Biosafety Guide for Vanderbilt University Research Cores: Identifying and Minimizing Biomaterials Risk

Biological materials used in research such as clinical specimens, cells, tissues, and microbiological agents can present an infectious disease hazard to lab workers exposed to these materials. They can also be a source of cross-contamination when not properly handled in shared environments. For these reasons, it is important for core managers and personnel to be fully informed of the risks associated with biomaterials they plan to accept and handle themselves or permit end users to work with in the core facility. Below is a table that characterizes the common categories of biomaterials used in research and what biosafety policies and actions apply.

BIOMATERIAL	EXAMPLES	APPLICABLE POLICIES/ACTIONS
Human-derived materials (low infectious disease risk)	 Established cell lines Clinical specimens or tissues collected on studies that exclude or do not target infected subjects 	Policy: Human-derived Materials & BloodbornePathogens in Basic Research ApplicationsAction: If core personnel or end users handle thesematerials, provisions of this policy apply for trainingand medical surveillance.
Human-derived materials (known or suspected infectious disease risk)	Clinical specimens or tissues collected on studies that target infected individuals	Policy: Human-derived Materials & Bloodborne Pathogens in Basic Research Applications; BSL-2 with Enhanced Practices for Handling COVID- 19/SARS-CoV-2 Specimens Action: If core personnel or end users handle these materials, provisions of this policy apply for training and medical surveillance.
Live infected animal (ABSL-2) models	Live infected animals brought to the core for analyses	Action: Contact your entity's Biosafety Officer to develop a containment plan/procedure before approving activity. If core personnel or end users must handle live infected animals, these individuals will need to complete <i>ABSL-2 training</i> in addition to satisfying OAWA requirements. Medical surveillance may apply depending on agent.
Other potentially infectious materials	 Viable body fluids or tissues from infected animals Pathogenic bacteria, viruses, or media containing these agents Unfixed human or animal brain (prion risk) 	Action: Contact your entity's Biosafety Officer to develop a containment plan/procedure before approving activity. If core personnel or end users must handle these materials, these individuals will need to complete <i>Biosafety 201: Risk Assessment</i> <i>Applications for BSL-2</i> (or equivalent) training. Medical surveillance may apply depending on agent.
Macaque-derived materials	 Viable body fluids, cells, or tissues from Macaque (including Rhesus) monkeys 	 Policy: Macaque Tissues, Body Fluids and Cells in Basic Research Action: If core personnel or end users handle these materials, provisions of this policy apply for training and medical surveillance.
Biological toxins and venoms	Cells/media containing toxin	Policy: Research Use of Biological Toxins and VenomsAction: Contact your entity's Biosafety Officer to determine if specific additional practices are needed.
Biomaterials containing foreign DNA (including synthetically derived)	 Modified cells Viral vectors Modified microorganisms 	Action: If core personnel or end users will handle these materials for analyses, they could be exposed to recombinant DNA. Minimally, they will need to complete <i>Biosafety 101: Standard Microbiological</i> <i>Practices</i> and report any spills or exposures involving biological materials to their entity's Biosafety Officer.

Identifying Biomaterial Risk During the Request for Service/Sample Intake Process

By collecting information up front to characterize biomaterials, core managers can ensure that they have the appropriate biocontainment measures in place before accepting the materials into their lab spaces. This information is also important to have on record in case a <u>spill or exposure incident occurs involving these</u> <u>biomaterials</u>. Specific questions that could be used to collect these details include:

- 1. Are specimens/biomaterials from a source known or suspected to contain an infectious agent? If yes, what agent(s)?
- 2. Are specimens/biomaterials from a macaque monkey (including rhesus macaques)?
- 3. Do specimens/biomaterials contain a biological toxin or venom? If yes, what is it and what is the expected concentration in the specimen?
- 4. Do specimens/biomaterials contain recombinant nucleic acids? (In other words, have they been genetically modified to contain foreign DNA that is expressed?) If yes, describe the modification(s).

Cores that accept and handle human clinical samples and/or plan to accept materials with a "YES" response to any of the four questions above should pursue biomaterials registration with their entity's Institutional Biosafety Committee (IBC). Doing so will facilitate collaboration between the core and <u>VU EHS Biosafety</u> or <u>OCRS</u> <u>Biosafety</u> to efficiently address service requests with special consideration.

Additional Biosafety Pointers/Resources for All Core Facilities and Operations

- 1. Be aware of permit requirements that may apply to sample receipt. This is especially relevant if you will be receiving biomaterials (including clinical or environmental samples) from a foreign country. <u>CDC</u> or <u>USDA</u> (or other agency) permits may be required for import of these samples, and lack of permits when required will delay or terminate shipments. Import permits generally require material access restrictions and specific waste treatment practices. Please contact your entity's Biosafety Officer for assistance if you plan to acquire a permit or have questions or need additional information on biomaterials permits.
- 2. Be familiar with high-risk infectious agents and consult with Biosafety before accepting these materials. While there are only a limited number of high-risk agents actively in use at Vanderbilt, biomaterials (especially specimens from collaborators) are less regulated for shipment and transfer compared to other hazardous materials. Therefore, basic recognition of high-risk agents is key. The IBC Policy entitled <u>Safeguarding Research Labs Against Accidental Exposure to High-Risk Biological Agents</u> contains links to lists of these agents and provides guidance about necessary actions for those who wish to receive samples containing inactivated agents. Please contact your entity's Biosafety Officer for guidance if you receive a request for service regarding high-risk biological agents.
- 3. Promote the use of secondary containers to reduce the potential for spill and contamination. Almost all core services will require biomaterials to be transported on campus. When any hazardous materials are transported through public areas, appropriate spill containment measures need to be taken to protect all along the transport route. The <u>Transporting Biological Materials on Campus</u> guidance document should be followed by all who are moving research materials between lab spaces. Additionally, the use of secondary containers within the core facility can help minimize the potential for spills in this shared user environment.
- 4. Be prepared for spills. Whether biomaterials are to be handled by core personnel or by researchers using core equipment, the potential for spills to occur is ever-present and preparation is key. If liquid or wet biomaterials are handled in the facility, or glass primary containers are used, a biomaterials spill kit should be available in the facility. Additionally, biomaterial spills that occur in a public area and all biomaterial exposure incidents need to be reported to your entity's Biosafety Officer as soon as possible. Refer to Responding to Personnel Exposures and Spills Involving Biomaterials for more information. Contact your entity's Biosafety Office for assistance with assembling a spill kit suitable for core facility needs.
- 5. If human-derived materials will be present in the core facility, select disinfectants that are EPA-rated for HIV and Hepatitis B virus. The OSHA Bloodborne Pathogens Standard requires the use of products with this rating for disinfection at the conclusion of work with these materials. Refer to the <u>Guide to</u> <u>Disinfectants for Bloodborne Pathogens in Research Labs</u> for examples of products with this rating and additional disinfection pointers. Please note that these disinfectants may not be suitable for sensitive devices or instruments. Refer to equipment manuals for cleaning and disinfection guidance in these cases.