1. **PURPOSE:** This SOP explains the necessary steps, in accordance with good clinical practices for obtaining myocardium tissue removed from but not limited to: LVAD placement or removal, heart transplant, heart organ donation, or blood plasma samples. IRB authorizes approved personnel to obtain cardiac tissue removed during these procedures for research. The procurement of samples is time-sensitive and a biologic material that must be carefully handled. Collection of tissue products must be carefully coordinated and stored.
2. **SCOPE:** The activities described in this SOP are to ensure efficient and safe collection, transport, dissection and storage of all myocardium human tissue samples received. Approval based on IRB #46103, PI: Kenneth Campbell.
3. **RESPONSIBILITIES**:
   1. Principal Investigator (PI) – primary individual responsible for the preparation, conduct and administration of project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.
   2. Co-Investigator - an individual assigned by the institution along with one or more other co-investigators to direct a project or activity.
   3. Program Coordinator - manages collection, storage, and distribution of research samples as well as recruit participants, obtain informed consent, and data management.
   4. Study Personnel (e.g. fellows, postdoctoral researchers, graduate and undergraduate students) – laboratory or clinical personnel obtaining informed consent, collecting and processing cardiovascular specimens.
4. **DEFINITIONS and ABBREVIATIONS:**
   1. Autoclave - a strong heated container used for chemical reactions and other processes using high pressures and temperatures, e.g., steam sterilization.
   2. Biohazard - a risk to human health or the environment arising from biological work, especially with microorganisms.
   3. Hashcode – used to identify sample without providing any patient information.
   4. Hepatitis B (Hep B) – an infectious disease caused by the hepatitis B virus that affects the liver.
   5. Institutional Biosafety Committee (IBC) – responsible for reviewing protocols that involve certain biological agents and ensuring safety in biological laboratories.
   6. Institutional Review Board (IRB) – An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
   7. Kentucky Organ Donor Affiliates (KODA) – statewide educational and organ donor procurement network.
   8. Liquid nitrogen – nitrogen in a liquid state at an extremely low temperature used as a coolant.
   9. Operating Room (OR) – facility within a hospital where surgical operations are carried out in a sterile environment.
   10. Occupational Safety and Health Administration (OHSA) – agency established to assure safe and healthy working conditions, enforce standards, and provide training, outreach, education and assistance.
   11. Personal Protective Equipment (PPE) – specialized clothing or equipment worn by an employee for protection against infectious materials.
   12. Procurement - the action of obtaining or procuring something.
   13. Protected Health Information (PHI) - any information about health status, provision of health care, or payment for health care that is created or collected that can be linked to a specific individual.
   14. Sterile field - an area immediately around a patient that has been prepared for a surgical procedure.
   15. Ventricular Assist Device (VAD) - electromechanical circulatory device that partially or completely replaces the function of a failing heart.
5. **SAFETY AND QUALITY CONTROL:**
   1. Follow appropriate precautions based upon policy, OSHA guidelines, infection prevention and control policies, and/or the institutional procedure manual for the handling of bodily fluids. PPE is required for handling human tissue or blood specimens.
   2. The Hep B vaccine is optional but strongly recommended when working with human tissue.
   3. Always follow sterile procedure when in the OR. Never touch equipment, surgical instruments, patient, and/or personnel that are in the sterile field.
   4. Ensure all necessary containers are labeled with a biohazard sticker.
   5. Ensure use of biohazard bags for the autoclave.
   6. Always keep human tissue samples on ice, dry ice or in liquid nitrogen for proper preservation.
   7. Ensure all personnel have IBC and IRB approval, OR training and any other required training prior to handling human tissue, PHI or entering the operating room.
6. **MATERIALS, REAGENTS, and EQUIPMENT:** Various materials, reagents, and equipment are required for the procurement of human cardiac tissue samples. Generalized items may include, but are not limited to OR attire, PPE, dissecting instruments, lab materials and disinfectant.
7. **PROCEDURE:**
   1. To gain appropriate access to be a part of the Procurement Team, contact the Biorepository Program Coordinator. Coordinator will ensure proper training is completed.   
      7.1.1 OR training (*See CVBR Operating Room Training Checklist)*

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| * + 1. IBC training and approval | *(See CVBR:001 – Study Personnel Training)* |
| * + 1. Scrub machine access     2. IRB training and approval |

* 1. Procurement Team phone:
     1. During standard operating hours (7:30am-4:00pm) the Program Coordinator will be the point of contact for specimen retrieval. After hours, weekends, and/or the absence of the Program Coordinator, approved lab personnel will be “on-call” for specimen(s) procurement.
     2. The phone should be monitored and answered 24 hours a day, 7 days a week.
     3. Personnel monitoring the phone should remain within 30 minutes of the hospital to avoid any delay in obtaining specimen(s).
     4. Answer **ALL** calls.
  2. Preparation for collection of tissue sample:
     1. All personnel that might encounter PHI must have prior IRB approval. HIPAA guidelines must be followed when handling PHI.
     2. During operating hours, Program Coordinator will monitor Citrix OR Manager for cardiovascular cases.
     3. Coordinator will contact Circulating Nurse (RN) for all desired cardiovascular cases with intent to collect.
     4. A member of the OR circulating nurse will call the Procurement Team phone (859) 813-0199 to alert of upcoming procedure. Please ask what type of procedure is being performed so the team will know what type of sample to prepare for and what time the procedure is expected to begin. You may also ask the nurse to call back when the surgeon has made the first cut.
     5. Change into OR scrubs. Scrubs can be removed and returned from scrub machines using UK ID badge. Scrub machines are located on the 2nd floor of Pav H and 3rd floor of Pav A.
     6. Setup required lab material, dissecting instruments, and any other necessary equipment needed for tissue dissection.
     7. Obtain specimen sheet containing hashcode from Cardiac Specimen Logbook. If no sheets are available, contact Program Coordinator for hashcode and/or additional sheets. Kenneth Campbell, PI, will be responsible for generating hashcodes for Program Coordinator.
     8. Use hashcode to enter specimen into OnCore. (See *Oncore and REDCap Data Management*  CVBR:008).
     9. Text members of Dr. Latif’s lab -Mahmoud (859) 539-2418 and Laskhman (859) 421-1663 to alert them of tissue procurement.
  3. Labeling of Vial(s):
     1. Program Coordinator will ensure vials are pre-labeled with hashcode and region.
     2. In the event a pre-labeled bag is unavailable, use a sharpie to label tubes as follows:
        + LVAD
          - Hashcode and region (Core size will vary. Section into epi, mid, and endo – if possible.)
* Transplant
  + 2 x Epi Fat
  + 8 x LV Epi
  + 8 x LV Mid
  + 8 x LV Endo
  + 8 x Septum
  + 8 x RV
  + 3 x RA
  + 3 x LA
* Donor Heart
  + 20 x LV Epi
  + 20 x LV Mid
  + 20 x LV Endo
  + 20 x RV
  + 12 x Septum
  + 2 x Epi Fat
  + 6 x RA
  + 6 x LA
  1. Collection of specimen(s):
     1. RN will call when specimen(s) are available for collection.
     2. Once you have been contacted for available specimen, take cooler with biohazard sticker to MS518 (entry code 749518) and fill bottom with normal ice on your way to the OR.
     3. Enter the designated OR room with OR scrubs, hat and/or bouffant, face mask, and shoe covers. Hat, mask, and shoe covers are located at the entrance hallways of the OR.
     4. Locate the circulating RN to make them aware of your arrival. Ask for a patient ID sticker.
     5. Do not go within 2 feet of any sterile area or personnel.
     6. The specimen will be placed in a container by the surgeon or surgical tech. The nurse will take the container from the sterile field and give specimen(s) to procurement team. Wear exam gloves if you handle the sample.
     7. The specimen should be labeled with a specimen sticker containing patient ID. (*See CVBR:003 – Operating Room & Surgical Pathology)*
     8. Remove mask after exiting OR.
     9. VAD cores should go directly to surgical pathology after collection unless after hours (*See CVBR:003 – Operating Room & Surgical Pathology*). Donor and explanted hearts will go directly to the Campbell Lab (MS533).
  2. Transporting specimen(s):
     1. Do not use public elevators for biohazard material. You ***must*** use service elevators or stairwells.
     2. Ensure specimen is in a closed container and labeled with biohazard sticker.
     3. Specimen should be on ice or saline slush.
  3. Dissecting heart tissue:
     1. Upon return to the lab place patient ID sticker on the Cardiac Collection Form. Slide completed form under door of MS567 after processing.
     2. Fill liquid nitrogen bucket with liquid nitrogen.
     3. Before dissection take a picture of the specimen with designated camera, if applicable.
     4. Place ice in one weigh boat. Place the other weigh boat on top. Use this weigh boat to sit sample while you dissect to keep cool. Work as quickly as possible to minimize sample degradation.
     5. Left ventricular tissue should be processed first. Separate LV tissue into epicardial, midmyocardial, and endocardial. Place layers in a cryogenic vial and drop in liquid nitrogen bucket. Vials should be labeled with hashcode and tissue type.
     6. Section a small portion of LV epi and endo tissue for Dr. Latif’s lab. Ensure tissue is as close to apex as possible. Tissue will be placed in tubes with solution (provided by Dr. Latif) in the fridge. Include a copy of the collection form with date and time next to tubes. Be sure tube is labeled with hashcode and tissue type.
     7. Then process RV (no layer separation), septum, atria and aorta (when applicable). Place in cryogenic vial. Label the vial and drop into liquid nitrogen.
     8. Blood samples should be processed last.
     9. After dissection, all remaining tissue should route through surgical pathology. (*See CVBR-003 – Operating Room & Surgical Pathology*)
  4. Storage of specimens:
     1. Remove all of the frozen tubes, vials, etc. from the liquid nitrogen using a ladle and place in a cryogenic transfer storage box.
     2. Place cryogenic transfer box in an open storage slot in one of the liquid nitrogen dewars.
     3. Fill out the Human Tissue Recovery Log in the black binder. Be sure to write the location of the transfer box.
  5. Cleaning, disinfecting equipment:
     1. Place dissecting tools in tupperware. Fill half way with Decon and the rest with water. Let soak for 10 minutes.
     2. Dump ice from cooler in sink.
     3. Spray countertop and cooler (inside and out) with Conflickt disinfectant spray. Leave for 10 minutes.
     4. After 10 minutes, dump the fluid from the tupperware in the sink. Rinse the tools and tupperware with water. Lay a paper towel on the countertop. Place tools on the paper towel to dry. If possible, open scissors to ensure proper drying.
     5. After 10 minutes, wipe down countertop and cooler.
     6. Clean tupperware according to lab dish cleaning protocol.
     7. Place all material used for dissection in a biohazard bag (gloves, underpad, weigh boats, mask, hat, paper towels).
     8. Take biohazard bag to autoclave.
  6. Autoclave biohazardous material:
     1. After collecting all biohazard waste (underpads, paper towels, gloves, hat, mask) *loosely* tiethe bag and place into one of the white rectangular autoclave bins.
     2. Consider adding a piece of autoclave-indicator tape to the side of the bag.  The indicator tape changes color when exposed to high temps for a period of time.
     3. Immediately take bin to autoclave. Start autoclave using the BIOBAG40 protocol.  Make sure to sign the BetaStar autoclave log sheet with your name, lab, our room number, the time of the protocol and which protocol (BIOBAG40).  Also make sure to say "yes" on the biohazard column.
     4. 60 minutes after beginning the BIOBAG40 cycle remove the waste. Dump the waste into one of the provided trash bins in the room. Bring the empty bin back to the lab.
     5. Note that the bin will be hot. Wear appropriate gloves and/or other necessary protective equipment.
  7. Return OR scrubs to scrub machine.

1. **REFERENCES:**
   1. University of Kentucky Cardiovascular Biorepository IRB approved consent form

UK Healthcare Policy and Procedure – Department of Perioperative Services -Dress Code (#OR 03-01) (<https://ukhealthcare.mc.uky.edu/policies/departmental/_layouts/15/WopiFrame.aspx?sourcedoc=/policies/departmental/Perioperative%20Services/OR%2003-01%20Dress%20Code.docx&action=default>)

* 1. University of Kentucky HIPAA in Health Research (<http://www.research.uky.edu/ori/HIPAA/main%20page.htm>)
  2. UK Biosafety Manual (4.0-University of Kentucky Biological Safety Requirements, 5.3-Exposure Incidents, 10.0-Decontamination and Disposal of Biohazardous Waste) (<http://ehs.uky.edu/docs/pdf/bio_uk_biosafety_manual_0001.pdf>)
  3. Gill Heart & Vascular Cardiovascular Biorepository *Operating Room & Surgical Pathology*, CVBR:003
  4. Gill Heart & Vascular Cardiovascular Biorepository *OnCore and REDCap Data Management,* CVBR:008.