

## Biosafety Guide for Research Cores: Identifying & Minimizing Biomaterials Risk

Biological materials used in research such as clinical specimens, cells, tissues and microbiological agents can present an infectious disease hazard to personnel exposed to these materials. They can also be a source of crosscontamination when not properly handled in shared environments. For these reasons, it is important for core 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)	<ul> <li>Established cell lines</li> <li>Clinical specimens or tissues collected on studies that exclude or do not target infected subjects</li> </ul>	Policy: Human-Derived Materials & BloodbornePathogens in Basic ResearchAction: If core personnel or end users handle thesematerials, provisions of this policy apply for training andmedical surveillance.
Human-derived materials (known or suspected infectious disease risk)	<ul> <li>Clinical specimens or tissues collected on studies that target infected subjects</li> </ul>	Policies: Human-Derived Materials & BloodbornePathogens in Basic Research; BSL-2 with EnhancedPractices for Handling COVID-19/SARS-CoV-2 SpecimensAction: If core personnel or end users handle thesematerials, provisions of these policies apply for trainingand medical surveillance.
Live infected animal (ABSL-2) models	<ul> <li>Live infected animals brought to the core for analyses</li> </ul>	Actions: Contact <u>Biosafety</u> 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 ABSL-2 training in addition to satisfying OAWA requirements. Medical surveillance may also apply depending on agent.
Other potentially infectious biomaterials	<ul> <li>Viable body fluids or tissues from infected animals</li> <li>Pathogenic bacteria, viruses, or media containing these</li> <li>Unfixed human or animal brain (prion risk)</li> </ul>	Actions: Contact <u>Biosafety</u> 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 <u>Principles &amp;</u> <u>Practices of Biosafety</u> (or equivalent) training; participate in medical surveillance if applicable.
Macaque-derived materials	<ul> <li>Viable body fluids, cells or tissues from Macaque (including rhesus) monkeys</li> </ul>	<ul> <li>Policy: Macaque Tissues, Body Fluids and Cells in Basic Research</li> <li>Action: If core personnel or end users handle these materials, provisions of this policy apply for training and medical surveillance.</li> </ul>
Biological toxins and venoms	Cells/media containing toxin	Policy: <u>Research Use of Biological Toxins and Venoms</u> Actions: Contact <u>Biosafety</u> to determine if specific additional practices are needed.
Biomaterials containing foreign DNA	<ul> <li>Modified cells</li> <li>Viral vectors</li> <li>Modified microorganisms</li> </ul>	Actions: 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 Biosafety 101: Standard Microbiological Practices training and report any spills or exposures involving biological materials as outlined in this link.

## 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 in their labs. This information is also important to have on record in case a <u>spill or exposure incident occurs involving these 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?
- 2. Are specimens/biomaterials from a macaque monkey (including rhesus)?
- 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 DNA? (In other words, have they been genetically modified to contain foreign DNA that has been expressed?) If yes, describe the modification.

Cores that will accept and handle human clinical specimens and/or are planning to accept materials with a "YES" response to any of the 4 questions above should pursue registration with their entity's Institutional Biosafety Committee (IBC). In doing so, this will facilitate collaboration between the core and Vanderbilt Biosafety to efficiently address service requests with special considerations.

## Additional Biosafety Pointers/Resources for All Core Facilities & Operations

- Be aware of permit requirements that may apply to sample receipt. This is especially relevant if you will be receiving biomaterials from a foreign country. Here is a <u>link</u> to a resource document that summarizes the various permitting agencies and how to access more information on biomaterials permits. Please contact\_<u>Biosafety</u> for assistance if you plan to acquire a permit.
- 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 the <u>Biosafety Officer</u> for guidance if you receive a request for service regarding a high-risk agent.
- 3. Promote use of secondary containers to reduce spill and contamination potential. Almost all core service scenarios will require biomaterials to be transported on campus. When any hazardous material is 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> document should be followed by all who are moving 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 the 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 the <u>Biosafety Officer</u> as soon as possible. Refer to <u>Responding to Personnel Exposures and Spills Involving Biological Materials</u> for more information. Contact <u>Biosafety</u> 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 & Hepatitis B virus. The OSHA Bloodborne Pathogens Standard requires the use of disinfectants with this rating for disinfection at the conclusion of work with these materials. Refer to the <u>Ready-to-Use BBP</u> <u>Disinfectant Guide</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.