



SOUTHWESTERN UNIVERSITY

Institutional Review Board (IRB) Policy Use of Human Materials for Research Purposes

Southwestern University is committed to protecting the rights and welfare of human subjects in research. The purpose of this plan is to comply with ethical and legal requirements for the conduct and oversight of Human Research.

Southwestern's IRB – Use of Human Materials Plan and Biosafety Plan is a system designed to ensure the Investigators/Researchers/Team Members meet their obligation to protect the rights and welfare of human subjects in their research activities.

It is the responsibility of the IRB to review and approve research that involves the collection, use, and storage of human materials (e.g., blood, saliva, sweat, tissues, urine, etc.). The IRB will review all university research involving human material collection and use to determine if the activity is classified as human subjects research and what level of review is required.

Biopsies (muscle)

Biopsies will be carried out by experienced research personnel as determined by the IRB. Only trained and experienced faculty Principal Investigators (PI) will take muscle biopsies. At least two personnel (with blood borne pathogens training) will be present during the biopsy (one of which is qualified to take biopsies). Blood borne pathogen (BBP) training requires completion of two modules annually, both the Southwestern BBP-Exposure Control Plan (ECP) module via Safe College Learning Management System and the Occupational Safety and Health Administration (OSHA) BBP module. Trained personnel will have performed 10 biopsies under supervision of a licensed medical professional. Students will not be allowed to take muscle biopsies under any circumstances.

Blood Collection (finger stick, heel stick, ear stick or venipuncture)

- Research involving blood collection will require full IRB review and approval.
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- All blood collection will be carried out by trained personnel. Only certified phlebotomists are authorized to collect blood using venipuncture. Students will be able to perform sticks after receiving BBP training and under the supervision of the PI.
- Participants should be healthy nonpregnant adults.
- Participants must weigh at least 110 lbs for venipuncture.
- There must be no special health reasons (e.g., anemia) to contraindicate blood withdrawal. The IRB will review screening and consent information for exclusion criteria prior to approval.
- For adults, the cumulative volume withdrawn or collected may not exceed 450 ml per eight-week period (this maximum includes blood being drawn for clinical purposes) from patients 18 years of age or older in good health and not pregnant.
- Justification for the volume selected must be described in the protocol.

Consent Form

The Principal Investigator must include appropriate procedure/risk language (in clear layman's terms) in the consent form for the IRB to review. The assumption of risk language should be inclusive of all risks and indicate most common adverse side effects.

Data Safety Monitoring

All research must have a data and monitoring plan that is appropriate to the type of research. This should include a plan for monitoring subject reactions and reporting any unanticipated problems or adverse events to the IRB.

Ethical Principles

Southwestern Investigators/Researchers/Team Members are expected to follow the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," also known as "The Belmont Report": Respect for Persons, Beneficence, Justice.

Exposure Control Plan (ECP)

All research personnel are required to follow the university's ECP which is also known as the BBP Policy. The plan will be updated to include employees and affected students working with human materials (Employee Exposure Determination). The PI will be responsible for ensuring compliance with the university ECP/BBP.

Engineered safe sharp devices must be used for blood collection

Facilities

Facilities where human materials are collected or handled will be designed for clinical samples. This includes tiled or sealed flooring (no carpet), a handwashing sink, and access to an eyewash. No food or drink is permitted in the room unless related to the research protocol.

Field Collection

Researchers collecting human materials in the field will provide details in their initial IRB protocol application. Any deviation from the procedures outlined in the initial protocol application must be reported to the IRB as an Incident Report.

Informed Consent

The PI/Researcher is responsible for obtaining and documenting effective informed consent using IRB-approved consent documents, and for ensuring that no human subjects are involved in research prior to obtaining their informed consent. A copy of the signed consent form should be provided to the research subject. Keep the originals in your secured research file for at least seven years.

Inspections

Inspections will be conducted annually by the Safety and Risk Management Office to ensure compliance with the university ECP and this policy.

Lower Risk Human Materials (Buccal swabs, saliva, stool, sweat, urine)

While considered a lower bloodborne pathogen risk, the university considers all human materials as potentially biohazardous. All human materials will be handled using Universal Precautions (as outlined

in the ECP) and researchers should consult the university exposure control plan. Specific procedures outlining collection, storage, handling, and disposal must be included in the IRB proposal.

Personal Protective Equipment

Researchers will wear disposable gloves and eye protection at a minimum when collecting human material. Lab coats or scrubs should be worn when collecting/handling blood or any tissue samples.

Personnel

- Research Personnel at Southwestern University includes faculty, staff, and students.
 - All research personnel are required to comply with the ECP/BBP.
 - Student research personnel are financially responsible for any research injury (needlestick).
- It is strongly recommended that all personnel collecting or processing human materials receive the Hepatitis B vaccination. All personnel with reasonable risk of contact with BBP should be informed of the importance of the Hepatitis B vaccine.
 - The Hepatitis B vaccination is available to employees at no charge.
 - Student personnel are financially responsible for their own Hepatitis B vaccination.
 - Personnel have the option to decline.
 - All personnel shall be required to sign the Hepatitis B acceptance or declination form found in the ECP/BBP.
 - The Principal Investigator is responsible for maintaining documentation of acceptance or declination.

Refrigerated Storage of Human Materials

Human materials will be stored in dedicated and properly signed refrigerators or freezers. No food or drink can be stored with human materials. Units should be lockable or kept in rooms that can be locked when unattended.

Shipping and Transportation

Human materials must be transported on campus and/or in vehicles using the following procedure. Please describe transporting in your IRB protocol application.

- Use two forms of packaging to transport materials (leak-proof bag and sealed/closed box/cooler)
- Include absorbent material in bag with specimen container
- Use cushioning material (bubble wrap)
- Place biohazard sticker on outer container

If material needs to be shipped or dry ice used, contact **the PI for the research project**.

Shipping human material to another institution requires a Material Transfer Agreement (MTA) which can be found here: <https://www.southwestern.edu/policy/faculty-research-scholarship/institutional-review-board/forms/>.

Standard Operating Procedures (SOPs)

Principal Investigator (PI)-specific SOPs are required for all protocols involving human materials and should be included in the protocol submission. The IRB may require a copy of the SOP upon request.

Sterilization of Equipment

- Bergstrom needles or cannula used for muscle biopsies must be sterilized between each use.
- Sterilization will include soaking in appropriate disinfectant before transporting to the autoclave.
- Autoclave cycle and time will follow manufacturer directions.
- Each autoclave load will be verified using autoclave tape to ensure sterilization.
- Record sterilization event.

Students

Students (not paid or volunteer) participating as researchers will be expected to follow the requirements of this policy including the university's Exposure Control Plan.

Training

- All personnel collecting or processing human materials must complete Bloodborne Pathogens Training annually.
- All personnel collecting or processing human materials must also complete the training session on the University ECP/BBP via the Safe Colleges Learning Management System annually.
- The PI/Researcher is responsible for ensuring that all affected personnel are assigned and complete both training modules on an annual basis. The PI/Researcher is also responsible for keeping a record of completed training.
- Personnel conducting venipuncture must be a certified phlebotomist.
- Additional training requirements such as First Aid, Cardiopulmonary Resuscitation (CPR)/Automated External Defibrillator (AED) may be required as determined by the PI and approved by the IRB.

Waste (Biomedical)

- Items that come in contact with human materials must be decontaminated using an approved disinfectant or disposed as biomedical waste. Regulated medical waste (including saturated gauze) must be disposed of in red bags (or labeled containers), non-regulated waste (with a small amount of blood/other potentially infectious material (OPIM) and cotton gauze that absorbs all liquid fluids) must be disposed of in yellow bags (to indicate precaution).
- Autoclaving of regulated medical waste is not permitted.
- The university provides biomedical waste disposal at a central collection location: Prothro Center – Health Services Office
- Researchers that generate biomedical waste will transport sealed containers to the central collection location. Students are not authorized to transport biomedical waste.



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Standard Operating Procedure (SOP) – Blood Draw

PROTOCOL TITLE: _____

PI NAME: _____

Definition: The collection of blood, usually for laboratory testing.

Possible Risks to Participants: Drawing blood may cause discomfort, bruising, excessive bleeding or infection at the site of puncture. Light-headedness or fainting may occur.

Equipment and Supplies: Non-Latex Exam Gloves, Alcohol Swab/Pad, Vacutainer(s), Sterile Double-Ended Safety Needles or Butterfly Needles, Non-Latex Tourniquet, Gauze and Tape or Band-Aid, and Sharps Container.

Supplemental Lab Resources: Juice or other beverage for faintness.

Any individual drawing blood must:

- 1) have prior IRB approval;
- 2) be current in (1) the Occupational Safety and Health Administration (OSHA) blood borne pathogen (BBP) training and (2) Southwestern's Exposure Control Plan (ECP)/BBP Training via Safe Colleges Learning Management System (both trainings must be done annually);
- 3) be current in CPR/AED Training or have someone current in CPR/AED Training present
- 4) have another individual present to provide assistance, if needed;
- 5) have completed Human Subjects training and have a current certificate on file with the IRB (Human Subjects training must be done once every three years)

Procedures:

1. Assemble all equipment and supplies (see equipment and supplies above)
2. Check participants are not taking any medications (as outlined in the risk screening and consent form for the study) that would preclude participation in the blood draw.
3. Wash hands thoroughly and put on exam gloves. When multiple participants are having venipuncture, exam gloves should always be changed between participants, and hand sanitizer should be used each time gloves are changed.
4. Open sterile, packaged equipment and supplies in the presence of the participant so that they can see that these items come from original packaging.
5. Clean the draw site with an alcohol swab (70% isopropyl alcohol) in a circular motion from the center of the area and allow the alcohol to dry. DO NOT touch the draw site again.

6. Vacutainers should be used in the following sequence, based on Clinical and Laboratory Standards Institute guidelines, to limit contamination of tube additives from tube to tube, which may cause erroneous result with some tests: Blood Culture, Royal Blue, Red (No additive), Light Blue (Sodium Citrate), Serum Separation, Green (Sodium Heparin), Yellow (ACD Solution), Pink (TMS), Pearl, and then Lavender (EDTA).
7. If the venipuncture is not successful, a second attempt can be made on the other arm. If the second attempt is not successful, the procedure should be terminated.
8. Discard the needle in the designated sharps container.
9. Using gauze, apply firm pressure to the venipuncture site for 2 minutes or until bleeding stops.
10. Apply tape and gauze or a Band-Aid to the venipuncture site and discard the used gauze into a biohazard container.
11. Remove gloves.
12. Wash hands.
13. Provide participant copy of Venipuncture Information Sheet.
14. Advise participant to consult with primary care provider and inform the investigator if any complications develop at the site of venipuncture.

Dealing with Lightheadedness or Fainting:

Individuals having venipuncture may experience lightheadedness or fainting (sudden transient loss of consciousness with concurrent loss of postural tone). This usually results from any mechanism that decreases cerebral blood flow. The common faint is often precipitated by fear, anxiety, or low blood sugar levels due to prolonged fasting and may be accompanied by dimming vision, sweating, nausea and loss of balance.

If the participant feels lightheaded or faint:

- Remain with the participant and summon help from a colleague.
- Help the participant lie down on the floor and raise legs above the level of the heart.
- When the participant no longer feels faint, allow the participant to sit up in place.
- When the participant is able to tolerate sitting without feeling faint, assist him/her into a chair.
- Offer sips of juice.
- When the participant is able to tolerate sitting in a chair without feeling faint, assist him/her with standing and walking.
- Retain the participant for 15-20 minutes to verify recovery, then allow him/her to leave.

If the participant loses consciousness:

- Remain with the participant and summon help from a colleague.
- Attempt to wake the participant by loudly calling his/her name and briskly tapping shoulder. If the participant is unresponsive and not breathing or not breathing normally (only gasping), have a colleague call 911 and obtain the AED.
- While 911 is being called and the AED being obtained, if radial pulse cannot be palpated within 10 seconds, begin CPR.
- If there is no pulse, or are unsure, begin and continue CPR until emergency responders arrive.
- If there is a pulse, begin and continue rescue breathing until emergency responders arrive.

- Aid the emergency responders by providing information as needed until they have assumed responsibility for the participant.

Notify the IRB Chair and Director of Safety and Risk Management:

- If the person performing the procedure is not the PI for the study, they should immediately inform the PI of the incident and ensure that the procedures outlined in the protocol are followed.
- Within 2 hours of the incident, the PI will notify the IRB chair and Director of Safety and Risk Management.
- Principal investigator will submit an incident report to the IRB chair and Director of Safety and Risk Management.

Dealing with Excessive Bleeding:

Excessive bleeding at the venipuncture site may occur. Causes include: laceration of the vein, excessive tourniquet pressure, or failure to apply enough pressure after withdrawal of the needle.

1. If excessive bleeding occurs, apply firm pressure at the site for several minutes.
2. If the bleeding is not controlled or if bleeding occurs in spurts (suggestive of arterial bleeding) the person performing venipuncture should:
 - a. Call 911 or ask a colleague to call 911 (the individual placing the call should follow the directions for calling emergency responders posted in the room they are calling from. If a colleague is available the colleague should then go to the front of the building to help guide emergency personnel to the room).

Notify the IRB Chair and Director of Safety and Risk Management:

- If the person performing the procedure is not the PI for the study, they should immediately inform the PI of the incident and ensure that the procedures outlined in the protocol are followed.
- Within 2 hours of the incident, the PI should notify the IRB chair and Director of Safety and Risk Management.
- Principal investigator will submit an incident report to the IRB chair and Director of Safety and Risk Management.



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Venipuncture Information Sheet

****Please keep this information sheet accessible until your venipuncture site has fully healed.****

Care of the site from which blood was drawn

Keep the gauze or band-aid on your blood draw site dry for several hours, until the site has had adequate time to heal. You may change this gauze/band-aid if necessary.

Potential Complications

Bleeding -- A small amount of bleeding is normal after blood is drawn, but this bleeding should stop after firm pressure has been applied for several minutes. If you have continued bleeding from the site, continue to apply firm pressure for a few more minutes. If the bleeding persists, contact your primary care provider for advice. If you do not have a primary care provider, proceed to a medical clinic or the emergency room for attention.

Infection -- The risk of infection following blood draws is minimal, but should be taken seriously.

Signs of infection include:

- Excessive pain, warmth, redness or swelling at the site
- Oozing/drainage from or around the site
- Fever, chills, fatigue, increasing aching or stiffness in your joints

Nerve irritation—Irritation of a nerve may occur during blood draws.

Signs of nerve irritation include:

- Localized numbness
- Localized tingling
- Localized weakness

If you experience any of the above signs, you should contact your primary care provider for advice. If you do not have a primary care provider, proceed to a medical clinic or the emergency room for attention.

You should also notify the investigator of bleeding or infection problems.



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Biosafety Manual

(Revised 8/2019)

Note:

This is a general manual for biosafety procedures. The principal investigator is responsible for including protocol-specific procedures for addressing hazards.

I have read, understand, and agree to adhere to the biosafety procedures contained within:

Printed Name

Signature

Date

PI:

Personnel Review of Manual:

Principal Investigator Responsibilities

The Principal Investigator (PI) has the primary responsibility for ensuring that their research is safe. They must adhere to university policy and applicable regulations.

In addition, the PI will:

- Develop written **SOPs** and train their personnel on them
- Maintain documentation of **specialized** training and make readily available for audits
- Provide personal protective equipment (PPE) and instruction on use
- Ensure biohazardous waste is properly disposed
- Report spills, exposures or incidents to the Safety and Risk Management Office
- Immediately complete Accident Report with Human Resources and send a copy to the Safety and Risk Management Office

Staff/Student Responsibilities

- Follow approved procedures and safety guidelines
- Know emergency procedures
- Complete all required training
- Report any unsafe conditions to the PI and Safety and Risk Management Office
- Utilize all required PPE
- Use appropriate equipment

General Emergency Information

If there is an emergency, call 911

Notify your Principal Investigator.

Eyewash

In case of exposure, proceed to the nearest eyewash station. Hold eyelids open with thumb and forefinger and rinse for at least 15 minutes. Wash from the outside edges towards the inside to prevent washing chemicals back into the eye.

Rinse should be aimed at the inner corner of the eye (near the nose) not directly at the eyeball. “Roll” eyes around and up and down to ensure full rinsing.

Contact lenses (if worn) should be removed as soon as possible. Have someone call for emergency response immediately. The area around the eye wash station must remain clear at all times.

The PI is responsible for implementing Southwestern’s Emergency Eyewash Program, conducting monthly inspections to ensure properly functioning eyewash stations, maintaining all eyewash program records, and participating in safety audits.

Spills

Notify your PI if a spill occurs!

- Use appropriate PPE when cleaning.
- Use a disinfectant and spray the spill and at least six inches around it.
- Let the disinfectant sit for a few minutes before wiping up.
- Dispose of all cleanup material as biohazardous waste.

Spills Inside Centrifuges

If the spill occurs inside a centrifuge, turn off the equipment and leave the lid closed for at least 30 minutes to reduce aerosol exposure before cleaning up the spill. Follow manufacturer's instructions for proper decontamination protocols prior to using centrifuge. Document spill and cleanup.

Exposures (including needlesticks)

All exposures must be reported to the PI Immediately!

- Wash hands and exposed skin with soap and water.
- Employees: Fill out a worker's compensation form even if you are not sure if your illness was acquired at work. This must be done if you need to file a claim later.
- Complete the Human Resources Office Accident Report and the Safety and Risk Management Office BBP Incident Report and submit copies to both offices.

New Employees

Personnel should be aware of the potential hazards associated with the work and be proficient in the specified practices and procedures.

If you are using a piece of equipment for the first time, be sure to ask for training, equipment manual or SOP for proper operating procedures.

Housekeeping

Eating, drinking and smoking is prohibited.

Work surfaces should be decontaminated with approved disinfectant after completing work.

Security

Access to human materials should be restricted. The door to room is kept closed and locked when unattended.

Sharps

Extreme precautions should be taken while handling needles and other sharp instruments. In any situation, do not break or bend needles; use single-use needles and syringes.

Do not recap needles. Needles and syringes, butterfly needles and associated tubing, and similar devices should be discarded intact into a sharps container. Do not fill these containers more than ¾ full.

Transport to Prothro Center – Health Services in a secondary sealed container.

Safe needle devices should be used whenever possible. Safety devices such as needle or scalpel guards or retractable devices should be employed.

Broken glass should never be handled by hand, but should be disposed of with a broom and dustpan or tongs.

Shipping Human Materials

The shipping of human materials with dry ice is regulated by the Department of Transportation and the International Air Transport Association. Shipments must be completed by a certified shipper. Please consult with the PI if materials need to be shipped. MTA forms will be required and can be found here: <https://www.southwestern.edu/policy/faculty-research-scholarship/institutional-review-board/forms/>.

Transporting Human Materials

Human materials must be transported on campus and in vehicles using the following procedure.

- Use two forms of packaging to transport materials (leak-proof bag and secondary sealed/closed box/cooler)
- Include absorbent material in bag with specimen container
- Use cushioning material (bubble wrap)
- Place biohazard sticker on outer container

Appendix (Protocol-specific hazards-PI completes)

Use of Potentially Hazardous Equipment:

Provide a description of potentially hazardous equipment used. Examples include centrifuges, use of needles, etc.

Special Practices:

Provide a description of potentially hazardous procedures conducted. Examples include venipuncture, biopsy, etc.