/if an activated detector is found, try to locate the cause.
 - a. Always feel doors before opening them.
-

- b. If fire or smoke is found, or a door is hot, proceed with the RACE steps
- C. If you SMELL smoke call facility emergency number. Areas outside facility call building security.
- D. If you SEE smoke or flames - Implement **R-A-C-E-R** in your area.
 - 1. **RESCUE**
 - a. Rescue persons in immediate danger. Lend assistance and remain calm.
 - b. Evacuate all employees, and check drawing rooms, special procedures rooms, lab lounges, conference rooms and rest rooms. Provide assistance for people with disabilities.
 - c. Never use the word "fire" around patients and visitors.
 - 2. **ALARM** -Sound the alarm.
 - a. Go to the nearest alarm and pull handle. (See procedure notes)
 - b. ALSO call facility emergency number and give fire location and the nature of the situation. Areas outside facility call 911.
 - c. Code Red location will be paged overhead.
 - d. If no alarm system call emergency number.
 - 3. **CONTAIN** - Close all doors and windows in the area.
 - 4. **EXTINGUISH** - NEVER USE AN EXTINGUISHER ON A PERSON; USE A BLANKET OR HAVE THEM DROP AND ROLL.
 - a. Obtain the nearest fire extinguisher and fight the fire. If the size of the fire causes you to question your ability to extinguish it – don't! The facility fire brigade will fight the fire until the city fire department takes over.
 - b. When using a fire extinguisher, remember **P-A-S-S**. (Also see procedure notes)
 - PULL** - Pull the retention ring. You must break a plastic seal to remove the ring.
 - AIM** - Aim the extinguisher at the base of the fire.
 - SQUEEZE** - Squeeze the extinguisher handle to discharge the spray.
 - SWEEP** - Extinguish the fire in a sweeping motion.
 - 5. **RELOCATE** - personnel away from the fire.
 - a. Always consider horizontal evacuation first, then vertical evacuation as instructed by those in your command center.
 - b. Follow department plans for supplies needed when relocating.

H. Evacuation

1. Lab management will check to be sure that all employees have been evacuated.
2. Following evacuation, all employees are to congregate in the designated area for their site.-
Corner of SUTTER and Scott Street

PROCEDURE NOTES

A. Fire alarm station:

1. Lift or open any cover over the alarm station if present.
2. Place your fingers on the ledge indicated and pull down (or push in) until you feel it click.
3. The ledge should remain in this down (in) position until the firemen come to release it.

B. Fire extinguishers

1. Types and uses of fire extinguishers
 Class ABC - May be used on any fire.
2. Because of the weight of the fire extinguisher it is best to set it on the ground when attempting to pull the pin, the pin cannot be removed if the handle is being squeezed.
3. Extinguishers make a loud noise, be prepared.
4. Extinguishers build up STATIC electricity during use. Never touch someone using an extinguisher.
5. The hose/horn of an extinguisher gets very cold. Handle only rubber parts.
6. Extinguishers are effective for 18-30 seconds depending on their size. USE THEM EFFECTIVELY, spray low.
7. Never use an extinguisher on a person.

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPath		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

NRGBB-SF EMPLOYEE TRAINING AND ORIENTATION

SOP Number: NRGBB-SF-SA-3
Author(s): Sandy DeVries

Version: 7.0
Effective Date: 4/1/15

PRINCIPLE/PURPOSE

To ensure that all employees of the NRG Biospecimen Bank- SF are oriented and familiar with the University of California at San Francisco's safety regulations and required training. This SOP helps ensure that all UCSF required training is completed by all new employees.

PROCEDURE

A. Lab Safety Orientation:

We are committed to conducting our work efficiently and in a way that ensures the protection of workers, the public, and the environment. The Integrated Safety and Environmental Management System (ISEMS) integrates safety into work practices at all levels. "Each individual is directly responsible for ensuring his or her own safety and for promoting a safe, healthy and environmentally sound workplace and community."

EMERGENCY PHONE NUMBERS

For life-threatening emergencies or fire call from any UCSF land line: 9-911
For life-threatening emergencies or fire call from cell phones, SF County: 553-8090
Chemical/Biological/Radiological Spill 9-911
NeedleStick Hotline (24 Hour Pager): 9-719-3898
For non-life-threatening emergency, suspicious person sighting (UCPD): 9-911
For facilities/equipment emergencies call: 476-2021

EMERGENCY ACTION PLAN (EAP)

Before starting work in your lab you must read your Department Emergency Action Plan.

1. a. In a global emergency, that requires entire building to be evacuated, leave the building and proceed to your designated assembly area at: Bush and Scott.
 - b. In a local emergency, if you are in a high rise (over 6 floors) evacuate to 4 floors below your level. If the alarm is sounding on that level, evacuate to your designated assembly area.
 - c. Check in with your floor wardens, Michael Restrepo/Sandy DeVries before leaving assembly area.
2. In an emergency while you are alone in the lab or at home, or in an event that prevents you from coming back to work, such as earthquake, fire, power outage, call your Lab Manager or the UCSF Hotline, 502-4000.
3. Be familiar with Emergency Shutdown Procedures for your area. The procedures should be executed before evacuating the building only if it is safe to do so. Delegated individuals may be permitted into the building to perform shutdown.

4. KNOW THE LOCATIONS OF:

<u>Item</u>	<u>Location</u>
Emergency Exit	_____
Fire Extinguishers	_____
Fire Alarms	_____
Emergency Eye Washes	_____
Emergency Showers	_____
First Aid Kits	_____
Fire blankets	_____
Flashlights + batteries	_____
Emergency kit	_____
Chemical spill supplies	_____
Material Safety Data Sheets (contain important information on chemicals)	Bookmark the EHS website: http://www.ehs.ucsf.edu/MSDS/oehsmsds

5. If you are injured at work and require immediate attention call 9-911 or go to the Emergency Room. For other injuries inform your supervisor and determine if you need to call Occupational Health Services (885-7580). Complete Employee Incident Report and submit to Human Resources - Disabilities Management Services <http://ucsfhr.ucsf.edu/files/EIR.pdf>.

REPORT ALL ACCIDENTS AND HAZARDOUS SITUATIONS TO YOUR SUPERVISOR IMMEDIATELY.

B. Researcher Orientation Checklist

Name: _____ Lab PI: _____

University Orientation: (contact your Department Administration) Date _____

1. Obtain a university proxy ID badge and have it activated. _____
2. Obtain a lab coat and get an email account. _____
3. Complete mandatory HIPAA training. _____
<http://www.research.ucsf.edu/CHR/HIPAA/HIPAAtrng/hipaa1.HTM>
4. File Contact information with: _____
5. Sign out key(s)/codes(s) and activate proxy card. _____
Location _____

Basic Safety Training: <https://www.researchonline.ucsf.edu>

1. Request a Research On Line/RIO account: <https://www.researchonline.ucsf.edu/requestLogin.asp>.
2. Fill out the Mandatory Universal Hazardous Use/Training Form* _____
3. Check with your supervisor to determine which training you need:
 Lab Safety for Researchers _____
 Lab Safety for Assistants _____
 Radiation Safety _____
 UCSF Bloodborne Pathogen Standard Training _____
 Hazardous Waste Management _____
 Controlled Substances Safety _____
 Safe Shipper Training _____
 UCSF Human Subjects Protection Training _____
 UCSF Fire Safety _____
 Liquid Nitrogen Safety _____
 Ergonomics training _____
 BSL2 Training _____
 Animal training (see Animal Welfare page for details)...

4. Submit the appropriate forms to support your training (from <http://www.ehs.ucsf.edu>):
 Dosimetry Request Card _____
 Information for Authorized User of Controlled Substances _____

- Ask your PI or lab manager to request addition of your name to appropriate Hazardous Materials Authorizations (radioactive, biological & controlled substances) before performing any work.

Occupational Health Program (OHP) & Health Questions:

- If you work with patients or human samples, refer to attached document, Preparation for working with Human Patients or Tissues.

UCSF Policy Regulations

1. Obtain Material Transfer Agreements (MTA) to send proprietary reagents
2. Know how to keep proper lab notebooks by consulting this link
<http://www.otm.ucsf.edu/docs/otmLabProc.asp>
3. Be aware of University whistleblower policy: <http://whistleblower.ucsf.edu/>
4. Familiarize yourself with harassment policies: <http://www.ucsf.edu/oshpr/>

Overall Safety Check:

1. Emergency Action Plan I have read and understand the EAP
2. Emergency Phone numbers I know where these are posted
3. Basic Lab Safety Rules I have read and understand attached rules
4. Emergency Evacuation Route: my Dept/ neighborhood emergency assembly site

 Signature

 Date

Keep copies of all training records and your Research OnLine login and password.

C. Basic Lab Safety Rules:

All jobs are performed within the guidelines of the Illness and Injury Prevention Program (IIPP); Review <http://www.ehs.ucsf.edu/P&S/IIPP/oehsiPPManual.asp> before beginning work; tasks should be identified, the associated hazards evaluated, and a set of safety standards and requirements established. This is most easily done by performing a "dry run" in advance.

1. Be familiar with the hazards, handling procedures and disposal methods for all the chemicals you will be using in an experiment. Review Material Safety Data Sheet (MSDS) online and/or check with your Departmental Safety Advisor (DSA) <http://www.ehs.ucsf.edu/P&S/FindDSA.cfm>.
2. It is your responsibility to use appropriate Personal Protective Equipment: lab coats, gloves, protective eyewear, etc. for the work you are doing. Be familiar with appropriate PPE for the work you do and where it is located. It is highly required that ankle length clothing, knee-length lab coats and closed-toed shoes be worn in labs while experiments are being carried out. Lab coats are always required when working in BSL2/BSL3 labs, when handling radioactive materials and/or when working with hazardous chemicals.
3. Do not walk through office areas, conference, and eating rooms with lab coats or lab materials.

4. Lab Gloves should not come into contact with door handles, elevator buttons, or phones, etc.
5. Food or drink storage is allowed only in designated refrigerators. No eating or drinking is allowed in labs. No food or drink waste should be disposed of in lab trash cans.
6. If you handle human tissue or blood, prepare yourself by adhering to the guidelines in, "Preparation for Working with Human Patients or Tissues."
7. Liquid Nitrogen can cause severe burns. When handling it, use appropriate PPE: clothing, eyewear and gloves. It is highly recommended that users take the "Liquid Nitrogen Safety" course available through Research Online.
8. Phenol can cause severe burns. When handling it, work in fume hood with appropriate PPE: lab coats, goggles and gloves. Take extra precautions when working with phenol:chloroform mixtures, as chloroform can dissolve gloves, exposing skin to phenol burns. Please note: Neither nitrile nor latex gloves will provide adequate protection from phenol:chloroform exposure. EH&S recommends 8 mil ChemTek gloves (designed by Ansell Healthcare specifically for phenol:chloroform protection) available through Fisher Scientific.

Waste Disposal guidelines:

1. Needles, syringes, glass Pasteur pipets, razor blades and scalpels must be disposed whole in sharps container to be collected by EH&S.
2. Broken glass or other sharp objects should not be placed in normal trash containers. Place in appropriate box (i.e. sturdy cardboard, lined with plastic).
3. All Biohazard or Medical Waste must be put in a RED bag placed within a hard-sided biohazard container with a tight-fitting lid. The bags must be sealed. See your lab supervisor for the correct procedure.
4. Chemical waste must be properly labeled and tagged by user for pickup by EH&S, within 60 days. See your lab supervisor for the correct procedure.
5. Radioactive waste must be segregated and tagged by user for pick-up by EH&S. See your lab supervisor for the correct procedure.

D. Preparation for Working with Human Patients or Tissues.

Anyone in the lab working directly with human blood, human cell lines and/or patients, must understand the risk factors associated with their work and must be properly immunized. For immunization screening and documentation, you must schedule an appointment with the Occupational Health Program (OHP) and complete the appropriate forms. All of the forms indicated below will be sent to you by the OHP when you schedule an appointment.

General Requirements:

If you work directly with human blood, human tissues and/or human cell lines, you will need to:

1. Complete the Bloodborne Pathogen Standard Training course.
 - Go to <https://www.researchonline.ucsf.edu/> to access this course.
 - Bloodborne Pathogen training must be refreshed annually.
2. Contact OHP (information below) for the Hepatitis B Vaccination Status/Declination Form, screening, or immunization and schedule an appointment if necessary.

Needle Stick Hotline - 24Hour pager: 415-719-3898

E. Employee Contact Information

Note: This information is given voluntarily. It should be filed with a lab manager but it is confidential. The lab manager will keep it secure and will not distribute it.

Name: _____ File Date: _____

Lab PI: _____

Lab Department: _____

Location of Lab bench/Office: _____

Employee at Work: Email: _____

 Phone: _____

 Cell Phone: _____

 Pager: _____

Employee at Home: Phone(s): _____

 Home Address: _____

Emergency Contact: _____

Relationship of Contact to Employee: _____

To reach Contact Person at Work:

Email: _____

Phone: _____ Cell Phone: _____ Pager: _____

To reach Contact Person at Home:

Phone: _____ Cell Phone: _____ Pager: _____

Home Address: _____

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPATH		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

NRGBB-SF PREVENTION OF ERGONOMIC / REPETITIVE MOTION INJURIES

SOP Number: NRGBB-SF-SA-4

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4/1/15

PRINCIPLE/PURPOSE

The purpose of this policy is to provide a method of evaluation and intervention to address ergonomic concerns identified by employees. It is the NRG Biospecimen Bank's intention to prevent and to promptly address ergonomic concerns of employees. The principle behind ergonomics is that by fitting the job to the worker, either by adjusting the workstation, rotating the job between workers, or using mechanical assistance, certain workplace injuries can be greatly reduced or eliminated.

DEFINITIONS

Ergonomics is a science of designing equipment and duties to maximize worker productivity by reducing operator injury, discomfort, and fatigue. Ergonomic injuries result from poor or faulty ergonomic conditions that are typically caused by a worker repeatedly performing the same movement or by improper lifting, carrying, pushing or pulling of objects.

ABBREVIATIONS

- A. **MSD:** Musculoskeletal Disorders
- B. **OSHA:** Occupational Safety and Health Administration

DOCUMENTATION/RECORDS

- A. Hazard Communication—Department Managers or designee will conduct an annual review to appraise their department's workstations. Communications to the employee(s) of the assessment should be documented.
- B. All records generated under this policy, including medical records, incident reports, employee training records, and so forth, shall be kept as required by the OSHA Ergonomic Program Standard (29 CFR 1910.900). Medical records shall be preserved and maintained for at least the duration of employment, plus 30 years, in Human Resources or Employee Health.
- C. Annual Evaluation— A self assessment will be conducted annually by the employee. UCSF Office of Environmental Health and Safety (EH&S) will conduct a "Laboratory Self-Assessment" on an as needed basis.

POLICY

- A. An employee who has an ergonomic concern may request an ergonomic evaluation of the work site,
-

specific tasks, or general situation.

1. Employee should first consult Online Office Ergonomics Training at the Research Online website www.researchonline.ucsf.edu
2. All new employees have been provided with a login and password, which can be used to access [Office Ergonomics Training and Self Evaluation](#), under Training heading
3. Completion of online training will involve self evaluation and modification of workspace.
4. Any employee that requires further modification of workspace may contact the Department Safety Officer, being sure to cc. the department manager.
5. The Ergonomics Team is also available to help with situation evaluations upon request:

Primary Contact: Tim Orozco (415) 476-1480 tim.orozco@ucsf.edu

6. If the situation results in injury, employees can submit a formal report to Physical Disability Management Department, for more information, refer to <http://ucsfhr.ucsf.edu/index.php/dismgmt/>

B. The Department Safety Officer will monitor the situation to assess if symptoms persist and if further modifications are necessary.

POLICY NOTES

A. Symptoms that may appear include pain, swelling, numbness, tingling, restricted range of motion or weakness in the affected body part, with varying degrees of severity.

B. At the first sign of discomfort, EH&S policy recommends the worker begin to take an anti-inflammatory medication, if not medically prohibited. Apply ice to the affected area. Your Department Safety Officer must be notified. A work analysis is often performed to correct problems that may be causing or aggravating the condition.

C. Employees should also realize that obesity, pregnancy, recent weight gain, smoking, lack of general physical conditioning, and emotional stress may contribute to the development of these disorders. Additionally, activities and hobbies at home can contribute to these same symptoms and adjustments may need to be made. Stress management, exercise programs, smoking cessation, and EAP counseling often are added as part of overall medical management.

REFERENCES

- A. OSHA Ergonomic Program Standard (29 CFR 1910.900)
- B. UCSF OFFICE OF ENVIRONMENTAL HEALTH AND SAFETY
ERGONOMICS PROGRAM <http://www.ehs.ucsf.edu/Ergonomics/oehsErgonomics.asp>

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPATH		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

NRG BB-SF- CHEMICAL HYGIENE PLAN (CHP)

SOP Number: NRG BB-SF-SA-5

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4/1/15

PRINCIPLE/PURPOSE

The NRG Biospecimen Bank- SF is committed to providing a safe working environment. This Chemical Hygiene Plan (CHP) has been written in conjunction with the UCSF's Office of Environmental Health and Safety (EH&S) Manual in compliance with the OSHA Hazard Communication Standard. The CHP includes policies specific to the NRG Biospecimen Bank- SF for the purpose to inform employees of the potential hazards and the proper handling of hazardous chemicals.

All employees will have access to safety information and be provided with, at no cost to the employee, the safety and personal protective equipment necessary to carry out their assigned duties.

RESPONSIBILITIES

Chemical safety monitoring is the responsibility of the NRG Biospecimen Bank- SF Safety Officer, the site chemical safety officer and the site safety committee. The assignment of a safety representative is the responsibility of the department supervisor or lab manager. Ultimately, all employees share responsibility for laboratory safety.

ABBREVIATIONS

A. PPE: Personal Protective Equipment. B. MSDS: Material Safety Data Sheet

PROCEDURE

A. Personal Protective Equipment (PPE)

1. Personal protective equipment is not to be worn out of the laboratory or in areas where food is permitted. PPE is to be changed when it becomes soiled or contaminated. All employees have been outfitted with appropriate PPE by UCSF EH&S.
 - a. Lab coats are to be worn, buttoned, with the sleeves rolled down. Impervious gowns or aprons must be worn when saturation by fluid contamination is likely.
 - b. Wear disposable gloves when there is potential for direct contact with hazardous chemicals. Inspect the gloves before each use and replace them periodically.
 - c. Eye protection such as safety glasses, goggles or face shields are to be worn whenever splashes, spray or droplets may be generated. Barrier splash shields may also be used.
2. Self-contained respirators and disposable face masks (labeled as "respirator"):
 - a. Employees must complete a respirator medical evaluation form, fit-test and training before wearing respirators. Contact EH&S for respirator training and fit testing.

- b. Self-contained breathing apparatus respirators are only to be considered when exposure levels cannot be controlled by any other method and must have prior approval from the EH&S Industrial Hygiene Officer.
- c. Disposable nuisance odor/dust masks are not protection against hazardous vapors that exceed the permitted exposure levels.

B. Labels

1. Manufacturer labels provide an immediate source of information and are not to be defaced or removed. Labels on hazardous materials identify the material and warn of any potential hazard.
2. All chemicals and solutions must be labeled. The only exception is containers for immediate use by an employee performing and completing a procedure in a single shift. When appropriate, received, opened and expiration dates will be written on the label.
3. The diamond shaped, National Fire Protection Agency (NFPA) precautionary labels are routinely used (Attachment B: NFPA Label). They are completed by filling in the chemical name and the color-coded hazard class rating, which can be found in the MSDS specific to the chemical:
 - a. **BLUE** - Health Hazards: The rating scale ranges from 0- No hazard, up to 4- Deadly.
 - b. **RED** - Flammability Hazards: The rating scale is based on the flash point ranging from 0-Will not burn, to 4- Ignites below 73°F
 - c. **YELLOW** – Reactivity: The rating scale ranges from 0- Stable, to 4- May detonate
 - d. **WHITE** -Special Hazards: represented by symbols, W - Water reactive, OX – Oxidizer, Δ Δ -Radioactive, COR – Corrosive, ACD – Acid and ALK- Alkali.

C. Material Safety Data Sheets (MSDS)

MSDS provide more information about a hazardous chemical than can be found on the label.

1. MSDS are available to employees online by visiting <http://www.ehs.ucsf.edu/MSDS/oehsMSDS.asp>.
2. The Environmental Health and Safety at each facility maintains a web-based MSDS master file.

D. Signs

1. Areas are posted to warn employees where PPE is not allowed or where it is required.
2. Signs are posted that identify areas where food/beverage is allowed.
3. Signs are posted in areas of the laboratory to warn of specific hazards, chemical spill procedures and the MSDS Hotline.
4. Refrigerators are labeled to identify appropriate use, ie, "food only", biohazard, chemical, etc.

E. Training

1. Initial training is received in the new employee orientation, in cooperation with the Hospital Education Department, the Employee Health Nurse, and Safety & Security. Laboratory orientation provided by the QA/Education/Safety Team includes Chemical Hygiene Plan Training and Competency testing covering the following:
 - a. Location of potentially hazardous chemicals within the Laboratory
 - b. Chemical labeling and its meaning
 - c. How to obtain and read an MSDS
 - d. Identity of Chemical Hygiene Officer
 - e. Protective clothing and its use
 - f. Emergency procedures in the event of a hazardous chemical spill
 - g. Environmental monitoring protocol
2. All employees are required to complete the Laboratory CHP annual review and competency.
3. All employees are required to complete annual Hospital JCAHO Safety Training Booklet.
4. Employees using respirators must be fit tested annually.

F. General Principles When Working With Chemicals

1. Control chemical exposures: Exposure can occur by way of inhalation, skin absorption or ingestion. Do not smell or taste chemicals. Wear appropriate PPE. Prevent fumes from escaping into the working atmosphere by keeping containers closed and using fume exhaust systems.
2. Minimize: Purchase the minimum quantities of chemical necessary for the project. A quantity of hazardous chemical not ordered is one to which workers are not exposed, storage need not be found, no inventory required and no waste disposal costs.
3. Estimation of risk: When possible substitute less toxic materials. Plan ahead, before a substance is received, information regarding proper handling, storage and disposal should be known to those involved. Read the MSDS. Handling precautions should be used even for substances with no known significant hazard. Unless known otherwise, assume any mixture will be more toxic than its most toxic component and all substances of unknown toxicity are hazardous.

G. Basic Rules When Working With Chemicals

1. Accidents and Spills: Check MSDS for the chemical for specifics regarding this.
 - a. Eye contact - flush eyes with water for 15 minutes then seek medical attention.
 - b. Ingestion - encourage the victim to drink large amounts of water, seek medical attention.
 - c. Skin contact - flush affected area with water, remove contaminated clothing, (use safety shower if needed) may seek medical attention.

- d. Promptly clean up small spills using appropriate protective equipment, department spill kits, and appropriate disposal techniques.
- e. In the event of a large or extremely hazardous chemical spill call 9-911 for the Hazardous Chemical Spill Response Team

CLEAN:

Contain the spill

Leave the area

Emergency: eyewash, shower, seek medical attention

Access MSDS

Notify a supervisor

2. No eating, drinking, applying cosmetics, manipulation of contact lenses, or taking of medication in testing or specimen handling areas of the laboratory.
3. Do not use damaged glassware.
4. Use equipment only for its designed purpose.
5. Mouth pipetting is prohibited in the laboratory.
6. Dress safely when handling hazardous chemicals, confine long hair, avoid excessive jewelry, sandals and open toed shoes are not allowed in the laboratory area.
7. Wash hands frequently, always after removing gloves and before leaving the laboratory.
8. Keep the work area clean and uncluttered, return chemicals to their proper place, put supplies away upon receipt.
9. Keep walkways clear and unobstructed.
10. Avoid behavior that might startle or distract another co-worker.
11. Correct any unsafe conditions if possible and inform a supervisor or safety officer

F. Chemical Inventory

1. Each laboratory will maintain a chemical inventory of the chemicals on site, updated annually. A copy is forwarded to EH&S
2. During inventory chemicals will be examined for expiration, deterioration and container integrity.
3. Identify chemicals that are known or possible carcinogens, reproductive toxins and highly acute toxins. Special handling procedures for these chemicals are noted in the written procedures where they are used.

G. Chemical Storage

1. *General chemical storage considerations:*

Avoid storing chemicals above eye level or on top of cabinets. Maintain a clearance of at least 18 inches from the sprinkler heads.

Do not store chemicals directly on the floor; bulk storage must be on pallets.

Avoid storing chemicals on bench tops and in hoods except those in current use. Do not store chemicals in direct sunlight or near heat sources.

2. *Seismic storage precautions:*

- a. Shelving and other storage units should be secured.
- b. Shelving should contain a front-edge lip to prevent containers from falling off.
- c. Glass containers of hazardous liquid should be stored in a secondary container (tray) to hold the liquid should the bottle break.

3. *Flammable storage:*

- a. The total volume of Class I, II, and IIIA liquids outside of approved storage cabinets and safety cans shall not exceed 3.78 L (1 gal) per 100 ft².
- b. The total volume of Class I, II, and IIIA liquids, including those contained in approved storage cabinets and safety cans, shall not exceed 7.57 L (2 gal) per 100 ft².
- c. Volumes larger than 1 L of flammable liquid cannot be stored in glass bottles (or over 500 mL of highly volatile liquid).
- d. Use only approved explosion proof refrigerators for storing flammables. The outside doors of refrigerators shall be labeled to denote whether or not they are acceptable for storage of flammable liquids. The NRGBB-SF one is in the yellow lab.
- e. Open flames are prohibited in areas of the laboratory where flammables are in use.

4. *Acid storage:*

- a. Store acids in a metal-free cabinet, segregated from bases.
- b. Separate organic from inorganic acids. They can be stored in the same cabinet if they are in separate trays.
- c. An acid bottle carrier must be used for bottles of acid over 500 ml.

5. *Cryogenics: Liquid Nitrogen and Dry Ice:*

- a. Due to the extreme cold, contact with cryogenics can cause tissue damage (frostbite). Wear thermal gloves and eye protection.
- b. Work in a well-ventilated area. Inhalation of the vaporized gases can cause asphyxiation.
- c. Don't use glass containers for dry ice or liquid nitrogen as the extreme cold temperature will shatter glass.
- d. Never store liquid nitrogen or dry ice in an airtight container. Cryogenics vaporize as they warm and the pressure build up will burst a tightly capped container.
- e. Be aware of slippery floors caused by condensation around dry ice bins and liquid nitrogen dispensers.

H. Employee Hazard Vapor Monitoring

1. Chemical vapor monitoring of employees exposed to formaldehyde, xylene and/or gluteraldehyde is conducted annually by the Chemical Safety Officer, using badge type monitors.
2. Should the monitoring results exceed the permissible exposure level, immediate action will be taken to correct the problem. Monitoring will be repeated until two consecutive readings are reported within the permissible levels.
3. Employees will be notified of their monitoring results within 15 days of the employer's receipt of the report. Vapor monitoring records are retained in the EH&S Employee Health personnel files.

K. Engineering Control

1. Fume Hoods are inspected and certified by EH&S Corporate Risk Management once a year. Approved hoods are tagged, documenting the readings, date and the inspector's initials.
2. Eye wash stations are to be tested monthly and documented.
3. Safety showers are tested semi-annually and documented.
4. Portable eye wash bottles must be replaced yearly and dated.
5. Safety equipment not passing inspection will be removed from service until repairs are made.

L. Medical Consultations and Examinations

1. Medical evaluations for the employee will be provided by NRG Oncology (UCSF employees) at no charge for the following:
 - a. Signs and symptoms develop which may be associated with a hazardous chemical.
 - b. When monitoring reveals an exposure level (PEL or TLV) above the action level and signs and symptoms develop.
 - c. Whenever an event takes place in the work area such as a spill, leak, or explosion resulting in hazardous chemical exposure.
 2. The Laboratory will provide the following information to the physician:
 - a. Identity of hazardous chemicals to which the employee may have been exposed along with a copy of the MSDS(s) involved.
 - b. A description of the conditions under which the exposure occurred, including quantitative exposure data if available.
 - c. A description of the signs and symptoms of exposure.
 3. For any medical consultations or examinations conducted as a result of the provisions of the OSHA Lab Standard, Employee Health will receive from the examining physician:

Results of the medical examination and associated tests along with a written opinion which includes the physicians recommendations for further follow-up.
-

Any medical conditions identified during the course of the examination which may place the employee at increased risk as a result of exposure to work place hazardous chemicals. The physician's written opinion will not reveal specific findings of diagnosis unrelated to the occupational exposure.

A statement that the employee has been informed (by the physician) of the results of the medical consultation/examination and informed of any medical condition that may require further examination or treatment.

K. Record Keeping

1. Employee training records:

Safety orientation documentation will be on file with employee's supervisor.

EH&S training will be on file with EH&S and a copy with employee's supervisor.

Department specific safety training records will be on file in the department employee file.

2. A Deviation and Problem Report (DAP), or facility specific occurrence/event form is filed in the event of a chemical accident, spill or a safety audit failure to be utilized by the laboratory for the purpose of documentation, tracking and trending.

3. Depending on the seriousness of an incident, a First Report of Injury and/or Incident/Event Report may be required by Risk Management.

4. The EH&S Employee Health Nurse at each site will maintain employee health records, including written medical opinions, work place exposure records and respirator training records. Employees are allowed access by contacting their Employee Health Nurse.

L. Hazardous Waste Disposal and Reduction

1. The following chemicals will interfere or destroy the biological activity of the water treatment plant and cannot to be discharged into the sewer system:

Concentrated acid or base.

Pollutants that may create a fire or explosion hazard.

Substances not miscible in water, including solvents, petroleum oil, and mineral oil.

Solid or viscous substances that may cause structural damage or obstruct the flow.

Any substance that generates toxic gases, vapors or fumes.

Solutions containing heavy metals.

Waste material is to be collected separately (unless otherwise noted), in leak proof, non-corrosive containers, labeled with "Hazardous waste", the chemical name and known hazards. Notify EH&S for pick-up. EH&S will complete the necessary paperwork (waste manifest), package and contact the Intermountain Healthcare designated licensed contractor for disposal.

Contact Safety & Security for disposing surplus and outdated chemicals.

REFERENCES

- A. EH&S Chemical Hygiene Program, Safety Policy and Procedure Manual. Access through <http://www.ehs.ucsf.edu/Manuals/CSM/oehsCSMC1.asp>
- B. National Research Council. Prudent Practices In the Laboratory Handling and Disposal of Chemicals. Washington D.C.: National Academy Press, 1995.
- C. Laboratory Accreditation Program. Laboratory General Checklist. Northfield IL: College of American Pathologists.

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPATH		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

NRGBB-SF: ELECTRICAL SAFETY

SOP Number: NRGBB-SF-SA-6

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4/1/15

PRINCIPLE/PURPOSE

To ensure that all NRG Oncology Biospecimen Bank- SF employees understand the hazards associated with electrical equipment and incorporate safe practices accordingly.

DOCUMENTATION/RECORDS

- A. Electrical safety checks documentation is kept at Environmental Health & Safety office and will be made accessible upon request.
- B. UCSF Event Report Form or UCSF electronic submission form
- C. UCSF Healthcare Employee injury/Illness report

PROCEDURE

- A. Preventative Electrical Safety Measures
 1. All electrical equipment shall be grounded using a three-pronged electrical cord and should be used according to National Electrical Code.
 2. Multiple plug adapters are prohibited. Approved surge protectors are permitted.
 3. Arrange equipment cords and cables away from foot traffic – to keep them off the stairs and out of aisles. Cords that cross traffic areas must be anchored to the floor or marked with bright tape
 4. When disconnecting equipment from an A/C wall outlet, grasp the A/C plug at the base and gently pull. Do not attempt to remove the A/C plug by means of pulling on the cord itself.
 5. Keep cables and cords protected from oil, chemicals, liquids, and sharp objects to prevent damage.
 6. All equipment and appliances in the lab must be checked before being put into service and on an annual basis by the Environmental Health and Safety Office. This check will include a general inspection, electrical check and operational verification. Do not use a device if the inspection date is not current.
 7. Work on electrical wiring or electrical equipment is permitted only under the oversight of an Authorized Lockout/Tagout Employee.
 8. Extension cords, of proper size and according to their use, are permitted in emergent power outage situations. If used, they must be three-pronged type or be properly grounded and be approved through engineering (for full set of restrictions, refer to the EH&S online safety manual).

9. Electrical panels are required to be in a location where a person has easy access to turn off the power to a piece of equipment or area in an emergency. This means they must be unobstructed 36 inches in front of and in all directions around the panel.
 10. For electrical outlets/switches an overload on the electrical system may be possible and cause an outlet to spark. For these reasons, outlets must meet the following requirements:
 - Be replaced by UCSF Facilities when broken.
 - Have an approved securely fastened cover plate. Although metal is permitted by the National Electric Code (NEC), it is not recommended by EH&S.
 - Be protected by a Ground Fault Circuit Interrupter (GFCI) when located within six (6) feet of a water source.
 - All combustible items e.g., trash cans, boxes of papers, etc., should be kept at least two (2) feet from either side of the outlet, when possible.
- B. Many equipment hazards that eventually result in an electrical shock are visible for a period of time prior to an accident
1. Frayed or damaged electrical cords, cables, plugs, or foot pedals should not be used until repaired or replaced.
 2. If a "tingling sensation" or a shock is felt while using electrical equipment, turn off the equipment and unplug the instrument and report the incident to your supervisor or UCSF Facilities department. Tag the device for repair.
- C. Repairs
1. If equipment is malfunctioning, has been dropped, or had liquid spilled on it, turn the unit off, disconnect the power cord from the outlet and report the problem to your supervisor and the appropriate engineering/service department(s).
 2. Repairs on electrical systems of the building are prohibited. Any work performed on switches, outlets or circuit boxes must be referred to Facilities engineering as well as the department supervisor. Never open a panel box or reset circuit breakers unless you are specifically qualified to do so as a part of your job assignment.
 3. Any equipment that fails annual inspections shall be sent to Facilities Engineering or to the manufacturer for repair.
 4. Document any occurrence that is not consistent with normal electrical safety or that may have potential for injury and/or property damage on the Intermountain Healthcare Event Report Form.
- D. For electrical fires use a type ABC extinguisher.
- E. In case of injury from faulty electrical equipment:
1. Determine if the victim is still exposed to the electrical current. If still in contact:
 - a. If possible, disconnect the power source

- b. Remove faulty implement from the victim by using something non-conductive such as a broom handle or a rubber or paper tool
- c. Call 9-911 or a code blue
- 2. Perform any necessary first aid
- 3. Document all job related injuries/illnesses on the employee injury/illness report form and forward to Employee Health within 24 hours.

APPROVAL

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Standard Operating Procedures

NRGBB-SF specific SOPs follow this page.

Pathology Specimens Processing/Receiving

SOP Number: NRGBB-SF-01

Author(s): Sandy DeVries

Version: 7.0

PURPOSE

To outline processing procedures for shipments of pathology materials which arrive by mail or overnight courier (UPS, Fed-ex, etc.). The purpose is to ensure that all pathology specimens are processed according to protocol and that the specimens are entered into the database in a timely manner.

ABBREVIATIONS

- A. STF- Specimen Transmittal Form
- B. FFPE- Formalin fixed paraffin embedded
- C. CRA- Clinical Research Associate

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

- A. Personal Protective Equipment (PPE): Gloves, Lab coat, Goggles (as needed)

SPECIMEN

- A. Specimen Type(s) – Paraffin Blocks, Stained Slides, Unstained Slides, Paraffin Block Punches
- B. Handling – FFPE blocks and glass slides are not considered to be biohazards and do not require personal protective equipment during handling. However, staff may opt to use appropriate personal protective equipment for handling glass or soft paraffin.

QUALITY CONTROL

- A. Upon receipt of specimens confirm that pathology numbers on the blocks, slides, pathology reports and STF match. If they do not match see procedures below.
- B. If material received is for an integral marker study then process immediately as per the study specific NRGBB-SF SOP for that protocol or as per Section 10 for that protocol.

PROCEDURE

1. Specimen Receiving:
 - A. When the pathology material arrives, open packages within 24 hours and check the contents. If the samples are frozen biospecimens unpack immediately in the approved
-

space for BSL2 lab work and refer to SOP-2 for Frozen Specimen Processing.

- 1) The package should contain a pathology report, a ST Form (appendix A2), and the pathology specimens. Record Date Received on STF and Pathology report. Before processing any material, check Section 10.0 of the study protocol (or review the Current Active Protocols List with Specimen Submission document) to verify what types of specimens should be submitted.
- B. If the protocol requires tissue collection and all three items (pathology report, STF and tissue) have been submitted, proceed with the following:
- 1) Verify the pathology number on the slides/blocks matches pathology report and STF
 - 2) Verify that patient consent has been checked on the STF. If it has not then contact the CRA who sent it and ask them to re-fax the form with it checked off with their initials and date. Do **not** check this for them. It is ok to not have this information.
 - 3) Verify that treatment type and time point of collection are completed. If they are not then contact the CRA who sent it and ask for the information, either over the phone or ask them to refax the STF with the complete information. Any changes made on the STF must be initialed and dated.
 - 4) Make a record of materials that have been received by using the daily log sheet ("Material log"; Appendix- A3). This is e-mailed to Carly Depuy at NRG Oncology Headquarters monthly informing them of all materials received by the tissue bank.
 - 5) Make sure ALL PHI information is redacted with black marker and WHITE out. Leave the accession number and date of procedure.
 - 6) The pathology report and STF should all be stamped with the date received and date entered in the database, then placed in the "to be scanned" area
 - 7) Enter the information regarding the cases into the NRG STARS database as per Appendix- A5.
 - 8) Label every specimen with a bar-coded label and assign it a position in the block or slides storage. Remove old labels.
 - 9) File the slides or blocks in their assigned positions
- C. When pathology reports are received **WITHOUT** slides/blocks, the procedure below should be followed unless the institution has reason for not submitting tissue (patient would not consent to tissue use, insufficient tissue remaining, institution will not release material)
- 1) Write the study and case number on the upper right hand corner of every page.
 - 2) Notify the institution and data manager of missing samples and request that the pathology slides/blocks be sent as soon as possible.
 - 3) When the requested pathology slides/blocks are received, pull the report from the pending material file and follow the normal procedures written in section B above.
 - 4) If informed that no tissue is available, make a record that no materials have been received by using the daily log sheet. In 'Specimen Type' column, put 'paperwork

only'. Pull the report and submission form from the pending material file and place in the to be scanned area.

- 5) The STF and pathology report should be stamped with the date received and the date entered in the STARS database

D. When pathology slides are received with a STF but without a pathology report, the below procedures should be followed:

- 1) Verify that the pathology number on the slides/blocks matches the STF
- 2) Call the data manager at the institution and request a copy of the pathology report. It may be mailed or faxed to the tissue bank. Make sure to ask them to de-identify the patient information.
- 3) Place the specimens and STF into the pending material file until the pathology report is received.
- 4) When the report is received, pull the pathology specimens and accompanying paperwork from the pending file.
- 5) Verify that the pathology number on the slides/blocks matches the pathology report and STF.
- 6) Make a record of materials that have been received by using the daily log sheet ("Material log").
- 7) Enter the information regarding the cases into the pathology database.
- 8) Label every specimen with a bar-coded label and assign it a position in the block or slides storage
- 9) File the slides or blocks in their assigned positions
- 10) The pathology submission form should be stamped with the date received and the date entered in the STARS database.

E. When the pathology report and pathology slides/blocks are received without a submission form, or the STF is incomplete, then the following procedures should be followed:

- 1) Verify that the pathology number on the slides/blocks matches the pathology report and STF
- 2) Call the data manager at the institution and request a copy of the STF. It may be mailed or faxed to the tissue bank.
- 3) Put the report and tissue in the pending material file and wait for the STF.
- 4) When the STF is received, pull the pathology specimen(s) and accompanying paperwork from the pending file.
- 5) Make a record of materials that have been received by using the daily log sheet ("Material log"). Enter the information regarding the cases into the pathology

database.

- 6) Label every specimen with a bar-coded label and assign it a position in the block or slides storage
 - 7) File the slides or blocks in their assigned positions
 - 8) The pathology submission form should be stamped with the date received and the date entered in the database
- I. If the protocol does not call for specimen collection, process only the pathology report. Discuss with the Manager or Director whether to keep or return the specimen(s) to the research associate with an explanation letter that material is not needed and indicate in the database that the specimen(s) has been returned to the submitting site.
- J. When all forms are complete
- 1) Scans of the pathology report and the pathology STF are scanned in batches weekly, and stored in the PHI identified folder titled 'Scans'.
 - 2) The original pathology report and pathology submission form are filed.
 - 3) Locate scanned pathology report and submission form on "NRG BB-SF shared PHI drive" Rename document with 'Study Number-Four digit case number'. (i.e. 9408-0001) Put renamed document in folders sorted by study number. Combine multiple PDFs for the same case
 - 4) Paperwork scans are FTPed to NRG Oncology monthly, and they are notified

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPath		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

NRGBB-SF Fresh Tissue Processing/Receiving

SOP Number: NRGBB-SF-02

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4/1/15

PURPOSE

To describe the procedure for receiving and processing Fresh Tissue for banking by the NRG Oncology Biospecimen Bank- SF. To assure that the storage and integrity of all samples received is optimized for future translational research projects.

ABBREVIATIONS

A. STF- Specimen Transmittal Form B. CRA- Clinical Research Associate

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

B. Personal Protective Equipment (PPE) Required: Gloves, Lab coat, Goggles

SPECIMEN

- A. Specimen Type(s) – Frozen fresh tissue in cryovials, in OCT, in RNA-later
- B. Handling – Treat all specimens as infectious agents. Wear appropriate PPE when handling specimens.
 - Fresh Tissue samples are considered biohazards and must be handled using PPE in the lab space approved for Biosafety level 2 lab work. Double gloving is highly recommended.
 - Dry Ice can burn exposed skin, even through exam gloves. Wear padded gloves if touching dry ice.

QUALITY CONTROL

- A. Upon receipt of specimens confirm that pathology numbers on the tissue samples match pathology reports and STFs to assure that the samples match up with the supporting documentation.
- B. Verify date of collection matches report.
- C. Keep specimens frozen, handle only on dry ice while processing.
- D. At end of the day, all samples should be put away in a -80 Freezer. A Biospecimen Bank employee must initial and time stamp the daily check out sheet verifying that all samples have been put away. At the end of the week (or on the day before a holiday) another assigned employee must also check that all samples have been put away and initial and date the daily check out sheet.
- E. All lab personnel following this SOP must review and sign it.
- F. Process and review sample for tumor content.

PROCEDURE

1. Specimen Receiving:

- A. When specimens arrive, open packages immediately (within 2 hours) and check the contents. The package should contain
 - i. A specimen transmittal form (STF; Appendix A-2)
 - ii. A pathology form may accompany the tissue, but is not necessary
 - iii. Frozen Specimens on dry ice.
- B. If the protocol requires specimen collection and all the appropriate items (submission form and specimens) have been submitted, proceed with the following:
 - i. Verify that date of collection on the submission form matches the date of collection listed on the specimens.
 - ii. Verify that patient consent has been checked on the STF. If it has not then contact the CRA who sent it and ask them to re-fax the form with it checked off with their initials and date. Do **not** check these boxes for them. It is ok to continue without the box checked.
 - iii. Verify that the treatment and timepoint information has been filled out. If it has not then contact the CRA who sent it and them to refax the STF with the needed information. If they give the information over the phone note on the STF that information was provided by them. Do not enter UNKNOWN unless it is clearly incorrect. Each protocol has specific timepoints.
 - iv. Verify that the tissue type is identified. Some protocols have different requirements (tumor and normal, skin etc). Make sure it is clear what they sent and that the information is noted in the database.
 - v. Make a record of materials that have been received by using the daily log sheet ("Material log"; Appendix A3). This will be emailed to Carly Dupey at NRG Oncology Headquarters monthly, informing them of all materials received by the tissue bank.
 - vi. The Specimen Transmittal Form should be stamped with the date received and the date entered into the database
 - vii. If received, the pathology form is scanned into the study folder for that case.

2. Specimen Processing:

- A. Review section 10 of the protocol to review what types of materials we will be storing. Verify that all of the proper materials have been received.
- B. Prepare a sample for pathology Review: **Process In the biological hood**
 - i. Have samples on dry ice while processing to prevent thawing.
 - ii. For each sample take a 3mm punch (or larger for large tissues) of the frozen

- tissue. This can be done directly in the tube or on a Teflon surface. You can also try to cut/chip off a piece with a scalpel. Should be done cold on ice.
- iii. Place the core upright in a small cryomold and cover with OCT. Freeze on top of the Dry Ice.
 - iv. Make a 6-8 micron section with the cryostat on a positive charged slide. Store slides at -80°C and notify the Cancer Center Tissue Core to stain.
 - v. Once stained the frozen H&E should be reviewed using the pathology review form to document presence and % of tumor content.
- C. If all the correct materials have been received and specimens do not require further processing, enter all of the information into the database as per Appendix- A5
 - D. Label every specimen with a bar coded label
 - E. Assign its position based on study number and location in Freezer.
 - F. Place frozen samples in the assigned position in the freezer on the 1st floor.
 - G. Identify H&Es as Frozen Section H&Es.
3. If any specimens arrive without dry ice, at room temperature and/or thawed:
- A. Contact the CRA who sent them to see if they can provide another tissue sample
 - B. Determine why the sample thawed (FedEx, wrong address, not enough dry ice, etc) and give this information as input to the CRA in order to avoid it from happening again.
 - C. Make a note on the STF that samples arrived thawed
 - D. Discard samples according to EH&S guidelines: For tissue if it is less than 0.5mm cube it can be discarded in biohazardous red bags. For bigger samples please dispose of in the pathology department as pathological waste (grey containers).
4. If any tissue samples arrive in broken cryovials process them as described
- A. Wear all PPE (goggles, double glove, lab coat).
 - B. Transfer them to new tubes if it is clear which case/tube they came from and relabel the tube.
 - C. If you are unable to confirm what sample they are then process them as a Biohazardous spill. This is only if you really cannot confirm which sample is which. For example : there are only two samples one normal and one tumor from the same patient then do not discard before discussing with the director or manager how to proceed.
 - D. If the spill is contained within a plastic bag or Styrofoam container, carefully wipe up any excess tissue with a paper towel, spray/wipe with bleach and discard paper towels and the container into the red biohazardous waste bag.
 - E. Contact the CRA who shipped the sample to let them know how many aliquots broke and to see if they might have more material to send.
 - F. Make a comment on the STF which samples arrived broken. These aliquots do not get

entered into the database

5. If the protocol section 10 does not call for specimen collection:
 - A. Return the specimen(s) to the research associate with an explanation letter that material(s) is/are not needed
 - B. Indicate in the database that the specimen(s) has/have been returned to the submitting site.

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPath		
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Sandy DeVries		

NRGBB-SF Blood and Urine Receiving/Processing

SOP Number: NRGBB-SF-03

Author(s): Sandy DeVries & Michael Restrepo

Version: 7.0

PURPOSE

To describe the procedure for receiving and processing whole blood, serum, plasma, buffy coat, urine and other blood product samples for banking by the Biospecimen Bank.

ABBREVIATIONS

A: STF- Specimen Transmittal Form

B: CRA- Clinical Research Associate

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

- a. Personal Protective Equipment (PPE) Required: Gloves, Lab coat, Goggles
 - Blood, serum, plasma, buffy coat, Urine and other blood product samples are considered biohazards and must be handled using PPE in the lab space approved for Biosafety level 2 work. Double gloving is highly recommended.

SPECIMEN

- A. Specimen Type(s) – Whole blood, Serum, Plasma, Buffy Coat, Urine, other. These samples will have been processed according to their kit instructions (attached).
- B. Handling – Treat all specimens as infectious agents. Wear appropriate personal protective equipment when handling specimens.

QUALITY CONTROL

- A. Visually compare all specimens to specimen transmittal form (Appendix A2) to verify that the samples match up with the supporting documentation.
- B. Verify date of collection matches report.
- C. At end of the day, all samples should be put away in a -80°C Freezer. A Biospecimen Bank employee must initial and time stamp the daily check out sheet verifying that all samples have been put away. At the end of the week (or on the day before a holiday) another assigned employee must also check that all samples have been put away and initial and date the daily check out sheet.
- D. All lab personnel following this SOP must review and sign it.

PROCEDURE

1. Specimen Receiving:
 - A. When specimens arrive, open packages immediately (within 1-2 hour)
 - B. Keep all vials on plenty of dry ice to keep frozen and check the contents. The package
-

should contain

- i. A specimen transmittal form (STF)
 - ii. Frozen specimens in cryovials, Urine tubes on dry ice.
- C. If the protocol requires specimen collection and all the appropriate items (submission form and specimens) have been submitted, proceed with the following:
- i. Verify NRG study number, case number and date of collection on the submission form match the information listed on the specimens. If any of this information is missing from the specimen labels or the STF, contact the CRA and ask them to verify this information.
 - ii. Verify that patient consent has been checked on the STF. If it has not then make a note in the Stars database.
 - iii. Make a record of materials that have been received by using the daily log sheet ("Material log"; Appendix A3).
 - iv. Stamp the STF with the date received.

2. Specimen Processing

- A. Review section 10 of the protocol to review what types of materials we will be storing. Verify that all of the proper materials have been received.
- B. If all the correct materials have been received and specimens do not require further processing, enter all of the information into the STARS database (Appendix A5)
- C. Using the database label every specimen with a bar coded label. Remove old labels if present. Assign its position based on study number and location in Freezer.
- D. If a single large tube is received instead of 1ml aliquots, then aliquot the specimens into 1ml aliquots. Record aliquots as having one thaw cycle. If aliquots are received in vials larger than 1ml, assign them to boxes designated for storage of larger vials.
- E. Place all samples in the assigned -80°C Freezer in their assigned boxes. If any specimens were not labeled the day they were received, place them in the -80°C freezer to be labeled later. Do not store them on dry ice overnight.

3. If any specimens arrive without dry ice, at room temperature and/or thawed

- A. Determine why the sample thawed (Fed ex, wrong address, not enough dry ice etc) and email this to the CRA in order to avoid it from happening again. Ask them to ask their study PI if they can re-draw blood. CC Nancy Soto at NRG Oncology, the director Richard Jordan and the Biospecimen Bank Manager.
- B. Make a note on the STF that samples arrived thawed, and the reason why.
- C. Enter samples into the STARS database, but do not bank- mark destroyed.

- D. Discard samples according to UCSF EH&S guidelines: for blood samples- place cryovials or blood draw tubes in red sharps containers. Urine is discarded in the restroom.
4. If the protocol does not call for specimen collection:
 - A. Contact the CRA in writing and ask whether they want you to destroy or return the specimens. If they ask you to return them then return the specimen(s) to the research associate with an explanation letter that material(s) is/are not needed and indicate in the database that the specimen(s) has/have been returned to the submitting site. Keep a copy of the Federal Express tracking information.
 5. If blood specimens arrive broken/leaking, process them as a Biohazardous spill:
 - a. Wear all PPE (goggles, double glove, lab coat)
 - b. If the spill is contained within a plastic bag or Styrofoam container, carefully wipe up any excess blood with a paper towel, spray/wipe with bleach or 70% ethanol and discard paper towels and the container into the red biohazardous waste bag.
 - c. If the samples are not "leaking" and frozen solid, then place tubes into secondary tubes or bags and freeze. These can be salvaged and should be entered into the database as above.
 - d. Contact the CRA who shipped the sample to let them know how many aliquots broke and ask them to ask their study PI if they can re-draw. Make a comment on the STF which samples arrived broken. Enter as non-reimbursed in the material log. These aliquots do not get entered into the Stars database.
 6. If all the correct paperwork has been received but the specimens do require further processing such as arriving in original blood draw tubes proceed with the following:
 - A. Contact CRA immediately and ask why samples were not processed and notify them that they should follow the NRG Oncology protocol SOPs for processing samples and if they should ask their study PI if they can redraw.
 - B. For red-top tubes (Serum)
 - i. If frozen: Discard samples, do **not** process.
 - ii. If shipped on ice overnight: Discard samples, do **not** process.
 - C. For EDTA tubes (lavender-top tubes) – If these arrive frozen or on ice they can be processed for whole blood collection but **not** for plasma
 - i. Mix the tube well after thawing
 - ii. Aliquot 1 ml into up to five 1.2 ml cryovials.
 - iii. Enter the information into the database (include a comment that they were aliquotted here)
 - iv. Label each aliquot with a barcode label.

- v. Assign a position in the freezer
 - vi. Place aliquots in the -80°C
7. Keeping Specimen COLD: ALWAYS keep specimens touching the dry ice, if working with boxes or Urine tubes in racks they must have DRY Ice around all sides. Do not stack boxes, racks. When touching vials, touch the cap, not the tube itself. Do not warm up the samples.
 8. End of Day SOP.
 - A. Place **ALL** samples in -80°C Freezer before end of day. **NEVER** leave on dry ice.
 - B. Freezer positions must be assigned within 48 hours of receiving them. (one week for large batch shipments).
 - C. Place all reusable empty kit boxes in the kit room next door.
 - D. Remove all lids to styrofoam boxes in processing room so that no boxes are covered up.
 - E. Discard any biohazardous waste in red bags. Replace lid when finished
 - F. Wipe down work bench area with 70% ethanol and wash hands
 - G. Verify on Daily Check Out Sheet that all samples have been put away- initial and date each day. On Fridays (or a day before a holiday) this must be done by 4pm as a second assigned person has to sign off at the end of Day Fridays (or day before a holiday).

ATTACHMENTS

- A. Blood Collection Kit Instructions
- B. Urine Collection Kit Instructions
- C. Example of Daily Check out sheet

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPath		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

NRG-BB-SF BLOOD COLLECTION KIT INSTRUCTIONS

This Kit is for collection, processing, storage, and shipping of serum, plasma, or whole blood (as specified by the protocol):

Kit contents:- Will contain supplies for all timepoints unless specified in shipment- Note pre-tx blood draw tubes will be provided with kits and site must provide their own draw tubes for subsequent timepoints or if tubes have expired.

- One Red Top tube for serum (A)-
- One Purple Top EDTA tube for plasma (B)- pre-tx draw only
- One Purple Top EDTA tube for Whole Blood (C)-
- Twenty-one (21) 1 ml cryovials
- Biohazard bags (3) and Absorbent shipping material (3)
- Styrofoam container (inner) and Cardboard shipping (outer) box
- UN1845 DRY Ice Sticker and UN3373 Biological Substance Category B Stickers
- Specimen Transmittal Form (STF) and Kit Instructions

PREPARATION AND PROCESSING OF SERUM, PLASMA AND WHOLE BLOOD:**(A) Serum (if requested): Red Top Tube**

- Label as many 1ml cryovials (5 to 8) as necessary for the serum collected. Label them with the study and case number, collection date, time, and time point, and clearly mark cryovials "serum".

Process:

1. Allow one red top tube to clot for 30 minutes at room temperature.
2. Spin in a standard clinical centrifuge at ~2500 RPM for 10 minutes at 4°C (preferred). If sites are unable to process samples at 4°C then spinning at room temperature is acceptable if done within 2 hours of draw but must be noted on the STF.
3. Aliquot 0.5 ml serum into as many cryovials as are necessary for the serum collected (5 to 8) labeled with NRG study and case numbers, collection date/time, protocol time-point collected (e.g. pre-treatment, post-treatment), and clearly mark specimen as "serum".
4. Place cryovials into biohazard bag and immediately freeze at -70 to -90° C, and store frozen until ready to ship. See below for storage conditions.
5. Store serum at -70 to -90° C until ready to ship on dry ice. See below for storage conditions.

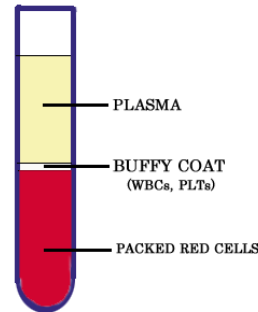
PLEASE MAKE SURE THAT EVERY SPECIMEN IS LABELED and include collection time point on the STF.

(B) Plasma (If requested): Purple Top EDTA tube #1

- ❑ Label as many 1ml cryovials (5 to 8) as necessary for the plasma collected. Label them with the NRG study and case number, collection date, time, and time point, and clearly mark cryovials "plasma".

Process:

1. After collection, invert tube(s) multiple times to ensure adequate mixing of EDTA.
2. Centrifuge specimen(s) within one hour of collection in a standard clinical centrifuge at ~2500 RPM for 10 minutes at 4°C (preferred). If sites are unable to process samples at 4°C then spinning at room temperature is acceptable if done within 2 hours of draw but must be noted on the STF..
3. If the interval between specimen collection and processing is anticipated to be more than one hour, keep specimen on ice until centrifuging is performed.
4. Carefully pipette and aliquot 0.5 ml plasma into as many cryovials as are necessary for the plasma collected (5 to 8) labeled with NRG study and case numbers, collection date/time point collected and clearly mark specimen as "plasma". Avoid pipetting up the buffy coat layer
5. Place cryovials into biohazard bag and immediately freeze at -70 to -90°C.
6. Store frozen plasma until ready to ship on dry ice.
7. See below for storage conditions.



PLEASE MAKE SURE THAT EVERY SPECIMEN IS LABELED and include collection time point on the STF

(C) Whole Blood for DNA (if requested): Purple Top EDTA tube #2

- ❑ Label as many 1ml cryovials (3 to 5) as necessary for the whole blood collected. Label them with NRG study, case number, collection date/time, time point, and clearly mark cryovials "blood".

Process:

1. After collection, invert tube(s) multiple times to ensure adequate mixing of EDTA. Blood can also be mixed for 5 minutes on a mixer at room temperature.
2. Carefully pipette and aliquot 1.0 ml blood into as many cryovials as are necessary for the blood collected (3 to 5) labeled with NRG study and case numbers, collection date/time, time point collected and clearly mark specimen as "blood".
3. Place cryovials into biohazard bag and freeze immediately at -70 to -80° Celsius.
4. Store blood samples frozen until ready to ship on dry ice.
5. See below for storage conditions.

PLEASE MAKE SURE THAT EVERY SPECIMEN IS LABELED and include collection time point on STF.

Freezing and Storage:

- Freeze Blood samples in a -80°C Freezer or on Dry Ice or snap freeze in liquid nitrogen.
 - Store at -80°C (-70°C to -90°C) until ready to ship.
If a -80°C Freezer is not available,
 - Samples can be stored short term in a -20°C freezer (non-frost free preferred) for up to one week (please ship out Monday-Wednesday only; Canada: Monday-Tuesday only).
- OR:**
- Samples can be stored in plenty of dry ice for up to one week, replenishing daily (please ship out on Monday-Wednesday only; Canada: Monday-Tuesday only).
- OR:**
- Samples can be stored in liquid nitrogen vapor phase (ship out Monday-Wednesday only; Canada: Monday-Tuesday only).
- Please indicate on Specimen Transmittal Form the storage conditions used and time stored.

Shipping/Mailing:

- Ship specimens on Dry Ice overnight **Monday-Wednesday (Monday-Tuesday from Canada)** to prevent thawing due to delivery delays. Saturday and holiday deliveries cannot be accepted.
- Include all paperwork in a sealed plastic bag and tape to the outside top of the Styrofoam box.
- Wrap frozen specimens of same type (i.e., all serum together, plasma together and whole bloods together) in absorbent shipping material and place each specimen type in a separate biohazard bag. Place specimen bags into the Styrofoam cooler and fill with plenty of dry ice (7-10 lbs/3.5kg minimum). **Add padding to avoid the dry ice from breaking the tubes.**
- Place Styrofoam coolers into outer cardboard box, and attach shipping label and UN3373 and UN1895 stickers to outer cardboard box.
- Multiple cases may be shipped in the same cooler, but make sure each one is in a separate bag and that there is enough room for plenty of dry ice. Add padding to avoid the dry ice from breaking the tubes.*
- For questions regarding collection, shipping or to order a Blood Collection Kit, please e-mail NRGBB@UCSF.edu or call (415) 476-7864.

Shipping Address:

Courier Address (FedEx, UPS, etc.): **For all Frozen Specimens**
NRG Biospecimen Bank- SF
University of California San Francisco
2340 Sutter Street, Room S341
San Francisco, CA 94115
For questions, call 415-476-7864 or e-mail: NRGBB@UCSF.edu

NRGBB-SF URINE COLLECTION KIT INSTRUCTIONS (4.1.15)

This Kit is for collection, processing, storage, and shipping of Urine Specimens**Kit Contents:**

- One (1) Sterile Urine collection cup
- Two 7 ml disposable pipets
- Absorbent Paper Towel
- Two 15 ml polypropylene centrifuge tubes
- Biohazard bags
- Parafilm for sealing outside of tubes

Preparation and Processing of Urine Specimens:

- ❑ A clean catch urine specimen will be collected. To collect the specimen, use the following instructions:
 - Males should wipe clean the head of the penis and females need to wipe between the labia with soapy water/ cleansing wipes to remove any contaminants.
 - After urinating a small amount into the toilet bowl to clear the urethra of contaminants, collect a sample of urine in the collection cup.
 - After 10-25 mL urine has been collected, remove container from the urine stream without stopping the flow of urine.
 - Finish voiding the bladder into the toilet bowl.
- ❑ Aliquot 5-10 mls of Urine into each of two 15 ml polypropylene centrifuge tubes (disposable pipets are provided in the kit). Do not fill with more than 10 mls to avoid cracking of tubes due to expansion during freezing. Replace the cap and tighten on the tubes. Make sure the cap is not cross-threaded or placed on incorrectly or leaking will occur.
- ❑ Use parafilm to seal the cap around the outside rim of the urine tube to prevent leakage.
- ❑ Discard remaining Urine and collection cup. Do NOT ship Urine in cups.
- ❑ Label the specimen with the NRG study and case number, collection date and time, time point of collection, and clearly mark specimens as "urine"
- ❑ Wrap Urine Tubes with absorbent material (paper towels) and place into biohazard bag and seal the bag. Freeze and store Urine samples in a -20°C or -80°C Freezer until ready to ship

Storage and Shipping:**Freezing and Storage**

Urine specimens may be sent in batches or with other frozen biospecimens, if within 30-60 days of collection. Store at -20°C or 80°C (-70°C to -90°C) until ready to ship. If a -80°C Freezer is not available,

- Samples can be stored short term in a -20° C Freezer (non-frost free preferred) for up to one week (please ship out Monday-Wednesday only- Canada Mon-Tues).

OR:

- Samples can be stored in plenty of Dry Ice for up to one week, replenishing daily (please ship out on Monday-Wednesday only- Canada Mon-Tues).
- Please indicate on Specimen Transmittal Form the storage conditions used and time stored.

Shipping/Mailing:

- ❑ Ship specimens on Dry Ice overnight **Monday-Wednesday (Monday-Tuesday from Canada)** to prevent thawing due to delivery delays. Saturday and holiday deliveries cannot be accepted.

- ❑ Specimens received thawed due to insufficient dry ice or shipping delays will be discarded and the site will be notified.
- ❑ Include all paperwork in a sealed plastic and tape to the outside top of the Styrofoam box.
- ❑ Place sealed specimen bags into the Styrofoam cooler and fill with plenty of dry ice (7-10 lbs/3.5kg minimum). Add padding to avoid the dry ice breaking the tubes.
- ❑ Place Styrofoam coolers into outer cardboard box, and attach shipping label and UN3373 and UN1895 stickers to outer cardboard box.
- ❑ *Multiple cases may be shipped in the same cooler, but make sure each one is in a separate bag and that there is enough room for plenty of dry ice. Add padding to avoid the dry ice from breaking the tubes.*
- ❑ For questions regarding ordering, collection, or shipping a Urine Collection Kit, please Email NRGBB@UCSF.edu or call (415) 476-7864 or fax (415) 476-5271

Shipping Address : **FedEx/UPS/Courier address (For all frozen samples)**

NRG Biospecimen Bank- SF at UCSF
2340 Sutter Street, room S341
San Francisco, CA 94115
Contact Phone 415.476.7864

C: Daily Check out Sheet

Daily End of Day Check - All Frozens have been put in -80C Freezer					
Date	Initials	Time	Second Check Initials	Time	Supervisor Check
11/22/2010					
11/23/2010					
11/24/2010					
11/25/2010	holiday	holiday	holiday	holiday	
11/26/2010	holiday	holiday	holiday	holiday	
11/27/2010	weekend	weekend	weekend	weekend	
11/28/2010	weekend	weekend	weekend	weekend	
11/29/2010					
11/30/2010					
12/1/2010					
12/2/2010					
12/3/2010					
12/4/2010	weekend	weekend	weekend	weekend	
12/5/2010	weekend	weekend	weekend	weekend	

Pathology and Biospecimen Storage

SOP Number: NRGBB-SF-04

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4.1.15

PURPOSE

This procedure outlines the storage protocol for all specimens in the NRG Biospecimen Bank- SF. The goal is to store biospecimens at optimal conditions for long term storage for future use in translational research projects and to store the information about their location in a secure database.

ABBREVIATIONS

- A. H&E- Hematoxylin & Eosin.
- B. FFPE- Formalin fixed paraffin embedded
- C. PPE: Personal protective equipment

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

- a. Personal Protective equipment (PPE) Gloves, Lab coat, Goggles (as needed):
- b. Handling
 - i. Formalin fixed paraffin embedded (FFPE) blocks and glass slides are not considered to be biohazards and do not require personal protective equipment during handling. However, staff may opt to use appropriate personal protective equipment for handling glass or soft paraffin.
 - ii. Fresh Tissue, Blood, Buccal Swabs, Urine, Cerebral Spinal Fluid are considered biohazards and must be handled using PPE in the lab space approved for Biosafety level 2 work.

SPECIMENS

- A. H&E stained slides
- B. FFPE Blocks/ punches
- C. Unstained Slides
- D. Tissue Microarray FFPE Blocks and slides
- E. Saliva
- F. Whole blood
- G. Plasma
- H. Serum
- I. Buffy Coat
- J. Urine
- K. Buccal swaps
- L. Fresh Tissue
- M. Cerebral spinal fluid (CSF)

QUALITY CONTROL

- A. All samples are labeled with an NRG Study ID number and Case ID number. There are no patient personal identifiers.
- B. The STARS database is kept on a server behind the UCSF Medical Center's firewall. All appropriate physical and network security precautions have been taken. The database is kept only on that computer's hard drive and is not available from the hospital network. The database is backed up daily onto magnetic tape and the backups are stored in a secure offsite location. The only authorized users are the tissue bank manager and Biospecimen Bank lab workers and the tissue bank directors. Both the manager and director have signed agreements to maintain confidentiality of samples within the Biospecimen Bank. They also have completed an Office of Human Subjects Research (OHSR) training course on the protection of human subjects.
- C. -80°C Freezers are monitored using a secure wireless monitoring system and are on emergency power and emergency liquid nitrogen for backup.

STORAGE PROCEDURE

- 1) **Storage Locations:** NRG Biospecimen Bank- SF is located at the UCSF Mt Zion Campus in the Mt Zion Cancer Research building at 2340 Sutter St and the Brunn Building at 1657 Scott Street, San Francisco, CA 94115
 - A) 2340 Sutter St: Room S341:
 - Six -80°C freezers. They are monitored using a secure web based monitoring system and are on emergency power. Four of the six are hooked up to emergency liquid nitrogen for additional backup. One of the six is used for emergencies, extra large shipments, and for storage during defrosting others.
 - One -20°C freezer, used for DNA storage
 - One Fridge for storage of unstained slides
 - Lab space for receiving and storage of FFPE blocks and Slides
 - BSL2 lab for receiving and processing frozen specimens, with a Biological safety cabinet and centrifuge available for use.
 - Office space for FFPE Processing, and data entry and computers
 - B) 620 Forbes (Oyster Point Freezer Farm):
 - Four -80°C. They are monitored using a secure wireless monitoring system and are on both emergency power and emergency liquid nitrogen or CO2 as backup.
 - C) 1657 Scott St First Floor, room E140:
 - Six -80°C freezers. They are monitored using a secure wireless monitoring system and are on both emergency power and emergency liquid nitrogen for backup.
 - D) 1657 Scott St, Second Floor:
 - Room E207: Five 4°C refrigerators. Checked daily.
 - Room E207: Saliva storage

- 2) **Sample Receiving:**

- A) All biospecimens are received in room S341. Depending on the specimen type they are processed according to that samples individual standard operating procedure (SOPs 1-3)
 - B) All biospecimens arrive with a specimen transmittal form (appendix A2), which is used to confirm what has been received is what was shipped, and is used for entering sample information into the database.
 - C) All biospecimens are given unique barcode labels using the database.
- 3) **STARS Database Entry:** See Appendix A-5.
- 4) **Storage Conditions:**
- A) H&E Slides:
 - Room S341
 - Received and stored at room temperature in metal slide filing racks.
 - Labeled and organized by study, case id.
 - Each slide is barcode labeled when received and is in the STARS database inventory.
 - B) FFPE Blocks/ punches:
 - Room S341
 - Received and stored at room temperature in plastic block storage racks
 - Labeled and organized by study, case id.
 - Each block is barcode labeled when received and is in the STARS database inventory. Punches are made into blocks and are handled the same as FFPE blocks.
 - C) Unstained Slides
 - 1657 Scott St Room E207
 - Received at room temperature
 - Stored at 4°C in plastic slide boxes and sealed in nitrogen filled, followed by vacuum removal of all air plastic bags with dessicant.
 - Labeled and organized by study, case id.
 - Each slide is barcode labeled when received and is in the STARS database inventory.
 - D) FFPE TMA blocks/slides
 - Room S341
 - Blocks stored at RT.
 - Unstained TMA slides- stored in slide boxes with dessicant, sealed under Nitrogen. Stored in –80°C Freezer.
 - H&E stained TMA slides are stored at room temperature.
 - Inventory of TMA blocks and slides is maintained in a spread sheet and a hard copy printout is kept in a binder by the TMAs
 - E) Saliva
 - 1657 Scott St Room E207
 - Stored in collection containers at room temperature in Saccomanno preservative. Stored in Flammable cabinets.
 - Labeled and organized by study, case id.
-

- Each sample is barcode labeled when received and is in the STARS database inventory.
- F) Blood:
- Stored in -80°C freezers
 - Frozen aliquots are received in cryovials on dry ice, stored in -80°C Freezers
 - Labeled and organized by study in cardboard freezer boxes.
 - Each sample is barcode labeled when received and is in the STARS database inventory
 - Aliquot locations are mapped into STARS inventory system
- G) Plasma:
- Stored in -80°C freezers
 - Frozen aliquots are received in cryovials on dry ice, stored in -80°C Freezers
 - Labeled and organized by study in cardboard freezer boxes.
 - Each sample is barcode labeled when received and is in the STARS database.
 - Aliquot locations are mapped into STARS inventory system
- H) Serum:
- Stored in -80°C freezers
 - Frozen aliquots are received in cryovials on dry ice, stored in -80°C Freezers
 - Labeled and organized by study in cardboard freezer boxes.
 - Each sample is barcode labeled when received and is in the STARS database.
 - Aliquot locations are mapped into STARS inventory system
- I) Buffy Coat:
- Stored in -80°C freezers
 - Frozen aliquots are received in cryovials on dry ice, stored in -80°C Freezers
 - Labeled and organized by study in cardboard freezer boxes.
 - Each sample is barcode labeled when received and is in the STARS database.
 - Aliquot locations are mapped into STARS inventory system.
- J) Urine
- Stored in -80°C freezers
 - Received frozen on dry ice, stored in -80°C Freezers
 - Stored in urine collection cups
 - Labeled and organized by study in racks.
 - Each sample is barcode labeled when received and is in the STARS database.
 - Location mapped into STARS s inventory system
- K) Buccal Swabs
- Stored in -80°C freezers
 - Frozen aliquots are received in cryovials on dry ice, stored in -80°C Freezers
 - Labeled and organized by study in cardboard freezer boxes.
 - Each sample is barcode labeled when received and is in the STARS database.
 - Aliquot locations are mapped into STARS inventory system
- L) Fresh Tissue
- Stored in -80°C freezers
 - Frozen aliquots are received on dry ice, stored in -80°C Freezers

- Aliquots can be as cryovials, OCT blocks, or in cryovials with RNA-later solution. Tissue that comes in RNA-later is study specific and is noted in the database as being stored in RNA-later solution.
 - Labeled and organized by study in cardboard freezer boxes.
 - Each sample is barcode labeled when received and is in the STARS database.
 - Aliquot locations are mapped into STARS database inventory system
- M) Cerebral spinal fluid
- Stored in -80°C freezers
 - Frozen aliquots are received on dry ice, stored in -80°C Freezers

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPATH		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

NRGBB-SF Returning Blocks / Slides

SOP Number: NRGBB-SF-SOP05

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4/1/15

PRINCIPLE/PURPOSE

To outline processing procedures for dealing with requests for returning blocks and slides to institutions requesting they be returned

ABBREVIATIONS

- A. FFPE- Formalin Fixed Paraffin Embedded

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

- A. Personal Protective equipment (PPE): Gloves, Lab coat, Goggles (as needed)

SPECIMEN

- A. Specimen Type(s) - Paraffin Blocks, Stained Slides,
- B. Handling - FFPE blocks and glass slides are not considered to be biohazards and do not require personal protective equipment during handling. However, staff may opt to use appropriate personal protective equipment for handling glass or soft paraffin.

QUALITY CONTROL

- A. For each request verify that the block or slide being requested is in inventory.
- B. Check Section 10 protocol as to what is required vs requested.

PROCEDURE

1. Request by Email for returning blocks:
 - i. Print out Email and place in Return Request File. Keep all correspondence together
 - ii. Check protocol section 10 to see what is required vs recommended. Reply to the email:
 - (1) Standard reply.. Dear, We received a request from you to return case# study number material. Can you please let us know the reason for this request? Please fill out the attached return request form. Thank you for your help with this.
 - (2) If they reply that it is for patient continuing care/review or legal matter then we must act within 24 hours:
 - (a) Prepare one unstained slide for an H&E and a 2 or 3mm punch, and ship the slides/blocks by overnight courier. Include a Notification of Materials received

- form for them to fax to us upon receipt. Keep all records together.
- (b) Scan any H&Es being returned into the Aperio Digital Imaging system as an archive.
 - (c) Check samples out of STARS (See Appendix V for STARS data entry)
 - (d) Enter the new H&E and new block into STARS inventory
- (3) When they reply, and they still want the block back then forward them the official NRG Biospecimen Bank- SF letter from the director and include a brief letter stating that we prefer not to return material unless it is for continuing care/review or legal reasons.
- (4) If they still request the slides/blocks back, then make one unstained to make an H&E and take a 3mm punch to make a block from. Do not return the only H&E on file.
- (a) Scan any H&Es being returned into the Aperio Digital Imaging system as an archive
 - (b) Check samples out of STARS, and ship them the specimens back with tracking information. Include a Notification of Materials received form for them to fax to us upon receipt.
 - (c) Enter the new H&E and new block into STARS inventory
2. Request by Mail/ Fax or letter with specimen.
- A. Place letter in Return Request File. Keep all correspondence together. Scan and file.
 - B. Check protocol section 10 to see what is required vs recommended. Reply to the request by:
 - (1) If request is for patient continuing care/review or legal matter then act within 24 hours:
 - (a) Make one unstained slide for an H&E and a 3mm punch
 - (b) Ship them the specimens by with tracking information. Include a Notification of Materials received form for them to fax to us upon receipt.
 - (c) Scan any H&Es being returned into the Aperio Digital Imaging system as an archive
 - (d) Check out samples from STARS as distributed.
 - (e) Enter the new H&E and new block into STARS inventory
 - (2) If the request is just for the pathology department then send them the official NRG Biospecimen Bank- SF letter from the director.
 - (a) If they still request the slides/blocks back, then make one unstained to make an H&E and take a 3mm punch to make a block from. Do not return H&Es.
 - (b) Ship them the specimens by Fed Ex with tracking information. Include a Notification of Materials received form for them to fax to us upon receipt.

- (c) Scan any H&Es being returned into the Aperio Digital Imaging system as an archive
- (d) Check samples out of STARS.

ATTACHMENTS

A. NRG Biospecimen Bank- SF letter from the Director requesting to keep the blocks and slides.

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPath		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		



Advancing Research. Improving Lives.™

NRG Oncology Biospecimen Bank
University of California San Francisco
2340 Sutter St, Room S341
San Francisco, CA 94115
Tel: 415-476-7864/ Fax: 415-476-5271

Dear Colleague:

We write to inform you about the ongoing NRG Oncology tissue banking efforts being made by the pathology community to enhance our abilities to successfully treat cancer patients. NRG is part of an NCI-funded national clinical trials network that explores through clinical trials new therapeutic options involving radiation therapy or surgery in combination with other modalities for cancer patient treatment. NRG Oncology's membership roster is comprised of over 1,900 member sites (including at your institution) including institutions on five continents. Our investigators represent all of the oncologic medical specialties and disciplines.

The NRG Biospecimen Bank is a repository (Tissue Bank) for biospecimens collected from patients consenting to enrollment into these trials. The NRG principal investigator and research associate at your institution has information about how enrolled patient tissue materials are to be collected and shipped to the NRG Biospecimen Bank, and how your institution is reimbursed for these efforts.

Being pathologists ourselves, we are aware of the extra effort needed from your department to provide these materials to NRG. If it is not possible to send the tumor block, your institution could instead submit 2 mm punch(es) from a tumor-containing region (or the NRG Bank can do this and return the block(s) to you). The NRG Biospecimen Bank provides a kit and instructions for this activity. Some protocols allow unstained slides to be submitted as acceptable alternative specimens. You should submit your request for reimbursement to the Principal Investigator of the NRG grant at your specific institution as pathology reimbursement is now included in the patient enrollment reimbursement. We can provide that information if you are not sure who is the NRG PI at your institution.

We also understand that due to regulatory and compliance issues, you might be reluctant to release patient materials from your facility, especially if this is the diagnostic material of record in your files. For most protocols a duplicate cut stained H&E slide is acceptable and does not have to be the slide that the diagnosis was made from. **Please keep in mind that these patients enrolled in NRG Oncology clinical trials have explicitly consented to release of their materials to NRG Oncology.** The NRG Biospecimen Bank keeps these materials in a centralized location, and is capable of returning them to you whenever needed for clinical or legal reasons (usually within 24 hours).

I hope that you find the above information useful and that it encourages your help and participation in NRG Oncology efforts. Attached with this letter is additional information to answer other questions that you may have about the NRG Biospecimen Bank and its activities. We look forward to working with you and we are here to help answer any other questions you might have about these efforts.

Sincerely,

Richard Jordan, DDS PhD FRCPath - Director NRG Biospecimen Bank- SF
Jeffrey Simko, MD PhD, Co-Director Ken Aldape, MD, Co-Director

NRG Oncology Biospecimen Bank

University of California San Francisco

Box 1800

San Francisco, CA 94143-1800

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The NRG Tissue Bank pathologists are all anatomic pathologists practicing in a large tertiary care hospital. We are well aware of the concerns you might have over removal of blocks from your files because they are being removed from ours as well, but hopefully the following addresses your concerns:

1. *Patient Consent:* Each Patient, as part of enrollment into NRG studies, signs a study-specific consent form explicitly stating permission to use their tissues for research purposes. Tissues used for research are only labeled by NRG case number in a HIPAA-compliant manner, and no patient identifying information can be obtained by researchers. These are population-based studies, which look at population characteristics rather than individual patient related issues. We know from our previous experience that patients want these studies to be done, and they have only rarely declined participation in tissue bank studies.
2. *Access of Institution to Tissue Blocks and Requirement for 10 years of Storage to Satisfy Regulations (CAP):* The tissue blocks are stored in a cool, dry place by accession number. The location of blocks and material disposition is available on a database that is readily available. Institutions needing their blocks returned because of patient, physician or legal requirements can have their blocks returned overnight by faxing or e-mailing a request to the NRG Tissue Bank (contact numbers are above).
3. *Ability of Pathologists in the Institution to Perform Scientific Studies:* The storage of these tissues centrally does not preclude investigation using this material by anyone. Any scientist with a scientifically valid proposal, and the funds and methods to investigate it can use the tissue bank, and such access is a requirement of NIH funding of tissue bank activities. The bank makes it possible to study larger numbers of patients on which treatment is standardized and follow up is available. By sharing our resources, we are much more likely to answer important scientific questions related to cancer. Enrollment in clinical trials rarely involves more than 5% of patients of a particular tumor type and thus does not compromise the group of patients available for local studies in most cases.
4. *Gaining Access to these materials:* The tissue bank will permit the study of cases entered into NRG Oncology clinical trials by any qualified investigator (including pathologists) making an application regardless of affiliation; contact us about this application process. This tissue resource will allow correlative studies to be performed on clinically homogeneous patient populations, which will give us important information about prognostic factors, treatment selection factors and biologic behavior, if the resources are used wisely. Applications are reviewed semiannually by either an NRG or Intergroup tissue banking committee who will decide whether tissue can be allocated for the proposed project. All applications must be reviewed by NCI's CTEP program for final approval. The investigator must have funds and facilities available to carry out the proposed research project. Correlative studies are also funded as part of the clinical trial proposal. If you would like specific information about what has been discovered via previously supported projects, please contact us for a list of references.

PROTOCOL

PATHOLOGY QA REVIEW

- A) H&Es are reviewed as in B) below if they are accompanied by a block.
- B) FFPE Blocks and Tissue Punches:
 - i) On arrival and entry into the tissue bank, each case with a FFPE block is reviewed by one of the three NRG Biospecimen Bank- SF pathologists (Dr Jordan, Dr Simko, Dr Aldape) either as a slide with a microscope or as an Aperio digital image over the web.
 - ii) Any case that arrives as a tissue punch is sent to the UCSF Tissue Core for embedding and an H&E slide is made of the punch. This is then reviewed as a FFPE Block would be.
 - iii) The submitted pathology report is reviewed concurrently with the corresponding tissue. Using a standardized tissue banking template (attached) each case is confirmed for:
 - a) NRG Study Number and Case number identifiers
 - b) Block number
 - c) H&E creation
 - d) Presence or absence of lesional tissue
 - e) Diagnosis
 - f) Presence or absence of normal tissue
 - g) Size of tumor
 - h) Fraction of tumor cells present
 - i) Size of normal tissue
 - j) Potential number of sections from blocks
 - iv) If the diagnosis rendered at the NRG Biospecimen Bank- SF corresponds to the submitting pathologist's diagnosis then no further action is taken and the pathology review is entered into STARS for that case, and the sample is filed.
 - v) If there is a discrepancy between the NRG Biospecimen Bank diagnosis and the submitting pathologist's diagnosis, then a second review is requested from one of the other NRG Biospecimen Bank- SF pathologists.
 - a. If the discrepancy continues then other blocks associated with the case are requested from the submitting institution.
 - b. Re-review then ensues.
 - c. Discrepancies that persist will be referred to the pathologist assigned to the tissue site but outside the NRG Biospecimen Bank- SF.
 - vi) If it is deemed that no tumor is present on the submitted case then the case will be returned to the contributing institution with a request for other blocks associated with the case to be sent in to NRG Biospecimen Bank- SF for secondary review.
 - vii) Unusually difficult cases may be referred to a second NRG Biospecimen Bank- SF pathologist for review and consultation.

NRG Biospecimen Bank-SF Pathology QA Form

Study #: _____
Case #: _____

Histology Needed

- Embed punch in block
- Stain unstained slide
- Cut and stain H&E

Date sent to Tissue Core/ Outside/ Other: _____
Date returned from Tissue Core/ Outside/ Other: _____

Slide Review

Pathology Number _____ Block# _____

Evaluation of H&E: From Institution From Unstained New from Block

- Tumor is present. ***Please identify the tumor area with circle(s)/dot(s)***
 - Tumor \leq 1 mm diameter
 - Tumor 1-5 mm diameter
 - Tumor $>$ 5 mm diameter
 - Tumor Fraction \geq 70% Tumor Fraction $<$ 70%
- No tumor present in original H&E evaluated (see re-evaluation below)
- Other/Comments _____

- Non-neoplastic tissue present
 - Tissue \leq 1 mm diameter
 - Tissue 1-5 mm diameter
 - Tissue $>$ 5 mm diameter
 - NNP Fraction \geq 70% NNP Fraction $<$ 70%
- No non-neoplastic tissue present

Potential Block Sections:

- 0-10 10-50 \geq 50

RE-EVALUATION IF NO TUMOR FOUND IN LAST H&E

- Tumor present in re-evaluation. (see size above)
- No tumor present in re-evaluation

NRG PATHOLOGIST

- JORDAN SIMKO ALDAPE PERRY ROJIANI

Date reviewed: _____

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPath		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

Central Review

SOP Number: NRGBB-SF-SOP-07

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4/1/15

PRINCIPLE/PURPOSE

This procedure outlines the process for submitting pathology material for Central Review.

ABBREVIATIONS

- A. H&E- Hematoxylin & Eosin. B. FFPE- Formalin fixed paraffin embedded
C. IHC – Immunohistochemistry

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

- A. Personal Protective Equipment (PPE): Gloves, Lab coat, Goggles (as needed)
- Handling – FFPE blocks and glass slides are not considered to be biohazards and do not require personal protective equipment during handling. However, staff may opt to use appropriate personal protective equipment for handling glass or soft paraffin.

SPECIMENS

- i. H&E and/or IHC stained slides
- ii. FFPE Blocks
- iii. Unstained Slides

QUALITY CONTROL

- a) All samples are labeled with an NRG Study ID number and Case ID number
- b) Checklist
 - i. Letter with instructions- Email and send hard copy and on flash drive
 - ii. Slides- digital- refer to in letter with instructions/ OR manual in boxes.
 - iii. List of cases in excel spread sheet- Email and send hard copy and on flash drive
 - iv. One PDF of all prefilled P3 forms for reviewer to print out or write in electronically- Email and send hard copy and on flash drive
 - v. Single PDF files of all pathology reports- on flash drive
 - vi. Material received form- hard copy to be faxed back
 - vii. SOP for shipping slides back to NRGBB-SF.

PROCEDURE

1. After receiving a request for central pathology review create a detailed list for the reviewing pathologist describing exactly what is being sent. The list can either come directly from NRG Oncology headquarters or is generated from a search of the new STARS database for that study or the legacy Freezerworks database.
 - a. Record on the database list exactly what is being sent and the pathology number and block id for the case.

 2. Pull all the H&Es (and IHC's) that are requested
 - a. If any case does not have H&E's but has unstained slides or blocks, an H&E is requested to be made at the UCSF Tissue Core from the unstained or block.
 - b. Once the H&E is made, it is reviewed by one of the Biospecimen Bank pathologists for tumor content and entered into the STARS database, and a barcode label is made. If the H&E is made from one of the unstained slides in inventory, then change the specimen type in STARS to H&E.
 - c. For H&Es to be scanned by an automated slide scanner follow the SOP for Digital Slide review below.

 3. Digital Slide Review:
 - a. Scan H&Es into the Aperio Slide Scanner as a Project. See SOP-13 for procedure.
 - b. In Spectrum enter study Caseid and Block id.
 - c. Make a folder named "CentralReviewStudy#". Copy the scans for each case from the Rdrive/Scans into this folder. Make sure each scan has the pathology report present, keep scans as individual files.
 - d. Prepare a P3 form online (study specific) for each specimen by putting the institution name and number, study and case number, specimen accession number and date of biopsy on each P3 form for each case. Make one large pdf from these.
 - e. Include the Spectrum SlideID on the list of slides for the pathologist to review

 4. Manual Slide Review- for cases with plastic coverslips or non-scannable slides.
 - a. Package the slides to be sent:
 - i. Check the slides out of STARS for central review
 - ii. Put the slides back to back if possible in the mailing box in order of the case numbers. After a box is full, put paper towel in the top of the box to keep slides from moving and tape the box shut.
 - iii. Put "Fragile Handle With Care" labels on the front and back of the outer box.

 5. For either Digital or Manual review include the following by email or hardcopy with the slides
 - a. A copy of the database list that includes the detailed information for each case.
 - b. A "notification of receipt" letter to the pathologist. When they receive the material they will sign and date this letter and fax it back to notify us that it has been received
 - c. The P3 forms and the pathology forms as above.
 - d. A letter to the pathologist to inform him/her what protocol they are receiving and if they are receiving digital or manual Slides (in how many boxes) for review.
 - i. For digital Review include in the letter the following instructions:
-

Re: Central Review of Digital Images using the Aperio Slide Scanner and Spectrum Software for NRG Study # cases #-#

Dear Dr

Here are the instructions on how to access the images for Study #cases # for central review. Also attached is the list of cases and slides and a pdf of the P3 forms. The P3 forms are in PDF format for you to print/fill out. PDF scans of the pathology report for each case along with all this paperwork is on the enclosed flash drive. The pathology reports are labeled as "Study#-case #".

Go to <http://128.218.212.20> and enter Spectrum login information

Username: [reviewer's name]

Password: [to be named]

After logging in, go to: <http://128.218.212.20/linkforspecificprotocolproject>

Scroll down to "Project Digital Slides" to view the slide images.

Click on the CaseID header in the purple menu bar to sort the slides by case number. The BlockID field contains the block number of the slide.

To view the next page of slides, click on "next" above the purple menu bar on the right side, or use the dropdown menu to pick a specific page to go to.

To view the images, click on the thumbnail image of the slide.

Webviewer instructions: To zoom in, you can click on the plus sign at the bottom or double-click on the image. To zoom out, click on the minus sign at the bottom. To move around the slide, use the arrow keys or click-and-drag on the image.

Please let us know if you have any further questions

The NRG Biospecimen Bank- SF

6. Ship the package using Federal Express 2-day delivery and keep the tracking number.
 7. On the delivery date:
 - a. Print out a copy of the tracking sheet and keep it with the set of reports filed together in the permanent report files.
 - b. Upon receipt, file notification letter in permanent report files.
 8. When samples are returned
 - a. Return the slides back into STARS database
 - b. Send paperwork to HQ (Roseann Bonnani is the contact for this as of 7/6/2014)
- c)

ATTACHMENTS

- A. Specimen Transmittal Form (Appendix A2)
- B. STARS database entry protocols (Appendix A5)

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPATH		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

Translational Research Projects -- Outgoing Requests

SOP Number: NRGBB-SF-SOP-08

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4/1/15

PRINCIPLE/PURPOSE

This procedure outlines the shipping out and tracking of all biospecimens being shipped out for NRG Oncology Biospecimen Bank TRP requests. The purpose is to verify that samples exiting the Biospecimen Bank are being used for approved NRGBB-SF TRPs or seed grants.

ABBREVIATIONS

- A. H&E- Hematoxylin & Eosin. B. FFPE- Formalin fixed paraffin embedded
 C. PPE: Personal Protective Equipment.

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

- A. Personal Protective Equipment (PPE): Gloves, Lab coat, Goggles (as needed)
- Handling – FFPE blocks and glass slides are not considered to be biohazards and do not require personal protective equipment during handling. However, staff may opt to use appropriate PPE for handling glass or soft paraffin.
 - Fresh Tissue, Blood, Buccal, Urine, Cerebral Spinal Fluid are considered biohazards and must be handled using PPE in the lab space approved for Biosafety level 2 work.
 - All staff members are trained in safe shipping and handling of biohazardous materials.

SPECIMENS

- | | |
|--|--|
| A. H&E stained slides- | Shipped out ambient |
| B. FFPE Blocks/ punches | Shipped out ambient- on cold pack during summer. |
| C. Unstained Slides | Shipped out ambient- on cold pack during summer. |
| D. Tissue Microarray FFPE Blocks and H&E slides: | Shipped out on cold pack.. |
| E. TMA unstained slides | Shipped out frozen on dry ice |
| F. Saliva | Shipped out frozen on dry ice |
| G. Whole blood | Shipped out frozen on dry ice |
| H. Plasma | Shipped out frozen on dry ice |
| I. Serum | Shipped out frozen on dry ice |
| J. Buffy Coat | Shipped out frozen on dry ice |
| K. Urine | Shipped out frozen on dry ice |
| L. Buccal swaps | Shipped out frozen on dry ice |
| M. Fresh Tissue | Shipped out frozen on dry ice |
| N. Cerebral spinal fluid (CSF) | Shipped out frozen on dry ice |

QUALITY CONTROL

- A) All outgoing requests must be approved in writing and have a signed MTA prior to shipping out.
-

- B) All samples are shipped out with a STARS created label with the NRG Study ID number, a Unique Specimen Identifier (USI), specimen type and unique bar code.
- C) All samples shipped out are sent with a list of cases being sent and a Notification of Materials Received Form for the recipient to fax to us upon receiving the samples.

PROCEDURE

1. Sample Availability

All TRPs undergo an application process through NRG Oncology headquarters at Philadelphia. In 2015 all request will go through the NCI Navigator and Front door process. Each tissue site has a TRP panel which reviews all incoming requests. The Biospecimen Bank is consulted regarding availability of biospecimens for these projects both during the planning and application phases. When a request comes in regarding availability the following process is followed:

An advanced search is performed in STARS database specific to the request. NRG Oncology Data Management will give us a list which might include the studies/cases/specimen types that they are interested in.

- i) If the request is for a specific study then the search is narrowed by study.
- ii) If the request is for a specific specimen type this is also included
- iii) There are pre-assembled reports in the STARS database. In most cases the search should be done by selecting at the aliquot level. In the search windows there are other fields that can be added according to what information is requested.
- iv) Once the search is completed it is exported into excel by selecting the export menu. Use an already assembled export or make your own.
- v) A summary is prepared from the exported excel sheet in order to give the information needed- for example # of cases with blocks only, and those with unstained slides. Excel "Pivot" tables can be used to summarize data.

2. Approval Process

Once a TRP has been approved by NRG Oncology, it is sent to CTEP for approval. Once approved an MTA is created by NRG oncology with an exhibit A. The MTA includes the estimated cost for the material. Nothing can be shipped/pulled until the MTA is returned signed.

3. Shipping out specimens

Once NRG Oncology notifies the Biospecimen Bank that the TRP is approved in writing, the staff will pull the requested samples and process them according to the TRP request.

- a) If unstained slides need to be cut these are requested from the UCSF Tissue Core and re-charged to the TRP funds.
- b) If a TMA is to be constructed then the NRG pathologist for that tissue site will review the slides and a TMA is constructed by the UCSF Cancer Center Tissue Core (see TMA Creation SOP-09). These are re-charged to the TRP funds.
- c) The ship to address and contact information is emailed from NRG Oncology headquarters to the Biospecimen Bank.

- d) Once samples are ready to ship:
 - i. Aliquots are scanned out of STARS using the protocol for removal of biospecimens from STARS (see attached).
 - ii. The samples are packed well to avoid breakage and frozen material is packed on dry ice to prevent thawing.

Glass slides are shipped in hard cased glass slide boxes, back to back if they fit, and paper towel is used inside the box to make sure the slides won't move around during the shipping. The boxes are packed in hard sided boxes, except in hot seasons when Styrofoam boxes with cold packs are utilized.

Frozen samples are boxed up, and paper towel is used to prevent samples from moving around. Padding is placed around the boxes or containers to avoid breakage due to dry ice bouncing around during shipping. Liquids are shipped in secondary containers to contain any potential spills or leaks, as required by the shipping regulations for biospecimens. Enough Dry Ice is included in the box for two days.

A Notification of Materials Received (attached) form is sent with each shipment for the recipient (patient, physician or pathology department) to sign and fax to us that they received the specimens
 - iii) A complete list of all samples being sent is included.
 - iv) Samples are shipped out by overnight courier mail and an email is sent to the recipient with tracking information so that they know it is on the way.
 - v) Specimens will be returned to the Biospecimen Bank if they end up not being used for that TRP. They are never destroyed.

ATTACHMENTS

- A. Notification of Materials Received Form (Appendix A3)
- B. STARS Entry and Exit Protocols (Appendix A5)

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPath		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

Tissue MicroArray Creation

SOP Number: NRGBB-SF-SOP-09

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4/1/15

PRINCIPLE/PURPOSE

This procedure outlines the preparation and processing of tissue in order to make a high quality TMA consisting of anywhere from 10-200 specimens in a single paraffin FFPE block. This results in one slide being able to be used for a single assay instead of one for each case.

ABBREVIATIONS

- A. H&E- Hematoxylin & Eosin.
- B. FFPE- Formalin fixed paraffin embedded
- C. PPE: Personal Protective Equipment.

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

- A. Personal Protective Equipment (PPE): Gloves, Lab coat, Goggles (as needed)
 - Handling – FFPE blocks and glass slides are not considered to be biohazards and do not require personal protective equipment during handling. However, staff may opt to use appropriate PPE for handling glass or soft paraffin.

SPECIMENS

- A. Tissue Microarray FFPE Blocks and slides: Shipped out ambient or on cold pack during hot weather

QUALITY CONTROL

- B. All samples to be punched for the TMA must have an H&E marked & corresponding block checked for tissue quality/usability by a pathologist prior to constructing the TMA
- C. All TMAs must have a design map prior to being constructed.
- D. All TMAs should have up to 20 control tissue included.
- E. Review H&E on every fiftieth (50th) slide taken from the TMA blocks.

PROCEDURE

1. **TMA Design for the NRG Biospecimen Bank- SF**
 - a) Select Control tissues to include on the array based on potential/common antibodies tested and tissue type being used.
 - b) Make a design map before constructing the TMA.

- c) Tissue core samples for the TMA should be removed from the submitted FFPE blocks prior to sectioning or other tissue processing of the tissue block.
- d) The area of the block to be cored should be selected by a pathologist.
 - i) A fresh H&E section from the block should be used.
 - ii) The appropriate sampling sites should be circled or otherwise marked on the corresponding H&E before the array process is begun.
 - iii) Select tumor area (red or green pen), and if present also mark pre-malignancy, and benign tissue (blue pen) for the TMA.
 - iv) Areas of necrosis, inflammation, or fibrosis should be avoided unless required by the study.
- e) TMA core size and number of cores taken per specimen block should be pre-determined by the TRP or Pathology committee for the trial.
 - i) In general, taking three cores per specimen block is recommended (if size permits), with placement of one each in identical TMA blocks.
 - ii) Available core sizes are: 1.0 mm diameter, with 3mm spacing, or 0.6 mm diameter with 1.5mm spacing. Smaller diameter is used for larger arrays (>150 cores)
 - iii) The maximum number of cores that should be placed on a single block will vary depending on core size, block size, and IHC methodology, among other factors. Avoid placing so many cores on a TMA that the surface section of cores becomes larger than the antibody coverage area on the slide programmed by the auto-stainer, or that the cores are on the periphery of the slide and difficult to observe or image. Density: The distance between cores should NOT exceed the core diameter (otherwise, manual interpretation is hindered).
- f) A discussion of whether to take extra cores for nucleic acid extraction at the time of TMA construction should be made prior to constructing the TMAs
- g) Controls should be placed on each TMA block.
 - A. Tissue-specific control cell lines: if feasible, adding a number of cell line buttons for the tissue of interest is optimal. However, this is not required since such cell lines may not be readily available
If available, the following cell lines should be included:
 - Breast: SKBR3, MCF7, T47D, etc.
 - Prostate: PC3, LNCAP.
 - Head and Neck:
 - Brain: etc.
 - Other:
 - B. Benign tissue-specific controls: Place 3-5 benign normal cores from the same tissue type on each array.
 - C. Other IHC controls: Normal tissue, at a minimum, should contain: liver, kidney, endometrium, lymph node, colon, and testis. Other normal include adrenal gland, brain, breast, lung, pancreas, placenta, prostate, uterine myometrium (smooth muscle), and skin.

- h) Quality assurance measures for the TMA should include the following:
- A. Review H&E on every fiftieth (50th) slide taken from the TMA blocks.
 - B. Perform standard marker staining (e.g. ER, PR and HER2 for breast) on the TMA tissue upon sectioning and before distribution of TMA sections to researchers, even if data are available from the original pathology.
 - C. Central marker assessment may be necessary until such a time that such stains are performed in a standardized fashion across institutions. Central assessment as well as data collection **MUST** be done via the central banks/labs since future studies will compare findings with standard marker status of the tissue in order for the study to be meaningful.
 - D. The above tests should be reviewed by a pathologist.
- i) TMA layout: A discussion of the layout should take place before the maps are constructed:
- Core Size
 - Core spacing
 - Core distribution
 - Cores types (benign vs tumor)
 - # of replicates per TMA,
 - # of replicate TMAs
 - Types of controls
- B. In general a TMA layout should be asymmetric and irregular so that it is relatively easy to orient the TMA block. For example, the following features may be included:
- Blank rows and columns that do not run down the center lines of the TMA blocks
 - A blank corner
 - Asymmetric distribution of control cell lines and tissue controls
 - Labeling of one side of the TMA block
- C. Cores should start 3 mm away from the block edges, to prevent the paraffin from cracking.
- D. If same-patient cores are placed in multiple blocks, place them in the same location in each block. It must be noted that placing them in different positions is useful to avoid "edge" and other inconsistencies; however the NRGBB-SF standard practice is to place them in similar positions in multiple replicate blocks.

ATTACHMENTS

A. Example of a TMA Map

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPath		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

Example of an NRG Biospecimen Bank- SF TMA:

	Column A	Column B	Column C	Column D	Column E	Column F	Column G
	Slide Label Location						
	Sarcoma TMA 23						
Row 1							
Row 2							
Row 3				Blank			
Row 4							
Row 5							
Row 6							
Row 7							
Row 8							

Specimen Tracking IT

SOP Number: NRGBB-SF-SOP-10

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4/1/15

PRINCIPLE/PURPOSE

This procedure outlines the tracking of all biospecimens received and stored in the UCSF NRG Biospecimen Bank- SF. The purpose is to know the exact location of all biospecimens being banked.

ABBREVIATIONS

- A. H&E- Hematoxylin & Eosin. B. FFPE- Formalin fixed paraffin embedded
C. PPE: Personal Protective Equipment.

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

- A. Personal Protective Equipment (PPE): Gloves, Lab coat, Goggles (as needed)
- Handling – FFPE blocks and glass slides are not considered to be biohazards and do not require personal protective equipment during handling. However, staff may opt to use appropriate PPE for handling glass or soft paraffin.
 - Fresh Tissue, Blood, Buccal, Urine, Cerebral Spinal Fluid are considered biohazards and must be handled using PPE in the lab space approved for Biosafety level 2 work.

SPECIMENS

- A. H&E stained slides
- B. FFPE Blocks/ punches
- C. Unstained Slides
- D. Tissue Microarray FFPE Blocks and slides
- E. Saliva
- F. Whole blood
- G. Plasma
- H. Serum
- I. Buffy Coat
- J. Urine
- K. Buccal swaps
- L. Fresh Tissue
- M. Cerebral spinal fluid (CSF)

QUALITY CONTROL

- B. All samples are labeled with an NRG Study ID number and Case ID number
 - C. All samples which are shipped out are sent with a Notification of Materials Received Form for the recipients to fax to us upon receiving the samples.
-

PROCEDURE

- 1) Samples Received:
 - a. Samples are received and are entered into the NRG Biospecimen Bank- SF STARS database inventory according to their corresponding SOP.
 - b. A barcode label is assigned at the case, specimen type and aliquot level as per STARS data entry SOP
 - c. Their locations are assigned a position within their freezer or physical location.

- 2) Sample Return Request to Patient:

When requests are received to return samples to a **patient** for continuing care or legal matters then the aliquots the following is done:

- a. Aliquots are scanned out of the STARS database and returned to the patient by courier mail with tracking information. A note is made in the comments field in STARS.
- b. A Notification of Materials Received (attached) form is sent with each shipment for the recipient (patient, physician or pathology department) to sign and fax to us that they received the specimens.

- 3) Samples Return Request to Pathology Department:

When requests are received to return samples to a **pathology department**, SOP-05 "Return Requests" is followed. Briefly:

- a) Make every effort to keep all biospecimens in inventory and not to return samples for banking purposes at pathology departments. The patient has consented for us to bank their tissue for future research.
- b) If replacement samples can be generated from existing specimens (H&E or punch from a block) these aliquots are made and entered into the STARS database for that study and case. A 2mm punch is made from the paraffin block by a NRG-BB-SF pathologist. The UCSF Cancer Center Tissue Core embeds the punch in paraffin and makes an H&E slide from it. The new block and slide are entered as new aliquots for that case in the STARS database and get barcode labels.
- c) If the samples are returned to the pathology department they are scanned out of the STARS database (attached) and shipped to the pathology department by courier mail with tracking information. A note is made in the comments field that they were returned.
- d) A Notification of Materials Received form is sent with each shipment for the pathology department to sign and fax to us that they received the specimens.

- 4) Samples Sent Out For Central Review

Specimens can be requested for central review for particular studies. (SOP -06)

- a) These are pulled and scanned out from the STARS database, with a note "central review" entered into the comments field.

- b) They are shipped out to the study pathologist by courier mail with tracking information along with a Notification of Materials Received form. The receiving pathologist checks the materials received corresponds to what was shipped, signs, and faxes the form back.
 - c) Once central review is completed, specimens are shipped back to the NRG Biospecimen Bank- SF using courier mail with tracking information and re-entered into the STARS database inventory. Samples received are checked to the Notification of Materials Received Form with what was shipped out in 3b above.
- 5) Samples Sent for Translational Research Projects (TRP)
- a. After the TRP application has been approved by NRG central headquarters an email request for samples is received by the Biospecimen Bank, either directly from the TRP study investigator or from the NRG Oncology study coordinator.
 - b. Specimens are pulled and scanned out of STARS from the inventory.
 - c. Specimens are packed and shipped by courier mail with a detailed inventory list, a Notification of Materials Received Form and any other information requested for that TRP. Once the institute receives the specimens they check that they complete the Notification of Materials Received form, sign the form and fax it to the Biospecimen Bank. This gets filed with the corresponding TRP paperwork.
 - d. TRP specimens will be returned to the Biospecimen Bank if they end up not being used for that TRP. They are never destroyed.

ATTACHMENTS

- A. Notification of Materials Received Form (Appendix A3)
- B. STARS Entry and Exit Protocol (Appendix A5)

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPath		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

NRG Biospecimen Bank- SF Emergency Action Plan

SOP Number: NRGBB-SF-SOP-11

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4/1/15

PRINCIPLE/PURPOSE

To outline the Disaster and Emergency Action Plan for the NRG Oncology Biospecimen Bank- SF.

The purpose is to

- 1) Protect employee safety and the integrity of the Biospecimens during an emergency or disaster.
- 2) Ensure compliance with the UCSF Campus Emergency Response Management Plan, and the emergency planning policies and mandates of the University of California System and the State of California

PROCEDURE

EMERGENCY ACTION PLAN

This Emergency Plan is written for occupants of the following location.

Building/Room(s) #: 2340 Sutter Street rms S341, S333, S335, S336 and 1657 Scott Street, Room E223, E220, E210, E209, E207

Department or Neighborhood: Radiation Oncology

Division/Unit/Lab(s): NRG Biospecimen Bank- SF

Manager: EAP Plan Manager is Sandy DeVries

Phone/Email: 415-476-7864/5268 sandy.devries@ucsf.edu Campus Mailbox # 1800

Date Completed: 7/6/14

Approved by: Dr Richard Jordan, DDS PhD FRCPath

Title: Director of NRG Oncology Biospecimen Bank- San Francisco

DEPARTMENT "UNIT" EMERGENCY COORDINATOR (DEC)

Name:	Sandy DeVries	415-476-5268	Sandy.DeVries@ucsf.edu
Alternate:	M	415-476-7864	Michael.Restrepo@ucsf.edu

FLOOR WARDEN(S)

Assigned Floor:	Third Floor, South Wing, 2340 Sutter St		
Name:	Michael Restrepo	476-7864	Michael.restrepo@ucsf.edu
Alternate Floor Warden:	Mary Manning	476-7864	Mary.Manning@ucsf.edu

EMERGENCY ASSEMBLY AREA (EAA) - Assemble here following a building evacuation

Meet at corner: [Scott/Sutter Street](#).

DEPARTMENT ESSENTIAL FUNCTIONS AND SPECIAL NEEDS:

Comments: The NRG Biospecimen Bank- SF is a banking facility for biospecimens collected from thousands of patients enrolled in over 150 clinical trials. Specimens stored at room temperature include H&E stained slides, Paraffin blocks, and Saliva. Specimens stored at 4°C include 6 refrigerators of unstained slides. Specimens stored in fourteen -80°C freezers include blood, plasma, serum, buffy coat, tissues, buccal swabs and urine.

Cases are de-identified prior to being sent to the bank so there is no access to patient personal identifiers.

Laboratories: Located on the third floor in 2340 Sutter St. Freezers and Fridges are stored on the first and second floor in 1657 Scott St.

Biospecimens: Stored in the following locations. During a power outage that lasts more than six hours or after a natural disaster take the following actions.

Alternate locations to move samples to include Oyster Point Storage, UCSF Cancer Center at 2340 Sutter, Department of Lab Medicine at the UCSF China Basin building on Berry Street, Dept of Radiation Oncology at UCSF Mission Center Building on Folsom St.

A) First Floor 1657 Scott Street:

- Six -80°C freezers containing blood, urine and tissue from clinical trials.
 - Monitored using a secure wireless monitoring system, with battery backup power. The current status of the freezers is monitored from www.accsense.com. The unit are password protected with specific IDs as listed here
 - 1) 00149000109B
 - 2)
 - 3)

All are password protected. When the freezers reach a critical temperature of -50°C the sensor will notify the staff by telephone and by email of the situation.

- The freezers are on emergency backup power and emergency backup liquid nitrogen. If possible order a large tank of liquid Nitrogen immediately and Dry ice from Airgas – 415-648-9353, account# 1AJA1.
- These specimens should only be moved on Dry Ice if absolutely necessary (no backup power) and if other freezers located off site that can house the samples.

B) Second Floor 1657 Scott Street:

Room E207: Five 4°C refrigerators.

- Do not open.
- These contain unstained slides which can be at room temperature (RT) in an emergency situation for an extended period of time, but should be removed to an alternate location if the building is unsafe to occupy.
- These specimens should only be moved on ice if absolutely necessary (no backup power for more than a day) or if other refrigerators are located that can house the samples.

Room E207: Two flammable cabinets with Saliva

- Can remain at RT but should be removed to an alternate location if the building is unsafe to occupy.

C) 2340 Sutter Street Room S341:

FFPE block and Slide storage:

- Can remain at RT but should be removed to an alternate location if the building is unsafe to occupy.

Office space, computers.

- All information is stored on a secure server in a separate location which is on emergency power. The database is kept on a server behind the UCSF Medical Center's firewall. All appropriate physical and network security precautions have been taken. The database is kept only on that computer's hard drive and is not available from the hospital network. The database is backed up daily onto magnetic tape and the backups are stored in a secure offsite location. The only authorized users are the tissue bank manager and NRG BB lab workers and the tissue bank director. Both the manager and director have signed agreements to maintain confidentiality of samples within the Biospecimen Bank. They also have completed an Office of Human Subjects Research (OHSR) training course on the protection of human subjects.
- This server should be removed to an alternate location if the building is unsafe to occupy.

Six -80C Freezers: Are monitored using the secure accsense monitoring system as described above, and are on emergency power and emergency liquid nitrogen for backup

EMERGENCY SUPPLIES

Emergency supplies are maintained at 2340 Sutter Street in the UCSF Cancer Center Research building

Emergency supplies are in a plastic bin located in 2340 Sutter Street : (Complete Inventory on Page 4).

1 st Fl. N – Computer room near back of lab N-171	1st Fl. S – Room S184 Spill Center
2 nd Fl. N – Room N252 Spill Center	2 nd Fl. S – Room S252 Spill Center
3 rd Fl. N – Room N352 Spill Center	3 rd Fl. S – Room S632 Spill Center
4 th Fl. N – Room N452 Spill Center	4 th Fl. S – Room S462 Spill Center

NEAREST PUBLIC TELEPHONE and Campus EMERGENCY PHONE

Public Telephone Location/Number: 1600 Divisadero Mt. Zion Hospital - Near the main bank of elevators – Hospital lobby

Emergency Back-Up Telephone Location/Number: Red campus-only phones located in 2340 Sutter St at the Security desk **(242-3517)**

Building Status Recording: **273-4147**

Cancer Research Building Status Recording: **502-4800 / 273-4147**

We have an After Hours Emergency Notification and Communication Plan in place. See Page 10

LOCATION OF NEAREST FIRE ALARM PULL STATION: By all emergency exits

LOCATION OF NEAREST FIRE EXTINGUISHER (S): By all emergency exits

EVACUATION ROUTE: The Emergency stair exits are located at the back of the lab corridor and at the corner staircases in the front corridor

INDIVIDUALS REQUIRING SPECIAL ASSISTANCE IN AN EVACUATION:

There are no special needs individuals at this location.

STAFF WITH EMERGENCY RESPONSE SKILLS: Include name/contact list

First Aid Training-

CPR-

NERT Training (SF Neighborhood Emergency Response Team)- Sandy DeVries 476-5268

Other:

Key Staff Assignments: List Name/Duty:

Sandy DeVries- manager of NRG Biospecimen Bank- SF.

Facilities- access control, equipment/power issues-

2340 Sutter St: Mike Dزيestak: 1657 Scott St: Burt Mar- 885-3566

EHS for chemical and radioactive spills: 476-1300 or 9-911, Jennifer Scott is our EH&S DSA

Chain of Command:

2340 Sutter St: Adele Dow 514-0272; adow@cc.ucsf.edu

Brunn Building : FM Facilities Burt Mar- 885-3566 burton.mar@mcfm.ucsfmedctr.org

Cathy Garzio. Dept of Radiation Oncology Interim MSO. 415- 353-9796

Dr Richard Jordan, Director of NRG Biospecimen Bank- SF 415- 608-9378 Richard.Jordan@ucsf.edu

Sandy DeVries, Manager of NRG Biospecimen Bank- SF 415-476-5268/7864: sandy.devries@ucsf.edu

EMERGENCY SUPPLIES AND EQUIPMENT

****Each wing on each floor of 2340 Sutter Street has A supply bin. See pg 3 for Room numbers.

Quantity	Purchase/ Replacement Date	Item	Location
1	05-2003	Crank radio	See *** above
1	05-2003	Dust masks	
1	05-2003	Light sticks	
1	05-2003	Roll of duct tape	
1 ea	05-2003	Flathead/Phillips screwdrivers	
1 pr	05-2003	Work gloves	
1	05-2003	Permanent marker	
1	05-2003	4lbs. sledge hammer	
1 roll	05-2003	Caution tape – 3"x200'	
1	05-2003	33' nylon rope	
1	05-2003	Whistle	
1	05-2003	First aid guide	
1 pack	05-2003	Bandages (gauze and plastic strip)	
1 pack	05-2003	Eye pads	
1	05-2003	Scissors	
1	05-2003	Tweezers	
1	05-2003	Rescue blanket	
1	05-2003	Instant cold packs	
1	05-2003	CPR micro shield	

EMERGENCY PLANNING IMPLEMENTATION CHECKLIST

- Appoint a Department Emergency Preparedness Committee (optional).

- Appoint an Emergency Coordinator and Alternate for each work site location.
- Appoint a Floor Warden from your work site to participate in annual evacuation drills.
- Identify an Emergency Assembly Area for each work site.
- Encourage individuals with permanent or temporary disabilities that might require special assistance in an emergency, to self-identify. Assign a co-worker "buddy" to provide assistance during an emergency. Refer to the Campus Evacuation Policy for People with Disabilities Requiring Reasonable Accommodation.
- Monitor and report any non-structural earthquake and safety hazards to EH&S.
- Procure and maintain adequate emergency supplies for work site staff.
- Post yellow Campus Emergency Procedures chart. Call 476-5507 for copies.
- Develop emergency notification, reporting, and callback procedures for staff.
- Perform an annual review and update of the Emergency Action Plan. Submit updates to the UCSF Emergency Preparedness Coordinator. See address on cover page.
- Familiarize all staff with the EAP. Make sure new staff and students are oriented to emergency procedures.

APPENDICES

UNIT EMERGENCY ACTION PLAN 1-5

INTRODUCTION7

EMERGENCY NUMBERS7

DEFINITIONS 8-9

KEY STAFF ASSIGNMENTS10

DEPARTMENT EMERGENCY NOTIFICATION & COMMUNICATION PLAN10

EMERGENCY STATUS REPORT FORM.....11

PERSONNEL ROSTER12

EVACUATION PLANNING13

STAFF EMERGENCY PLAN ACKNOWLEDGMENT FORM14

DEPARTMENT EMERGENCY INFORMATION POSTER.....15

INTRODUCTION: Purpose of the Emergency Action Plan (EAP)

The complexity of a multi-site campus like UCSF requires the full support of faculty, staff, and students to successfully implement the Campus Emergency Preparedness Program.

Department Emergency Action Plans (EAP) are an integral part of the Program, and are vital to maintaining the preparedness and safety of the Campus community.

All Department units are expected to develop Emergency Action Plans specific to their individual locations.

Your Emergency Action Plan should address preparedness measures, emergency response and evacuation planning. The EAP is a way for your unit to prepare and plan for a variety of emergency situations, e.g., medical emergencies, citywide disasters; power outages, hazardous chemical spills, fires, bomb threats, a civil disturbance, and earthquakes.

It is important for staff to read and understand their work site emergency action plan before an emergency occurs. Managers should share safety information with faculty, staff, and students; brief all new personnel as they join the department; and keep copies of the Emergency Plan in accessible locations.

EMERGENCY NUMBERS

9+911 (if from a Campus phone)	Police, Fire, Medical Emergency, Haz Mat Incident
--------------------------------	---

911 (if from a non-campus or pay phone)	
476-1414	UCSF Police Non-Emergency
885-7890	UCSF Medical Center Security
476-2021, 476-1414	Building Damage, Utilities (gas, water, electricity)
476-1234	Code Blue-Parnassus (from phones with Code Blue Stickers Only)
353-1238	Long Hospital Emergency Department
502-4000	Campus Emergency Information HOTLINE Call to hear recorded emergency bulletins/status updates (activated following a major Campus Emergency)
1-800-873-8232	Back-up Emergency Hotline (activated only if campus telephone service fails)
885-STAT	Medical Center Emergency Information Hotline
SF Emergency Alert System (EAS)	KCBS-740 AM, KGO-810 AM, KNBR-680 AM
719-3898 Pager	Needlestick Hotline 24-Hour/7days
Red phones – 2340 Sutter Street Guard desk/N213/	UCSF Emergency Backup Telephones/Location
Adele Dow- 514-0272 (2340 Sutter) Burton Mar- 885-3566 (1657 Scott)	Building Manager Telephone
Sandy DeVries- 476-5268 (Cell: 613-3065)	Room Emergency Coordinator: Name/Telephone
502-4800 / offsite 273-4147	CRB Status Recordings – updated after info is received from campus Emergency Operations Committee

DEFINITIONS:

Alternates- individuals assigned as back-ups to staff assigned to emergency response positions.

Emergency Action Plan (EAP) – prepared by each Campus Administrative and Academic Department/Unit, the EAP is specific to each work site location, and outlines emergency responsibilities of staff, evacuation plans, emergency assembly areas, emergency supplies, etc.

Emergency Coordinator – the primary emergency contact for each work site location; responsible for implementation of the Emergency Action Plan; assists with the safe evacuation of the unit staff (with assistance of unit appointed Floor Monitors); assesses injuries and damage to unit personnel/property and reports status to the Site Emergency Coordinator.

Emergency Hotline - 502- 4000 an emergency information hotline, activated only after a declared campus emergency; provides the Campus community, recorded status updates on the emergency event.

Back Up Emergency Hotline - 1-800-873-8232 is used by the Campus and Medical Center to provide recorded emergency information and instructions, only if local telephone service is interrupted.

Emergency Assembly Areas (EAA) – Designated areas where building occupants assemble following an evacuation to await instructions and “all clear” notifications. The Campus has designated external EAA sites for the major Parnassus Campus buildings.

Emergency Operations Center (EOC). The EOC is where representatives from the various Campus departments assemble to manage the response to the emergency event impacting the Campus; emergency response teams are deployed; resources are allocated; and communication with the City EOC is established. The EOC follows the Campus Emergency Response Management Plan as a guideline for the emergency response and recovery. Status reports and requests for assistance are forwarded to the EOC from the Campus Site Emergency Coordinators.

Emergency Supplies – Departments are responsible for maintaining emergency supplies at each work site, e.g. first aid kits, flashlights/batteries, battery operated AM/FM radio, water, etc. Supplies should be replaced and updated annually.

Emergency Telephone System – Red emergency telephones located in strategic areas throughout the Campus and Medical Center for use in the event of an emergency, or when the Campus telephone system is not operational. Telephone numbers begin with the prefix 753-xxx. Refer to the Campus Telephone Directory for the location and numbers of the back-up emergency telephones.

Floor Wardens – Unit staff designated to monitor the safe evacuation of their assigned floors. Floor Wardens direct staff to emergency exits, monitor movement in stairwells, alert and sweep rooms for personnel, block access to elevators, and assist any disabled staff or visitors. Floor Wardens will receive an orientation to their role, wear an orange ID vest for identification, and participate in the annual building evacuation drill.

Site Emergency Coordinator (SEC) – is responsible for developing the Building “Site” Emergency Plan; is the communication liaison between the building occupants and the EOC following an emergency event impacting the building; and will manage the emergency activities at the site until arrival of campus or city emergency responders. Floor Wardens and Emergency Coordinators provide status reports to the SEC.

KEY STAFF ASSIGNMENTS

Suggestions: Evaluate your Department’s personnel resources. Assign personnel specific duties, during and immediately following a disaster. Identify staff with special expertise or training, who could offer assistance when necessary, e.g., Search & Rescue, First Aid, CPR, HAM Radio Operators. Assign “buddies” to assist disabled staff, patients, and/or visitors during an emergency evacuation. Include information in EAP.

DEPARTMENT EMERGENCY NOTIFICATION and COMMUNICATION PLAN

Include a plan to communicate University information, emergency notifications and instructions to your staff during business and non-working hours. Suggestions:

- Identify key department individuals who will function as emergency information contacts and coordinators to receive and distribute information to staff.

- Consider establishing a Department "Telephone Tree" and Hotline (voice mailbox) to provide information updates and instructions. Publicize Campus and Medical Center information Hotline numbers as sources for general information updates.
- Departments should maintain up-to-date employee recall lists (see personnel roster) to ensure that staff can be contacted in case of an emergency (if key personnel need to be called back to campus, or be consulted for crucial decisions and information, e.g. fire, chemical spill or a crime over a weekend).
- List location and numbers of campus emergency telephones (753-xxxx), and public pay telephones. Pay phones belong to Pacific Bell and may still be operational when other lines are not, or if the Campus telephone system fails. Their location is important to know because a 911 emergency call from a public pay phone can be made without coins and is given the highest priority during times of disrupted or limited service. Do not hang up if you do not hear a dial tone immediately.
- **After Hours Calling Plan for the NRG Biospecimen Bank- SF:**
- **Emergency Process Overview:** In the event of an after-hours emergency, the campus Emergency Operations Committee (EOC) will dispatch the on-call building engineers to check safety of all UC buildings. Buildings related to patient care are checked first. When our building is checked, the EOC will report status to the FM Building Manager. He/she will then call the Bank Manager or the Director and report status. For example, the status may be that the building has checked out safe and normal operations can continue on the next business day; or there may be utility outages or structural problems that prevent employee access until repairs are made. The information about building status will be disseminated via phone trees.
- **Phone Trees:** NRGBB-SF manager will call each person on the list to report the information received about the building. It will be the responsibility of those individuals listed to also contact the Bank manager or director.
- **Voice Mail Information Line:** Two numbers have been set up as informational recordings. When building status is received after an emergency, a recording will be made stating the date/time and the information we have about 2340 Sutter. Employees can call this number to find out if the building is open for normal access or closed for repairs. 502-4800 and 273-4147 (this number is not on the campus phone system, so will work if the campus phones are down). Employees are told to write these numbers on the back of proxy cards with a Sharpie or enter into cell phone. Additionally, there is a campus-wide information line with status on all buildings: 502-4000

Following a major disaster with significant operational impact to the campus, use this form to provide status reports of damage and injuries, and to request assistance from the Campus Emergency Operations Center (EOC).

UCSF EMERGENCY STATUS REPORT

- Use this form to communicate directly to the Emergency Operations Center (EOC).**
- Site Emergency Coordinators: Compile forms from Department Emergency Coordinators/Floor Wardens and forward to EOC. Report status by telephone, radios or runner.
- Department Emergency Coordinators/Floor Wardens: Give Status Reports to Site Emergency Coordinator.
- Report life-threatening emergencies immediately to the EOC.

Building/Floor/Room #: _____ Date: _____

Department: _____

Your Name: _____ Phone #: _____

Your Location: _____

Your unit evacuated to: _____

Problems/Urgent Needs	Exact Location / Details
Serious Injuries? ___ Yes ___ No	
First Aid Station Established ___ Yes ___ No	
Fire/Explosion? ___ Yes ___ No	
___ In progress	
___ Threat	
___ Extinguished	
Building collapse? ___ Yes ___ No	
People trapped? ___ Yes ___ No	
Disabled evacuated from Bldg. ___ Yes ___ No	
Hazardous materials spill? ___ Yes ___ No	
___ In progress	
___ Threat	
___ Extinguished	
Services functional?	
Electrical ___ Yes ___ No	
Emergency lighting ___ Yes ___ No	
Telephones ___ Yes ___ No	



Water ___ Yes ___ No	
Elevators ___ Yes ___ No	
Gas ___ Yes ___ No	
Other Observations/Needs: _____	

NO MAJOR PROBLEM AT THIS TIME

c:/EOC-Status Report Form



PERSONNEL ROSTER -Optional

You may find this list helpful to account for staff at your designated Emergency Assembly Area.

NAME	WORK LOCATION	Other work location	
Michael Restrepo	2340 Sutter St # s341	1657 Scott St	
Sandy DeVries	2340 Sutter St # s341/S335	1657 Scott St	
Dr Richard Jordan	2340 Sutter St # s333	1701 Divisadero St	
Mary Manning	2340 Sutter St # s341/ S335	1657 Scott St	
Dr Jeffry Simko	Mt Zion Hospital B616, and Mission Hall	2340 Sutter St # s341	

EVACUATION PLANNING

State law requires occupants to evacuate to a safe location when the fire alarm sounds, or when ordered to do so by emergency response personnel. Department Managers are responsible for ensuring that employees know their Emergency Assembly Area (EAA) location, and two evacuation routes from the work site location. In your Evacuation Plan:

- Note location of nearest emergency exits, fire extinguishers and fire alarm pull stations.
- Describe the evacuation route out of your building.



- Identify the Emergency Assembly Area (EAA) for the work site. EAAs are places for your department/unit staff to gather and wait for instructions and/or the "all clear" notification by emergency response personnel.
 - EAAs should be external to your building in a safe, open area, away from power lines and glass windows. NEVER assemble in any building where the fire alarm is sounding. (for Parnassus Campus buildings, see the EAA Map on the Emergency Preparedness Program web site)
- Develop a personal evacuation plan for any person in the Department who might require special assistance during an evacuation. (See Campus Evacuation Policy for People with Disabilities).
- Educate staff to the type of fire alarm system (e.g. sound/strobe lights/pre-recorded voice announcements) specific to your building. Alarm systems vary depending on the UCSF building. Check with your Building Manager if you are unsure. Go to the EH&S web site for information on the Building Fire Alarm System.

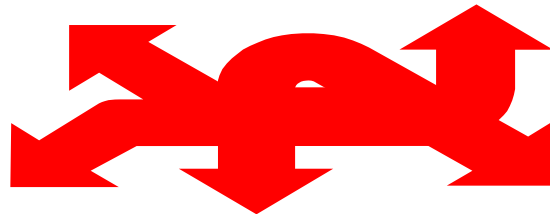
DEPARTMENT: Radiation Oncology

Unit/Division: NRG Biospecimen Bank- SF

I have read and understand my WORK SITE Emergency Action Plan

OPTIONAL

NAME	WORK SITE LOCATION	SIGNATURE	DATE
Michael Restrepo	2340 Sutter St		
Sandy DeVries	2340 Sutter St		
Dr Richard Jordan	2340 Sutter St		
Mary Manning	2340 Sutter St		
Dr Jeffrey Simko	2340 Sutter St		



UCSF EMERGENCY RESPONSE & EVACUATION INFORMATION

BUILDING __2340 Sutter St

FLOOR_3: rooms S341, S333, S335, S336

DEPARTMENT/Division __Radiation Oncology: NRG Biospecimen Bank- SF

EMERGENCY COORDINATOR __Sandy DeVries

ALTERNATE EMERGENCY COORDINATOR_____Michael Restrepo

EMERGENCY ASSEMBLY AREA__ BUSH/Scott;

EMERGENCY SUPPLIES AND

FIRST AID LOCATION: Office in room S341 and "Spill Room" in each wing on each floor of 2340 Sutter St

SITE "Building" EMERGENCY COORDINATOR: Adele Dow

FLOOR WARDENS Michael Restrepo

ALTERNATE FLOOR WARDEN__Sandy DeVries

This Facility's Emergency Phone Number: DIAL 9+911

Effective Date: _____4/1/15_____

Updated By: Sandy DeVries

If this information is incorrect or becomes outdated, please notify your Emergency Coordinator.

REPRODUCE AND POST IN DEPARTMENT

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPath		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		
Jeff Simko		
Michael Restrepo		
Mary Manning		

Kit Requests

SOP Number: NRGBB-SF-SOP-12

Version: 7.0

Author(s): Sandy DeVries

Effective Date: 4/1/15

PRINCIPLE/PURPOSE

To outline procedures for processing requests for Specimen Collection and Shipping Kits of frozen and pathology materials from requesting institutions.

ABBREVIATIONS

A. PO – Purchasing Order #

B. STF – Specimen Transmittal Form

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

A. Personal Protective equipment (PPE):

Gloves, Lab coat, Goggles (as needed)

MATERIALS USED

- A. Corning® Cryogenic Vials – 1.2mL and 5.0mL
- B. Fisherbrand® Specimen (Biohazard) Bag
- C. Sterile Urine Collection Cup
- D. 15mL polypropylene tubes
- E. Miltex Sterile Biopsy Punch – 1.5mm, 2mm, 3mm, 5mm
- F. Parafilm to seal collection cups
- G. Saccomanno's Fixative – for saliva collection kit
- H. RNA-*Later*™ for Preserved Fresh Tissue Kit
- I. Collection kit instructions
- J. UN 3373/1845 Stickers for Dry Ice and Biohazardous material shipping
- K. FedEx outgoing and return shipping labels

QUALITY CONTROL

- A. For each request, the tracking number and PO # is recorded in the PO # spreadsheet
- B. Check Section 10 protocol for the study as to what is required vs requested.
- C. For first time requests, follow-up with a reply email verifying shipping address and nature of request

PROCEDURE

1. Request by Email for kit:
-

- A. Flag email in Inbox and move to "Pending Kit Requests" folder
- B. Check protocol section 10 to see what is required vs recommended. Reply to the email verifying:
 - i. Number/type of kits to be sent
 - ii. Date institution needs the kits by
 - iii. If the institution has access to a -80 degree freezer and can batch ship specimens
2. Request by Mail/ Fax.
 - A. Call/email back indicating desired method of communication for a kit request
3. Prepare kit according to Collection Kit Instructions found in the study protocol
4. Put frozen specimen kits in insulated shipping box labeled with the Kit# on the outside of the box and the Styrofoam container.
5. Put punch biopsy kits in a FedEx Pak
6. Include the following paperwork in kit:
 - A. Collection Kit Instructions
 - B. Batch shipping letter
 - C. Kit request protocol
 - D. Copies of the STF
 - E. FedEx Return airbill and shipping instructions (see below)
 - F. UN 1845/UN3373 Stickers
 - G. Corning® Cryogenic Vial Product Information Sheet
 - H. FedEx label pouch
7. Prepare FedEx outgoing and return airbills on FedEx website
 - a. Log into Fedex.com
 - b. For outgoing shipments
 - i. Change the "From" information
 - ii. In the "To" box enter contact information if new, or see if their information is already in the pull down menu
 - iii. In the Package and Shipment Details:
 - iv. Check off "Perform Detailed Address Check"
 - v. Select FedEx Ground or FedEx Express Saver, unless the requester requires overnight shipping and has provided a FedEx account number to charge for outgoing shipping
 - vi. For incoming return shipments select priority overnight

- vii. Enter number of packages to that addressee
 - viii. Enter weight: 2 lbs per empty box
 - c. For return shipments – go to heading and select Create a Return Shipment
 - i. 12 lbs return assuming it will be with dry ice
 - ii. In Special Services- Check off Dry Ice and enter 10 lbs dry ice
 - iii. In Billing Details Window- Your Reference Number is the project specific BearBuy number, enter our code into the PO# and other info as instructed in the Fed Ex sheets
 - iv. Under sub-heading Email Notifications, email recipient with tracking information
 - b. For return shipments – can be printed or emailed
 - i. For emailed airbills – keep in mind they do expire and Institution must be notified
 - ii. For printed airbills – be sure to print return shipment instructions
 - c. For Canadian shipments:
 - i. Create a Commercial Invoice and be sure to declare all elements included in kit
 - ii. Print out airbill and Commercial Invoice – sign/date the bottom
 - iii. Include instructions for return of shipment, as we do not provide return labels for Canadian shipments but will provide a FedEx account number and one-time reference number for return shipments when requested
8. Seal box and drop off at FedEx drop-off location before 3pm at door at 2340 Sutter St rm S341, or Mt Zion Mail room in the basement of the hospital.

ATTACHMENTS

- A. NRG Biospecimen Bank- SF Collection Kit Instructions for Blood, Urine, Specimen Plug Kit

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPath		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		

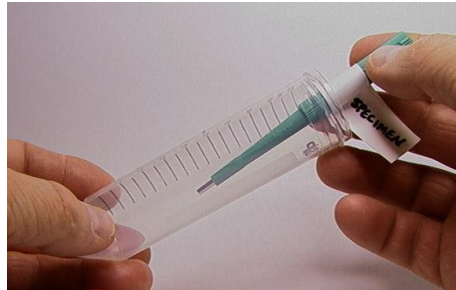
NRG Oncology Biospecimen Bank FFPE SPECIMEN PLUG KIT INSTRUCTIONS

This Kit allows sub-sampling of an FFPE block for submission to the NRG Biospecimen Bank- SF. The plug kit contains a shipping tube and a punch tool.



Step 1

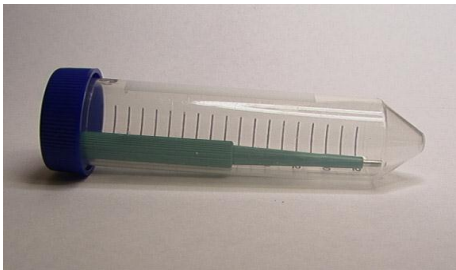
Place the punch tool on the paraffin block over the selected tumor area. (Ask a pathologist to select area with tumor.) Push the punch into the paraffin block. Twist the punch tool once around to separate the plug from the block. Then pull the punch tool out of the block. The punch should be filled with tissue sample.



Step 2

Label punch tool with proper specimen ID and block number. DON'T try to remove specimen from the punch

Use a separate punch tool for every specimen. Please do not mix specimens. Call or email us if you have any questions or need additional specimen plug kits.



Step 3

Once punch tool is labeled, place in shipping tube and mail to address below.

We will remove core specimen from the punch, embed in a paraffin block, and label with specimen ID and block ID.

*NOTE: If your facility is uncomfortable obtaining the plug but wants to retain the tissue block, please send the entire block to the NRG Biospecimen Bank- SF and we will sample a plug from the block and return the remaining block to your facility. Please indicate on the submission form the request to perform the plug procedure and return of the block.

Ship: Specimen plug kit, specimen in punch tool, and all paperwork to the address below:

US Postal Service Mailing Address: For Non-frozen Specimens Only
 NRG Biospecimen Bank- SF
 University of California San Francisco
 2340 Sutter Street, room S341
 San Francisco, CA 94143-1800

Courier Address (FedEx, UPS, etc.): For Frozen Specimens or Trackable shipments
 NRG Biospecimen Bank- SF
 University of California San Francisco
 2340 Sutter Street, room S341
 San Francisco, CA 94115

Questions: 415-476-7864/FAX 415-476-5271; NRGBB@UCSF.edu

NRGBB-SF BLOOD COLLECTION KIT INSTRUCTIONS

This Kit is for collection, processing, storage, and shipping of serum, plasma, or whole blood (as specified by the protocol):

Kit contents:

- One Red Top tube for serum (A)
- One Purple Top EDTA tube for plasma (B)
- One Purple Top EDTA tube for Whole Blood (C)
- Twenty-five (25) 1 ml cryovials
- Biohazard bags (3) and Absorbent shipping material (3)
- Styrofoam container (inner) and Cardboard shipping (outer) box
- UN1845 DRY Ice Sticker and UN3373 Biological Substance Category B Stickers
- Specimen Transmittal Form (STF) and Kit Instructions

PREPARATION AND PROCESSING OF SERUM, PLASMA AND WHOLE BLOOD:**(A) Serum (if requested): Red Top Tube**

- Label as many 1ml cryovials (5 to 8) as necessary for the serum collected. Label them with the NRG study and case number, collection date, time, and time point, and clearly mark cryovials "serum".

Process:

6. Allow one red top tube to clot for 30 minutes at room temperature.
7. Spin in a standard clinical centrifuge at ~2500 RPM for 10 minutes at 4°C (preferred). If sites are unable to process samples at 4°C then spinning at room temperature is acceptable if done within 2 hours of draw but must be noted on the STF.
8. Aliquot 0.5 ml serum into as many cryovials as are necessary for the serum collected (5 to 10) labeled with NRG study and case numbers, collection date/time, protocol time-point collected (e.g. pretreatment, post-treatment), and clearly mark specimen as "serum".
9. Place cryovials into biohazard bag and immediately freeze at -70 to -90° C, and store frozen until ready to ship. See below for storage conditions.
10. Store serum at -70 to -90° C until ready to ship on dry ice. See below for storage conditions.

PLEASE MAKE SURE THAT EVERY SPECIMEN IS LABELED and include collection time point on the STF.

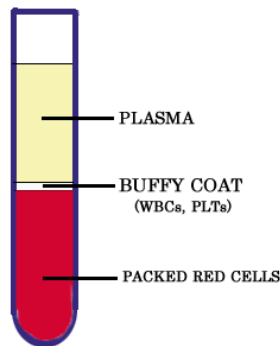
(B) Plasma (If requested): Purple Top EDTA tube #1

- Label as many 1ml cryovials (5 to 8) as necessary for the plasma collected. Label them with the NRG study and case number, collection date, time, and time point, and clearly mark cryovials "plasma".

Process:

8. After collection, invert tube(s) multiple times to ensure adequate mixing of EDTA.
9. Centrifuge specimen(s) within one hour of collection in a standard clinical centrifuge at ~2500 RPM for 10 minutes at 4°C (preferred). If sites are unable to process samples at 4°C then spinning at room temperature is acceptable if done within 2 hours of draw but must be noted on the STF..
10. If the interval between specimen collection and processing is anticipated to be more than one hour, keep specimen on ice until centrifuging is performed.
11. Carefully pipette and aliquot 0.5 ml plasma into as many cryovials as are necessary for the plasma collected (5 to 8) labeled with NRG study and case numbers, collection date/time point collected and clearly mark specimen as "plasma". Avoid pipetting up the buffy coat layer
12. Place cryovials into biohazard bag and immediately freeze at -70 to -90°C.
13. Store frozen plasma until ready to ship on dry ice.
14. See below for storage conditions.

PLEASE MAKE SURE THAT EVERY SPECIMEN IS LABELED and include collection time point on the STF.

**(C) Whole Blood for DNA (if requested): Purple Top EDTA tube #2**

- ❑ Label as many 1ml cryovials (3 to 5) as necessary for the whole blood collected..Label them with the NRG study and case number, collection date/time, and time point, and clearly mark cryovials "blood".

Process:

6. After collection, invert tube(s) multiple times to ensure adequate mixing of EDTA. Blood can also be mixed for 5 minutes on a mixer at room temperature.
7. Carefully pipette and aliquot 1.0 ml blood into as many cryovials as are necessary for the blood collected (3 to 5) labeled with NRG study and case numbers, collection date/time, time point collected and clearly mark specimen as "blood".
8. Place cryovials into biohazard bag and freeze immediately at -70 to -80° Celsius.
9. Store blood samples frozen until ready to ship on dry ice.
10. See below for storage conditions.

PLEASE MAKE SURE THAT EVERY SPECIMEN IS LABELED and include collection time point on STF.

Freezing and Storage:

- Freeze Blood samples in a -80°C Freezer or on Dry Ice or snap freeze in liquid nitrogen.
 - Store at -80°C (-70°C to -90°C) until ready to ship.
 - If a -80°C Freezer is not available,
 - Samples can be stored short term in a -20°C freezer (non-frost free preferred) for up to one week (please ship out Monday-Wednesday only; Canada: Monday-Tuesday only).
- OR:**
- Samples can be stored in plenty of dry ice for up to one week, replenishing daily (please ship out on Monday-Wednesday only; Canada: Monday-Tuesday only).
- OR:**
- Samples can be stored in liquid nitrogen vapor phase (ship out Monday-Wednesday only; Canada: Monday-Tuesday only).
- Please indicate on Specimen Transmittal Form the storage conditions used and time stored.

Shipping/Mailing:

- Ship specimens on Dry Ice overnight **Monday-Wednesday (Monday-Tuesday from Canada)** to prevent thawing due to delivery delays. Saturday and holiday deliveries cannot be accepted.
- Include all paperwork in a sealed plastic bag and tape to the outside top of the Styrofoam box.
- Wrap frozen specimens of same type (i.e., all serum together, plasma together and whole bloods together) in absorbent shipping material and place each specimen type in a separate biohazard bag. Place specimen bags into the Styrofoam cooler and fill with plenty of dry ice (7-10 lbs/3.5kg minimum). **Add padding to avoid the dry ice from breaking the tubes.**
- Place Styrofoam coolers into outer cardboard box, and attach shipping label and UN3373 and UN1895 stickers to outer cardboard box.
- Multiple cases may be shipped in the same cooler, but make sure each one is in a separate bag and that there is enough room for plenty of dry ice. Add padding to avoid the dry ice from breaking the tubes.*
- For questions regarding collection, shipping or to order a Blood Collection Kit, please e-mail NRGBB@UCSF.edu or call (415) 476-7864.

Shipping Address:

Courier Address (FedEx, UPS, etc.): **For all Frozen Specimens**
NRG Biospecimen Bank- SF
University of California San Francisco
2340 Sutter Street, Room S341
San Francisco, CA 94115
For questions, call 415-476-7864 or e-mail: NRGBB@UCSF.edu

NRGBB-SF URINE COLLECTION KIT INSTRUCTIONS (4.1.15)

This Kit is for collection, processing, storage, and shipping of Urine Specimens

Kit Contents:

- One (1) Sterile Urine collection cup
- Two 7 ml disposable pipets
- Absorbent Paper Towel
- Two 15 ml polypropylene centrifuge tubes
- Biohazard bags
- Parafilm for sealing outside of tubes

Preparation and Processing of Urine Specimens:

- ❑ A clean catch urine specimen will be collected. To collect the specimen, use the following instructions:
 - Males should wipe clean the head of the penis and females need to wipe between the labia with soapy water/ cleansing wipes to remove any contaminants.
 - After urinating a small amount into the toilet bowl to clear the urethra of contaminants, collect a sample of urine in the collection cup.
 - After 10-25 mL urine has been collected, remove container from the urine stream without stopping the flow of urine.
 - Finish voiding the bladder into the toilet bowl.
- ❑ Aliquot 5-10 mls of Urine into each of two 15 ml polypropylene centrifuge tubes (disposable pipets are provided in the kit). Do not fill with more than 10 mls to avoid cracking of tubes due to expansion during freezing. Replace the cap and tighten on the tubes. Make sure the cap is not cross-threaded or placed on incorrectly or leaking will occur.
- ❑ Use parafilm to seal the cap around the outside rim of the urine tube to prevent leakage.
- ❑ Discard remaining Urine and collection cup. Do NOT ship urine in cups.
- ❑ Label the specimen with the NRG study and case number, collection date and time, time point of collection, and clearly mark specimens as "urine".
- ❑ Wrap Urine Tubes with absorbent material (paper towels) and place into biohazard bag and seal the bag. Freeze and store Urine samples in a -20°C or -80°C Freezer until ready to ship

Storage and Shipping:**Freezing and Storage**

Urine specimens may be sent in batches or with other frozen biospecimens, if within 30-60 days of collection. Store at -20°C or 80°C (-70°C to -90°C) until ready to ship. If a -80°C Freezer is not available,

- Samples can be stored short term in a -20° C Freezer (non-frost free preferred) for up to one week (please ship out Monday-Wednesday only- Canada Mon-Tues).

OR:

- Samples can be stored in plenty of Dry Ice for up to one week, replenishing daily (please ship out on Monday-Wednesday only- Canada Mon-Tues).
- Please indicate on Specimen Transmittal Form the storage conditions used and time stored.

Shipping/Mailing:

- ❑ Ship specimens on Dry Ice overnight **Monday-Wednesday (Monday-Tuesday from Canada)** to prevent thawing due to delivery delays. Saturday and holiday deliveries cannot be accepted.

- ❑ Specimens received thawed due to insufficient dry ice or shipping delays will be discarded and the site will be notified.
- ❑ Include all paperwork in a sealed plastic and tape to the outside top of the Styrofoam box.
- ❑ Place sealed specimen bags into the Styrofoam cooler and fill with plenty of dry ice (7-10 lbs/3.5kg minimum). Add padding to avoid the dry ice breaking the tubes.
- ❑ Place Styrofoam coolers into outer cardboard box, and attach shipping label and UN3373 and UN1895 stickers to outer cardboard box.
- ❑ *Multiple cases may be shipped in the same cooler, but make sure each one is in a separate bag and that there is enough room for plenty of dry ice. Add padding to avoid the dry ice from breaking the tubes.*
- ❑ For questions regarding ordering, collection, or shipping a Urine Collection Kit, please Email NRGBB@UCSF.edu or call (415) 476-7864 or fax (415) 476-5271

Shipping Address : **FedEx/UPS/Courier address** (For all frozen samples)

NRG Biospecimen Bank- SF
2340 Sutter Street, room S341
San Francisco, CA 94115
Contact Phone 415.476.7864

Operating Aperio Slide Scanner and ScanScope

SOP Number: NRBB-SF-SOP-13

Version: 7.0

Author(s): Meredith West, Sandy DeVries

Effective Date: 4/1/15

PURPOSE

To outline processing procedures for scanning stained slides using the Aperio and viewing/storing the image files.

ABBREVIATIONS

None

SAFETY CONSIDERATIONS/PERSONAL PROTECTIVE EQUIPMENT

Handling – Glass slides are not considered to be biohazards and do not require personal protective equipment during handling. However, staff may opt to use appropriate personal protective equipment for handling glass or soft paraffin.

SPECIMEN

Specimen Type(s) – Stained Slides

QUALITY CONTROL

Slides are given a number value (out of 100) indicating the quality of the scan. This determines if the slides need to be scanned again.

PROCEDURE

- A. Operating the ScanScope
 1. Open ScanScope Console using icon on desktop
 2. Enter username and password
 3. For one slide you can place the slide on the stage on the side of the machine, and click Manual Load, get snapshot and give slide a description
 4. Place slides in racks in the machine – orient slides with labels up and facing into the machine. Slide number 1 will be closest to the front of the machine.
 5. Run all the slides automatically or preview all the slides individually
 - a. To run all slides automatically- click "One Touch", then use Spectrum to view slides
 - b. To preview slides (recommended), go to step 6
 6. Highlight all the slides, using control+click, blank out spaces without slides.
 7. Right click, then select "Get Snapshots"

8. Once snapshots are done, click on "Review Snapshots"
 - a. Adjust the green area to select scan area
 - b. Move the blue diamond to a clear point without tissue under the coverslip for calibration
 - c. Move yellow squares to change focus points
(You may need to change/add focus points if there is an area without a focus point or an area that shouldn't have a focus point)
 - d. Double click on an area to add a focus point
 - e. You may want to enter a phrase in "description" to make it easier to find images in Spectrum (by searching for that phrase)
 - f. Click next to go to the next slide
9. When finished, select "One Touch" to scan the slides
10. When scanning is done, the boxes representing the slides quality will show up as different colors
 - a. Green = good quality scan
 - b. Orange = poor/less than good quality scan (to check quality, double-click on the slide)
 - c. Red = did not scan
11. You may have to rescan orange and will have to rescan red slides

B. Using Spectrum/ viewing slides

You can use Spectrum remotely to view slides scanned by the Aperio slide scanner.

1. Access the Spectrum website using this address: <http://128.218.212.20/>
2. Login using your name and password (request one from NRGBB@UCSF.edu)
3. There are two ways to see all of the slides listed
 - a. On the first page after login, scroll down and click on "List all digital slides" under the heading "Digital slides", or:
 - b. Use the dark blue bar at the top of the screen and click on "All Digital Slides (as list)" under "Digital Slides"
4. To view the slides, click on the thumbnail
 - a. Slides will open in the webviewer in a new window
 - b. If you have ImageScope downloaded, the image will open in ImageScope (ImageScope is Aperio's viewing software can be downloaded from their website : <http://aperio.com/download-imagescope-viewer.asp>)
5. View data associated with slides by clicking on as slides "slideID"
BlockID, Case ID, description, etc. can be changed here by some users depending on viewing privileges
6. Search for a particular slide

- a. On the blue bar at the top of the screen, under Digital Slides, click on "Search Digital Slides"
- b. Click on the "+" next to "Use slide fields" to choose which fields to search
- c. Enter the term you are searching for and click on search
- d. You can click on "+" more than once to search multiple fields, i.e. caseID and BlockID

C. Organization

- a. Slides scanned with the Aperio are put into a default location based on the following conventions:
 - i. The files are given a 4 digit number for a file name
 - ii. The files are automatically saved on the local server in folders named according to the date the images were obtained
- b. Assign the images into new or designated projects by checking the box next to the slides you want to assign and clicking on "Assign to" above the purple toolbar in Spectrum
 - a. TMA slides should be assigned to the "TMAs" project (# 8)
 - b. NRG Study Slides should get moved into their NRG specific project
- c. Add information to Spectrum
 - i. TMA slides should have the name of the Array entered in "BlockID"
 - ii. Other NRGBB-SF slides should have the blocks number entered in "BlockID" and the case number entered in the "CaseID" field
 - iii. Non-NRG slides can be labeled according to the investigators' wishes
 - iv. Other information can be entered in other fields as needed
- d. For outside users, slides are moved to different data groups so that they can see only these slides (if they are not scanned into the proper data group already)

D. How to create jpegs or tif files

- a. The easiest way is to use the snapshot tool in ImageScope (click on the camera icon) that creates image files of what is currently on the screen
- b. You can also create an image of the whole slide with a new file type using Digital Slide - this will take a long time and will produce a much larger file – this is not recommended

E. Image Back-Ups

- a. Being done by Cancer Center Computer IT Support weekly

F. Maintenance

- a. Presnap- *Daily* in morning
 - i. Using a blank glass slide do a manual scan. Load Slide. The slide image will pop up. Click on pre-snap.
- b. Click Set line camera gains- *Every two weeks*
 - i. Use a core slide (same one)- manual load slide

- c. Power Down and Up- *Weekends*
 - i. Switch off scanner (on side)
 - ii. Shutdown computer
 - iii. Set light mode to sleep mode
 - iv. Server stays on.

APPROVAL

APPROVED BY	SIGNATURE	DATE
Richard Jordan, DDS PhD FRCPATH		
REVIEWED BY	SIGNATURE	DATE
Sandy DeVries		
Michael Restrepo		

12. Appendixes

A-1: Material Transfer Agreement Form (page 1 of 9)

NRG Material TRANSFER Agreement

The Radiation Therapy Oncology Group, henceforth known as RTOG, is pleased to be able to provide samples or derivatives thereof, (“MATERIAL”) specified in Exhibit A, for a research project proposal reviewed and approved by the RTOG Translational Research Program (incorporated by reference and hereinafter referred to as “RESEARCH,” to Investigator **Fill In here** at **FILL in here** (“RECIPIENT”). The RTOG is interested in supporting the research described in Exhibit A using the MATERIAL and will provide you with the MATERIAL subject to the following conditions on use of the MATERIAL. The conditions described below are necessary to insure that the MATERIAL is used solely for research and that the RTOG’s and RECIPIENT’s interests in any possible commercialization of the product of research performed on the MATERIAL are protected.

Explanation of the agreement

This agreement outlines the responsibilities and expectations of the listed RECIPIENT and the RTOG. By signing the document RECIPIENT agrees to all terms and conditions defined below and understands that the RTOG will uphold and enforce all terms and conditions outlined in the agreement, in accordance with Cooperative Group policy, upon release of any MATERIALS to RECIPIENT.

1. Scope of Work

MATERIAL is furnished to RECIPIENT for the purpose of the RESEARCH defined in Exhibit A and approved by the RTOG Translational Research Program scientific review committee. Scope and nature of RESEARCH must be limited to that described in Exhibit A unless amended and approved in writing by RECIPIENT and the RTOG.

2. Funding

All aspects of the RESEARCH must be financially supported.

- a. RECIPIENT agrees to arrange for payment of all additional charges associated with the processing and distribution of MATERIALS from the biorepository according to usual and customary charges of the NRG Biospecimen Bank- SF. The estimated cost is \$ **Fill in Here**
- b. Documentation that the project has financial support must be furnished, signed by RECIPIENT and must be provided to the RTOG prior to RESEARCH activation and MATERIAL distribution.

If financial support is discontinued during the course of the study and alternative funding is not secured, all research specimens and derivative samples will be returned to the respective biorepository, as specified herein under section entitled '*Termination of Agreement*'.

3. Safety of personnel

RECIPIENT assumes all responsibility for informing and training personnel in the dangers and procedures for safe handling of human biospecimens and biohazards. All biorepository personnel must abide by OSHA regulations pertaining to the handling of human specimens. RECIPIENT acknowledges understanding of and required compliance with OSHA regulations and will instruct staff to abide by these rules.

4. Stewardship of Material

All MATERIAL provided to RECIPIENT remains subject to the RTOG's stewardship and management. The Chairs of the Cooperative Groups agree that if samples are housed in more than one Cooperative Group, transfer of those samples to the RTOG or lead Cooperative Group repository will take place independently from this agreement.

5. Transfer of Material

- a. The MATERIAL may not be assigned or sold to any other parties.
- b. The MATERIAL may not be transferred by RECIPIENT to a third party/collaborator without first having obtained written approval of the transfer from the RTOG. All such approved transfers must be accompanied by an agreement between RECIPIENT and the third party. The RECIPIENT is responsible for third party/collaborator to understand and abide by this agreement.
- c. If the MATERIAL was obtained in connection with a study using a proprietary agent (i.e., device or drug in addition to the human specimen) the RTOG will assure that RECIPIENT may perform the stated RESEARCH on the MATERIAL.
- d. Both parties shall comply with all applicable laws and regulations, as amended from time to time, with respect to the collection, use, storage and disclosure of the MATERIAL and any related data, including without limitation, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), its implementing regulations (45 C.F.R. et. seq.) and the Common Rule (45 C.F.R. 46)
- e. RECIPIENT acknowledges that the conditions for use of MATERIAL are governed by an Institutional Review Board (IRB) in accordance with Department of Health and Human Services regulations at 45 CFR 46. RECIPIENT agrees to comply fully with all such conditions and to report promptly to the RTOG any proposed changes in RESEARCH and any unanticipated problems involving risks to subjects or others. RECIPIENT remains subject to applicable state or local laws or regulations and institution policies, which provide additional protections for human subjects. The MATERIAL may only be utilized

in accordance with the conditions stipulated by the IRB. Any additional use of MATERIAL beyond the RESEARCH requires prior review and written approval by the RTOG, and, where appropriate, by an IRB at the RECIPIENT site, which must be convened under an applicable OHRP-approved Assurance.

- f. RECIPIENT acknowledges that the RTOG will not provide any information through which RECIPIENT may directly or indirectly identify the human subjects from whom the transferred Materials and/or data were obtained. RECIPIENT agrees not to seek such identifying information or attempt to identify subjects by any other means. If identifying information is received, RECIPIENT must notify the RTOG immediately. RECIPIENT must promptly return the identifying information and/or MATERIAL as instructed by the RTOG.

6. Use of Material

- a. Use of the MATERIAL must be the RESEARCH and in compliance with any applicable laws and regulations governing the RECIPIENTS jurisdiction.
- b. The MATERIAL must not be used in human subjects, in clinical trials, for diagnostic purposes involving human subjects, or to make any derivatives or progeny, as applicable, thereof without the written consent of the RTOG.
- c. With respect to any invention or discovery arising from the RESEARCH, the RTOG shall have an option to license to practice the invention or have it practiced for or on the RTOG's behalf with terms to be determined, as consistent with the NCI Cooperative Group agreement and Cooperative Group Guidelines.

7. Satellite Repository Responsibility of RECIPIENT

Any MATERIAL obtained as part of the RESEARCH are collected under the auspices and guidelines of the RTOG whether or not the specimen is stored in the main repository or the RECIPIENT's laboratory. As such, all specimens and their derivatives are considered property of the RTOG and remain under the stewardship of the RTOG. RECIPIENT facility will serve as the interim repository for those specimens for the duration of the RESEARCH or until requested for return to the RTOG's repository.

8. Data Submission and Analysis

- a. Data analysis on data generated from RECIPIENT will be done by the RTOG's statistical center or under their direction, according to design and analysis considerations agreed upon at the initiation of the project. All data must be submitted in the appropriate pre-approved format.
- b. Availability of data generated in Cooperative Group studies will be in compliance with NIH and NCI data sharing policies and with Cooperative Group procedures.

9. Intellectual Property

The policy of the RTOG governing **intellectual property** rights continues through this agreement. This policy is based on the RTOG's Cooperative agreement with the NCI and NCI

Cooperative Group Guidelines and is available for review at <http://ctep.cancer.gov/industry/ipo.html>.

10. Publication

The RTOG must be acknowledged in all abstracts and manuscripts, following guidelines agreed upon at the initiation of the specific project. All publications shall be submitted to the RTOG for review and comment sixty (60) days prior to publication.

11. Confidentiality

- a. In general, RECIPIENT will utilize only coded specimens and data and will not have access to the link to identify individuals who have contributed specimens. RECIPIENT agrees to maintain the confidentiality of all data and not to seek access to the link or seek any method to identify study subjects. Patient contact is forbidden for any reason, except in cases of specific IRB approval for specific protocol conditions and as approved by the RTOG.
- b. This agreement sets forth the terms and conditions pursuant to which the RTOG may disclose certain Protected Health Information (PHI) to RECIPIENT. PHI may include associated demographic and clinical data that have been rendered a Limited Data set in compliance with 45 CFR section 164.514(e)(1).
- c. RECIPIENT ensures that any collaborator, as approved in writing by the RTOG, working with RECIPIENT will agree to the same restrictions and conditions in writing that apply throughout this agreement.

12. Conflict of Interest

It is assumed that conflict of interest issues are dealt with internally by RECIPIENT, according to institutional policies. Investigator agrees by his/her signature and date on this agreement that such an institutional process has been followed and that no conflict of interest exists.

13. Termination of Agreement

- a. Agreement will terminate upon conclusion of research to be performed using the Materials, or as a result of just cause upon request by the RTOG. RECIPIENT agrees to discontinue use of the MATERIAL and will arrange for the return to the RTOG, or its agent, or for the lawful disposal of all unused MATERIAL, as elected by the RTOG.
- b. This agreement may be terminated by the RTOG upon five (5) days written notice to RECIPIENT if RECIPIENT breaches any provision contained in this agreement and such breach is not remedied within the five (5) day period. If such remedy is provided, proof of remedy will be required within the five (5) day period. Non-cause termination may be invoked by the RTOG, in certain cases at RTOG's sole discretion.

14. Damage Waiver

- a. MATERIAL is provided as a service to the research community without warranty, express or implied. The RTOG assumes no responsibility for any injury (including death, damages, or loss) that may arise either directly or indirectly from their use. RECIPIENT agrees to assume all risks and responsibilities in connection with the receipt, handling, storage and use of MATERIAL.
- b. Any material delivered pursuant to this agreement is understood to be experimental in nature and may have hazardous properties. Any material provided is provided as is and the RTOG makes none and hereby disclaims all representations of warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of the material will not infringe any patent, copyright, trademark or other proprietary rights.
- c. **FOR STATE INSTITUTIONS:** RECIPIENT agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage or loss that may arise solely from the receipt, handling, storage and use of biospecimens received from the RTOG to the extent permitted under the laws of this State.
- d. **FOR U.S. GOVERNMENT AGENCIES:** On behalf of the United States Government, RECIPIENT assumes all risks and responsibilities in connection with the receipt, handling, storage and use of biospecimens received from the RTOG. The United States assumes liability for any claims, damages, injury or expense arising from the use of the material or any derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chap. 171).
- e. **FOR ALL OTHER INSTITUTIONS:** RECIPIENT agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of biospecimens. RECIPIENT agrees to defend, indemnify and hold the RTOG and its directors, trustees, employees, agents harmless from any claims, liabilities, damages and losses that might arise as a result of RECIPIENT'S use of the MATERIALS.

15. Use of Name

Neither party shall use the names or trademarks of the other party or of any of the other party's affiliated entities in any advertising, publicity, endorsement, or promotion unless the other party has provided prior written consent for the particular use contemplated. The terms of this section survive the termination, expiration, non-renewal, or rescission of this Agreement.

16. Signatory Requirements

- a. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.
- b. This agreement constitutes the final, complete and exclusive agreement between the parties with respect to its subject matter and supersedes all past and contemporaneous agreements, promises, and understandings, whether oral or written, between the

parties. This agreement shall be binding upon and inure to the benefit of the parties, their heirs, legal representatives, successors and assigns. This agreement may not be amended or modified except by a writing signed by both parties and identified as an amendment to this agreement. Neither this agreement nor any of the rights or obligations under the agreement may be assigned by RECIPIENT without the written consent of the RTOG. The failure of the RTOG to insist at any time upon the strict observance or performance of any of the provisions of this agreement, or to exercise any right or remedy as provided in this agreement, will not impair any such right or remedy and will not be construed to be a waiver or relinquishment of the right or remedy. Execution of this agreement can be effected by facsimile signatures.

- c. If you agree to these conditions, please sign in the space provided below as RECIPIENT Investigator and have an authorized representative of your Institution sign it also. The authorized representative should have authority over all investigators who might need access to the MATERIAL according to the terms of the research defined in Exhibit A.
- d. Return the original signed copy of the agreement to:

NRG BIOSPECIMEN BANK- SF

UCSF BOX 1800

2340 Sutter Street, room S341

SAN FRANCISCO, CA 94143-1800

(NRGBB@UCSF.EDU)

ACCEPTED AND AGREED

The undersigned expressly certify or affirm that the contents of any statements made or reflected in this document are truthful and accurate. The undersigned further agree to examine and consider the subject matter of the Confidential Information on the foregoing basis.

FOR PROVIDER

Administrative, Authorized Signatory

Sharon Hartson-Stine _____

Name

Senior Director, RTOG _____

Title

Signature

Date

Address:

1818 Market Street _____

Suite 1600 _____

Philadelphia, 19103 _____

FOR PROVIDER

Scientific oversight, Authorized Signatory

Dr Richard Jordan, DDS PhD FRCPATH _____

Name

NRG Biospecimen Bank- SF Director _____

Title

Signature

Date

Address:

FOR RECIPIENT INSTITUTION, Authorized Signatory

Name

Title

Signature

Date

Address:

RECIPIENT INVESTIGATOR

Name

Title

Signature

Date

Address:

A-2: Specimen Transmittal Form:

ST	NRG Oncology Specimen Transmittal Form	Study# _____ Case # _____ PLACE LABEL HERE				
		Institution _____ Institution No. _____ Participant's Initials _____ Participant's I.D. No. _____				
INSTRUCTIONS: This form must be completed and mailed with the specimens upon submission to UCSF. Please see protocol for list of required materials.						
STATUS	SPECIMEN OBTAINED DATE	TIME POINTS (per section 10 of the protocol)	*SPECIMEN TYPE (see table below)	NUMBER OF SPECIMENS	STORAGE METHOD	PATHOLOGY ACCESSION # / PT ID#
	MM - DD - YYYY					
	MM - DD - YYYY					
	MM - DD - YYYY					
	MM - DD - YYYY					
	MM - DD - YYYY					
	MM - DD - YYYY					

----- STATUS -----

1 Pre-treatment	6 Recurrence
2 Surgical treatment	7 Autopsy
3 During treatment	99 Unknown
4 Post-treatment	

ENCLOSURES: _____ Pathology Report(s) _____ Specimens (eg., Blocks, Slides, Blood, Etc.) _____ This Submission Form	SEND TO: <u>FedEx/Courier address</u> (all courier packages & all frozen samples) NRG Oncology Biospecimen Bank - San Francisco University of California San Francisco 2340 Sutter St., room S341 San Francisco, CA 94115 (contact: 415-476-7864)	*SPECIMEN TYPE 10 H & E Stained Slides (P2) 11 Paraffin Blocks (JB) 12 Punch Bx (JH) 13 Unstained Slides (JN) 14 Fresh Tissue (JF) 30 Whole Blood (JW) 31 Serum (JS) 32 Plasma (JP) 33 Buffy Coat (JK) 50 Urine (JU) 51 Saliva (JL) 52 Buccal Scrapings (JR) 60 CSF (JC) 99 Other, specify (JT)
<div style="border: 1px solid black; padding: 5px;"> Check all that apply. Patient consents to: <input type="checkbox"/> 1 Current research as specified in the protocol <input type="checkbox"/> 2 Cancer research <input type="checkbox"/> 3 Medical research <input type="checkbox"/> 4 Being contacted about future research </div>	<u>US Postal Service mailing address</u> (all non-courier packages) NRG Oncology Biospecimen Bank - San Francisco University of California San Francisco Campus Box 1800 2340 Sutter St., room S341 San Francisco, CA 94143-1800 Telephone: 415-476-7864 Fax: 415-476-5271 E-mail: NRGBB@UCSF.edu Website: NRGBB.UCSF.edu	

SUBMITTED BY: _____

TELEPHONE NO: (_____) _____ EMAIL: _____

A-4: CHR Approval Letter



**Human Research Protection Program
Committee on Human Research**

Notification of Expedited Review Approval

Principal Investigator
Richard C Jordan

Co-Principal Investigator
Dr. Jeffrey P Simko MD, PhD, Mack Roach

Type of Submission: Submission Correction for Continuing Review Submission Form
Study Title: Radiation Therapy Oncology Group Biospecimen Repository

IRB #: 10-04447
Reference #: 123733

Committee of Record: San Francisco General Hospital Panel

Study Risk Assignment: Minimal

Approval Date: 11/25/2014 **Expiration Date:** 12/22/2015

Regulatory Determinations Pertaining to this Approval (if applicable):

The requirement for individual Research HIPAA Authorization is waived for all subjects. The use or disclosure of the requested information does not adversely affect the rights and welfare of the individuals and involves no more than a minimal risk to their privacy based on, at least, the presence of the following elements: (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or if such retention is otherwise required by law; (3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule; (4) the research could not practicably be conducted without the waiver; and (5) the research could not practicably be conducted without access to and use of the requested information.

A waiver or alteration of informed consent is acceptable because, as detailed in the application: (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation. The waiver or alteration of informed consent applies to all subjects.

IRB Comments (if applicable):

All changes to a study must receive CHR approval before they are implemented. Follow the [modification request](#) instructions. The only exception to the requirement for prior CHR review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these [instructions](#).

Expiration Notice: The IRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for [continuing review](#) approval has been submitted by the required time. In addition, you are required to submit a [study closeout report](#) at the

completion of the project.

Approved Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to CHR approval and follow all applicable VA and other federal requirements. The CHR [website](#) has more information.

A-5: STARS Database Entry Protocol

There are two main types of entry FFPE and Frozen- these are outlined below in two sections

A-5-1: SOP for Entering FFPE Specimens in STARS

A) Accessioning FFPE specimens:

1. Click on Accessioning in STARS, enter study and case in Bank ID field (use ####-#### format) and click on the arrow next to that field.
 - a. If the Bank ID record exists, verify patient initials (in the “name” fields) and institution name match the ST form for new specimens to be entered.
 - i. If it matches, go on to step 2.
 - ii. If it does not match: do not enter specimens – verify study/case number with CRA and/or Headquarters.
 - b. For new records: on Patient Tab enter patient initials, institution ID, CRA contact information
 - i. Institution: enter either the NCI ID or RTOG ID and check institution name matches the ST form
 - ii. If institution ID is unknown, or if the ID number on the ST form is not in STARS, look it up in the Institution list or enter 0000 for unknown in the RTOG ID field
 - c. Adding to patient information (Contact name, phone number, etc) - Done from Manage->Edit Patient/Specimen. Enter bank id and select patient: click on edit patient/registration and add information.
 - d. Click on Shipment Tracking on the left hand side of the screen, enter the shipment mode and enter tracking number of the incoming package.
2. Click on Specimen Tab.
3. Enter only what is received, and not specimens that will be made (e.g. unstained slides cut for testing).
 - a. For each specimen, enter data in these fields: date received, collection date, time point, treatment type, specimen category, specimen type, quantity, SPID # (e.g. SP12 3456, exclude dashes or leading zeroes), block #, condition received.
 - i. Paraffin block: Specimen Category = Paraffin Embedded Tissue and Specimen Type = Paraffin Block Primary.
 - ii. Unstained slide: Specimen Category = Slides and Specimen Type = Paraffin Unstained Primary.
 - iii. H&E: Specimen Category = Slides, Specimen Type = Paraffin Stained Primary, and Stain Type = H&E
 - iv. Other Stain: Specimen Category = Slides, Specimen Type = Paraffin Stained Primary, and change Stain Type to the appropriate stain
 - v. Punches to be embedded: Specimen Category = Paraffin Embedded Tissue and Specimen Type = Paraffin Core Primary – for quantity be sure to enter the number of separate vials, not the number of punches.
 - a. If 1 vial is received that contains 3 punches, enter 1 Paraffin Core Primary.
 - b. If 3 vials are received and each contains a punch, enter 3 Paraffin Core Primary.

- vi. Embedded Punch Blocks: Specimen Category = Paraffin Embedded Tissue and Specimen Type = Paraffin Core Block Primary.
 - b. After entering the first specimen(s), if there are more specimens to enter from the same collection date/timepoint/etc. use the “Add More _____” to preserve that information for the next specimen.
 - c. Use of the “Add Specimen” button will clear out all the fields- this is useful when entering specimens from different timepoints.
4. Check list of added specimens – if there are any mistakes – delete the specimens and re-enter.
5. When finished with entering specimens, click on submit at the bottom of the page.

B) Processing

1. After clicking on “submit” from Accessioning it will send you to the processing page and will copy over the bank ID from the previous page and shows everything entered today.
 - a. If you are processing older specimens - you need to change the date either to the date that the specimens were received or clear the date field out entirely to see everything.
 - b. Banked or distributed specimens will not show up on the processing page
 2. Highlight specimens and click on Print Labels.
 3. For problems with the specimens: i.e. missing information, missing additional specimens:
 - a. Highlight specimens and click on “Mark Pending” which takes you to the “Manage – Pending Specimens/Cases” view.
 - b. Highlight the specimens and click on either “Mark Patient(s) As Pending” or “Mark Specimen(s) As Pending”.
 - i. Mark Patient(s) As Pending when institution number and/or patient initials are unknown and you have been unable to reach the CRA to get the info, etc.
 - ii. Mark Specimen(s) As Pending when information or additional information is missing which keeps us from processing/reviewing/banking the specimen.
 4. If you need to make a comment about specimens, click next to the specimens and click on Commentator (can also be done from Accessioning).
 - a. From Accessioning, the comments will apply to all the specimens you enter (e.g. 10 unstained will all have the same comment).
 - b. From Commentator on the processing page you can make a comment on specific specimens (e.g. 1 of the 10 unstained arrived broken).
 5. If specimens are ready to be reviewed, highlight all the specimens that will be reviewed
 - a. Click on “Transfer” then select “Reviewer Inbox” and click on “Distribute Specimens To”
 - b. Select the Reviewer.
 - i. For regular QA, select “Simko” – it can be assigned to “Jordan” later if necessary.
 - ii. For central reviews, select the name of the pathologist.
 - iii. These should all be “Internal Reviewers”.
 - c. For reviews including unstained: the unstained can be banked right away **after** being assigned to the Reviewer Inbox.
 6. If specimens need to be processed.
 - a. For specimens that will be sent to histology in batches:
 - i. Highlight the parent specimen(s) and click on “Add to Request”.
-

- ii. Next to “Department” select “CoreMorph” and then choose to either Add to Existing Request or Create New Request.
- iii. Specimens are placed in separate requests based on what needs to be done: cut an H&E, embed a punch, stain an unstained slide, etc.
- b. For specimens that will be processed and returned from histology same day (e.g., unstained slides for integral markers):
 - i. **After** the specimens come back, highlight the parent specimen and click on “Quick Process”.
 - ii. Select the appropriate Child Specimen type, #Made, description of what was made (from drop down next to #Made), Total Units (or Units Not Applicable, in the case of slides), edit the Processed Date/Time if not same day, and click on Add Specimen.
 - iii. Check the information on the added specimens, then click “Confirm” at the bottom (“Deplete and Confirm” may be used in the case of aliquotting blood or making a block from a punch).
 - iv. On next screen, change “Available Value” if necessary, then click on Done.

C) CoreMorph (processing of specimens)

1. From Processing, Distribution or Inventory page, click on specimens that will be processed in CoreMorph and click “Add to Request”
 - a. Select Department = CoreMorph
 - b. When adding to an existing request, select the request number from the “Add to existing request” dropdown and click “Add Specimens to Request”
 - c. If adding specimens to a new request, click “Create New Request”
 - i. On Request page, select a Project Type, click “Custom for the Request Type”, enter Contact Name and Phone, select due date (deadline for work to be completed)
 - ii. Click “Show Add Specimen Panel”
 - iii. For Specimen Sent to Core Morphology, change Specimen Category and Type to the kind of specimen that is being processed
 - iv. For Children Created by Core Morphology, enter the information for the specimen that will be made
 - v. If needed, for Grandchildren Created by Core Morphology enter the information for the specimen that will be made from one of the Children specimens
 - vi. Examples:
 - a. Specimen Sent = Paraffin Core Primary, Children = Paraffin Core Block Primary, Grandchildren = Paraffin Stained Primary H&E
 - b. Specimen Sent = Paraffin Block Primary, Children = Paraffin Stained Primary H&E, no Grandchildren
 - vii. Click “Save Request”
 - d. When all specimens have been added to the request and specimens are ready to be sent to be processed, go to Distribution -> Internal Requests -> Core Morph Requests
 - e. Check the box next to the request and click “Send to CM”
 - f. Verify specimen details, enter username, password. Click “Complete QC and Transfer”

- g. After specimens are at Histology lab, go to Lab Services -> Morphology Core, click next to the request and click "Mark as Received"
- h. When processed specimens are returned, go to Lab Services -> Morphology and Click "Process"
- i. On the CoreMorph processing screen, highlight the specimens received on the left side and click "PROCESS Specimens"
- j. Highlight the created specimens on the right side and verify amounts/details look correct, then click "Initial specimens" and enter username
- k. Highlight all specimens and click "Print Labels"
- l. For processed Paraffin Core Specimens, highlight the specimens on the right and click "DEplete Rcvd. Specimens"
- m. Click on the Home Button
- n. Highlight Request and click "Return to BPC"
- o. Go to Distribution -> Internal Requests -> Core Morph Requests
- p. Highlight the request and click "Mark as Received"
- q. Go to Inventory -> Specimens in Inventory and use Advanced Search to find all the specimens that were in the Core Morph request
- r. For Paraffin Core Block Primary specimens, enter units for size of the cores in each block
- s. Add all specimens from the request to Review Inbox, Distribution Project or Shipment, depending on what needs to be done with specimens

D) QA Path Review:

1. Specimens that are in Reviewer Inbox (should have been added from Processing page)
 - a. Go to Path Review -> Reviewer Inbox
 - b. Enter the Bank ID and click Search
 - c. If there are no specimens for that Bank ID, go to step 2, otherwise, highlight specimen to enter review and click "Enter Path Results"
 - d. Enter the path results on the next screen
 - i. Don't change these selections: Reviewed by = Reviewer, Is this review done for the case?... = No, Review Category = Initial, or SPID and Block # fields
 - ii. Change Reviewer name (if necessary), Reviewed date, and review fields
 - e. Click "Add Review"
 - f. Click "Return to Previous Screen"
 - g. Repeat process for additional specimens, if any
 - h. Highlight specimens and at bottom of page select "RTOG Bank" in the dropdown, then click the "Return specimens to:" button
 - i. If the review needs to be attached to any other specimens (e.g. unstained slides that will have the same review as an H&E), go to Path Review -> Inherit Specimen Review
 - i. Enter the Bank ID and click Search
 - ii. Highlight the reviewed slide and click "Attach Specimen Review"
 - iii. In the pop-up window, select the specimens that need to have the same review
 - iv. Click "Confirm Specimen Review"

2. Specimens that are not in Reviewer Inbox
 - a. Go to Distribution -> Start Distribution
 - b. Highlight non-banked specimens for review and click "Send to Dist. Inbox"
 - c. This will lead to the Distribution Inbox, from there highlight specimens and click "Enter Path Results"
 - d. Enter the path results on the next screen
 - i. Don't change these selections: Reviewed by = Reviewer, Is this review done for the case?... = No, Review Category = Initial, or SPID and Block # fields
 - ii. Change Reviewer name (if necessary), Reviewed date, and review fields
 - e. Click "Add Review"
 - f. Click "Return to Previous Screen"
3. Banked specimens that need to have a review
 - a. Go to Inventory -> Specimens in Inventory
 - b. Highlight banked specimens and click "Release from Inventory"
 - c. Highlight the no-longer-banked specimens and select "Send to Dist. Inbox"
 - d. From the Dist. Inbox
 - i. If the slides are already reviewed, go to instructions starting at 2.c. above to enter results
4. If the slides still need to be reviewed, highlight and at bottom of the page select "Distribute Specimen to: Reviewer Inbox" (then follow steps from part 1 after review has been done. Bank specimens when done)

E) **Banking**

1. Specimens that have not been banked yet:
 - a. Processing page – used if specimens will be banked immediately (not going into the review box).
 - i. Highlight specimens and click on BANK.
 - ii. Select the banking location from the dropdowns.
 - iii. Click on "Bank".
 - iv. Select "Back" once all specimens have been banked.
 - b. Distribution page
 - i. Leaving "View Banked Specimens" unchecked should show all the specimens that are not banked yet.
 - ii. Select specimens that will be banked together, using one of two options:
 - a. Click on "Scan Barcodes" and scan the barcodes of the specimens to be banked, then check off the boxes for all the specimens
 - b. Use the search function to see a group of specimens: e.g. search for all blocks from one protocol and then highlight the blocks that are going to be banked
 - iii. After highlighting all specimens, click "BANK"
 - iv. Select the banking location from the dropdowns
 - v. Click "Bank".
 - vi. Select "Back" once all specimens have been banked.
2. Banked Specimens that need to be moved – e.g. migrated data in RTOG Temp Inbox
 - a. From Case View - only work on one specimen type from one case at a time.

- i. Highlight the specimens (have to be from the same group) and click on “Edit Banking Location”.
- ii. Select the banking location from the dropdowns.
- iii. Click “Bank”.
- iv. Select “Back” once all specimens have been banked.
- b. From Inventory page – more useful for groups of specimens
 - i. Scan the barcodes or search (or BankID if only looking up one case) and “View Banked Specimens” should automatically be checked.
 - ii. Highlight specimens that need to be banked (verify barcode numbers) and click “Release from Inventory”.
 - iii. Highlight specimens again and click “Bank”.
 - iv. Select banking location from the dropdowns.
 - v. Click “Bank”.
 - vi. Select “Back” once all specimens have been banked.

F) Shipping

1. Integral markers:

- a. After specimens to be shipped are accessioned/processed, print out labels for specimens.
- b. From Processing or Start Distribution page, highlight specimens and click on “Add to Shipment”.
 - i. Processing is better to use if you add them to the shipment right after they are accessioned.
 - ii. Start Distribution is better if you need to use search criteria to find specimens.
- c. Click “Create New Shipment” or use the dropdown to “Add to existing shipment” if the shipment already exists.
 - i. For a new shipment, next to the Reviewer/Investigator dropdown select “Reviewer”.
 - ii. In the dropdown below select the name of the person receiving the shipment.
 - iii. Next to shipment type, select “PathReview” and select the appropriate Shipping Conditions below.
 - iv. The rest of the fields should auto-populate – except shipping/tracking # which can be added here, or later on before the specimens are marked as shipped.
 - v. If the correct name does not show up in the options, go back to Reviewer/Investigator and make it blank, then fill out the shipping address fields.
 - vi. Click on create shipment.
- d. Once all specimens are added to the shipment, go to the Shipping screen
 - i. Highlight the shipment and click on Quality Control (can also Print Shipping Manifest if needed).
 - ii. Verify the labels on the specimen and the information on the QC page, click the checkboxes next to everything if correct and enter username and password (note: this seems to have actually been designed with the intent that a second person should be QCing the shipment).
- e. After QCing the shipment, click “Ship”, and enter the information asked for on the pop-up window.
- f. After we receive notification that the material has been received, go back to Shipping page, highlight the specimen and click on receive.

2. Return Requests

From Start Distribution screen, look up the BankID for the specimens to be returned.

- a. Highlight the specimens that are being returned and click Release from Inventory.
 - b. If specimen needs to be processed (e.g. recuts) before return, do that after releasing from inventory.
 - c. Highlight the specimens and select add to shipment.
 - d. Click “Create New Shipment” or use the dropdown to “Add to existing shipment” if the shipment already exists.
 - i. For a new shipment, leave the Reviewer/Investigator option blank.
 - ii. Next to shipment type, select “Return” and select the appropriate Shipping Conditions below.
 - iii. Fill in the address fields below - tracking info can be added later when the specimens are shipped.
 - iv. Click on create shipment.
 - e. Once all specimens are added to the shipment, go to the Shipping screen.
 - i. Highlight the shipment and click on Quality Control - can Print Shipping Manifest if needed.
 - ii. Verify the labels on the specimen and the information on the QC page, click the checkboxes next to everything if correct and enter username and password.
 - f. After QCing the shipment, click on ship, and enter the information in pop-up window.
 - g. After we receive notification that the material has been received, go back to Shipping page, highlight the specimen and click on receive.
- 3) **TRP Request:**
SOP is In Process

A-5-2: SOP for Entering Frozen Biospecimens in STARS- (3/3/2014)

Note: The process from Accessioning to Banking is performed by one person per case. Once the specimens from a given case have been virtually and physically banked, the person can move onto the next case. If there are two people completing this task, they should not be working on the same study at any given time.

If excessive numbers of specimens are received and it is not be possible to bank the same day, two people can accession specimens, and the specimens are stored in the freezer and banked at a later date.

Part 1: Preparation- Refer to SOP for detailed instructions prior to proceeding.

1. Open all shipping boxes and pull out specimens. Place the specimens in the cooler in order by study, then by case. Write the FedEx tracking number on the bottom of each ST form.
 - a. If there are any large batch shipments from Canada or elsewhere, leave the batch shipment in the box it came in to be processed separately. Replenish the dry ice in that box as much as

necessary. If you are unable to process it the same day then place specimens in -80C Freezer until the next day.

2. Pull freezer boxes from the high accruing studies and store in cooler. Always make sure there is plenty of Dry Ice!!!!!!!!!!!! All boxes must be touching Dry Ice

Part 2: Accessioning

1. Open package and inspect specimens, comparing labels to the ST form for the specimens. Study number, case number, date of collection and specimen types must match the ST form, and the quantities of each specimen type must be accurate.
 - a. If there are any discrepancies between the specimen labels and the ST form, or if an essential part of the ST form is not completed (e.g. missing time point), the specimens will be marked as pending. These should still be Accessioned, but cannot be Banked until the issue is resolved with the submitting site.
 - b. Certain issues may make it impossible to accession the specimens until those issues are resolved (e.g. no ST form, institution number or Pt. initials missing from form). The site must be contacted immediately to see if the issues can be resolved. If not then place these in a pending bag with the date received.
2. In STARS, open the Accessioning tab and enter the bank ID, which is the 4-5 digit study number and the 4-digit case number separated by a hyphen. (e.g. 0534-0150; or BN001-0008)
3. If there is no patient information already displayed, enter the patient initials (three separate fields for last, first, middle), institution number and CRA contact info, then click "Specimen" on the left side. If patient info is already in STARS, compare patient info to the info on ST form. If it matches, click "Specimen" on the left side. **If it does not match, do not continue accessioning the specimens until the discrepancy has been resolved with the submitting site.**
 - a. If anything needs to be added to the patient information (Contact name, phone number, etc) this is done in the "Manage" tab: Manage->Edit Patient/Specimen-> Enter bank id and select patient-> click on edit patient/registration and add information.
4. In the Specimen window, enter the Date Received, Collection Date, Time Point and Treatment Type.
5. Select one of the specimen types being checked in, enter the quantity of vials, and click "Add More <specimen type>". This will add the specimens to the Grid at the bottom.
 - a. Enter specimens in this order: serum, plasma, buffy coat, whole blood, urine
6. Repeat step 5 for each specimen type, until all specimens to be accessioned appear in the Grid.
7. Click "Submit". At this point, the specimens are "created" in the STARS database, and you are taken to the Processing tab.
 - a. Place pending specimens in a separate box; these specimens will be put into the freezer in a large bag labeled with the date received, to be banked later. In the Processing tab, select the specimens and click

“Mark Pending”. On the next screen, again, select the specimens and click “Mark Specimen(s) as Pending”.

Part 3: Processing/ Banking

1. Remove the adhesive labels attached to the vials.
2. Visually inspect the serum/plasma/blood specimens and make any necessary notes about the quality of the specimens.
 - a. To make notes about specimen quality from the processing screen, simply select the appropriate specimens and click “Commentator” to add notes.
3. Determine which vials contain at least 0.3ml, and which vials contain less than 0.3ml. If any are clearly >0.5 ml enter this as 0.8 or 1.0ml. Expand each group of specimens and enter units in mL for each specimen. To enter units, select the vials and click “Enter Units”.
 - a. Enter one of three values: 0.3mL for any vials containing at least 0.3mL, or 0.1mL for any vials containing less than 0.3mL. Anything clearly more than 0.5ml must be noted.
 - b. Under each specimen type, vials with higher volume should be listed first (i.e.vials with 0.3mL are higher on the list than those with 0.1mL).
 - c. **If entering units for multiple vials at once, the total volume for all vials must be entered, not the volume for an individual vial. So, if entering 0.3mL as the volume for 6 vials, select the 6 vials, click “Enter Units”, and enter 1.8ml.**
 - d. Urine tubes are assigned as 5mL each- unless it clearly less. Note if bloody.
4. Select all specimens and print labels. **Before printing, make sure the specimens in each group are sorted by USI.**
5. Select all specimens and click “BANK”. On the banking screen, select which freezer/shelf/rack/box to assign the specimens to. **Again, make sure the specimens in each group are sorted by USI.** Then click “BANK” at the bottom of the screen.
 - a. Use the Freezer Inventory spreadsheet, located in the Inventory folder of the R drive, to determine which freezer box (or tray) to begin assigning blood (or urine) specimens to.
 - b. Before banking the day’s first set of specimens for a study, quickly check to make sure the number of available positions in the box matches the number displayed in STARS.
6. Label the specimens, making sure the labels are matched to vials according to volume, and place in the freezer box in order, starting with the first open position.

Part 4: Outgoing Frozen Biospecimens Processing and Shipping

1. Receive list of eligible cases for each study to be included with the TRP
2. Create an excel file with all the eligible case to be loaded into the STARS reporting system
***All cases must be in STARS Bank ID format (e.g. 0534-5555; or BN001-0002)**
3. Open STARS Reporting Services (<https://stars.rtog.ucsf.edu/reports>)
4. Select necessary report- in this case “UCSF BSR-Study Case Information”
5. Fill out appropriate fields on screen
 - a. The amount of information you enter in the fields will vary with each TRP, but more specificity will produce more specialized results
 - b. For the BANK ID field: paste the values from the excel sheet created in Step 2

*Note: Before continuing make sure that the cursor has not returned to next line in the field in which information was pasted into.

6. When finished click "View Report". A report is generated on the screen based on your search criteria. This report can be exported to an excel file.
7. Save the original report from the STARS reporting service
8. Create a "pull list" from a copy of the original report by removing duplicates and arranging by freezer position.
9. Using the "pull list" created in step 8, begin to pull specimens and put in designated TRP boxes separated by specimen type.
 - a. For any aliquots that cannot be found in the designated freezer position: investigate the original ST form and specimen notes in database
10. Once all specimens have been pulled, the barcodes on the vials need to be scanned into an excel spreadsheet using a barcode scanner.
11. Use the scanned barcodes to perform a "vlookup" in the long report from the STARS reporting service (created in step 6, saved in step 7)
 - a. There are two required fields to fetch in the "vlookup": 1)Specimen ID 2) External Specimen ID (even if blank this must be included)
12. Log in to the STARS Database (<https://stars.rtog.ucsf.edu>)
13. Go to the Distribution Tab and select "Start Distribution"
14. From the options on the right side of the screen select "Create Dist. Project"
 - a. Name the distribution project.
 - b. The "Investigator Source" and "Investigator Name" drop-down menus must be managed through Control Panel.
 - c. When complete select "Add Distribution Project"- the project can now be referenced in the STARS database
15. From the options on the right side of the screen select "Upload Dist. Worksheet"
 - a. This is where the excel worksheet created in Step 11 can be uploaded
 - b. Enter the file name or browse for the saved file and select which distribution project you are working on (this was created in step 14).
16. Once the Distribution Worksheet had been uploaded the distribution project will contain all of the scanned specimens. Specimens can be added or removed from this list.
17. When the specimens are ready to be shipped, the specimens must be "Added to Shipment"
 - a. Under the Distribution -> Start Distribution Tab perform a search for the distribution project- A list will generate with all the specimens associated with the project.
 - b. Select the specimens ready to be shipped and click "Add to Shipment".
 - c. Assign the specimens to a shipment previously created or create a new shipment from this screen.

18. Once the specimens have been “Added to Shipment” they must be QC’ed within STARS before they can be “shipped” To QC the specimens
 - a. From the Distribution -> Shipping Tab select the shipment and click “Print Shipping Manifest”
 - b. Use a printout of the shipping manifest to compare to the physical specimens, ensuring that everything matches. Change any discrepancies before continuing.
 - c. If all the specimens match, select all specimens in the shipment and click “Quality Control”.
 - d. Check the appropriate boxes and enter your STARS username/password
 - e. Click “QC Shipment”- Now the specimens can be shipped

*If any changes were made to the shipment, be sure to print an updated manifest
19. To finalize the shipment, select the shipment name and click “Ship”
 - a. The date and tracking number will have to be confirmed in the dialogue box that appears.

A-6: Notification of Materials Received Document



NRG Biospecimen Bank- San Francisco
 University of California San Francisco
 2340 Sutter St, rm S341
 San Francisco, CA 94115
 Tel: 415-476-7864 / Fax: 415-476-5271
 Email: NRGBB@UCSF.edu

Notification of Materials Received

Please date, sign, and fax back to NRGBB-SF at (415) 476-5271

Date Materials received: _____

Number of Boxes/Packages Received: _____

Type/Quantity of Specimen Received: _____

Study/Case Number(s): _____

I have received all materials that were specified in the list submitted by the NRG Biospecimen Bank- SF in good condition with the following exception(s):

Received by: _____

Phone/Email: _____

