This checklist is to be used in conjunction with Institutional Review Board (IRB) review of studies involving the collection, analysis, and/or experimental manipulation of sera, blood products, or other specimens (e.g., stool, urine, sputum, and other secretions) derived from human subjects.

Please review each category (I, II, III) to determine the type of Institutional Biosafety Committee (IBC) consideration/review required for your study.

**Select all that apply to your proposed studies and then refer to the guidance below.**

|  |  |
| --- | --- |
| **Category I** | |
|  | Human specimens received will be formalin-preserved samples. |
|  | Human specimens will be collected, analyzed, and/or manipulated in a laboratory with Clinical Laboratory Improvement Amendments (CLIA) or College of American Pathologists (CAP) certification. |
|  | Human specimens will be collected, analyzed, and/or manipulated in a licensed healthcare setting. |
| **Category II** | |
|  | This study will involve human specimens containing Risk Group 1 or 2 human pathogens1,2. |
|  | This study will involve human specimens of unknown pathogen status (i.e., collected samples will not be tested for specific human pathogens). |
| **Category III** | |
|  | This study will involve specimens known to contain Risk Group 3 or 4 human pathogens1,2. **Action**: Submit IBC [Form A](https://drexel.edu/~/media/Files/research/New%20Site/6_Compliance/Form_A_General_Biohazard_Form2017a.ashx?la=en) |
|  | This study will involve the generation and/or use of recombinant DNA (rDNA) or synthetic nucleic acids covered by the NIH Guidelines2,3. **Action**: Submit IBC [Form A](https://drexel.edu/~/media/Files/research/New%20Site/6_Compliance/Form_A_General_Biohazard_Form2017a.ashx?la=en) and [Form B](https://drexel.edu/~/media/Files/research/New%20Site/6_Compliance/Form_B_recombinant_DNA_Registration_Addendum2017a.ashx?la=en). |
|  | This study will involve the use of acute toxins, carcinogens, mutagens, or cytotoxic agents (including but not limited to 4-OHT, 4-thiouracil, urethane, colchicine, BRDU, CSA, Taxol/paclitaxel, rapamycin, methylazoxymethanol acetate, and/or tamoxifen). If you have questions about specific agents, please contact the IBC for guidance ([biosafety@drexel.edu](mailto:biosafety@drexel.edu)). **Action**: Submit IBC [Form A](https://drexel.edu/~/media/Files/research/New%20Site/6_Compliance/Form_A_General_Biohazard_Form2017a.ashx?la=en) and [Form C](https://drexel.edu/~/media/Files/research/New%20Site/6_Compliance/Form_C_Hazardous_Substance_Addendum2017.ashx?la=en). |

Review your selections above and then proceed according to the following instructions:

* If your only selections are in **Category I**, IBC review is not required.
* If you selected at least one statement in **Category II** but none in **Category III,** complete a Low-Risk Human Specimens Review Form (Form F). Submit the completed form to the IBC for review ([biosafety@drexel.edu](mailto:biosafety@drexel.edu)).
* If you selected at least one statement in **Category III**, submit the indicated forms to the IBC ([biosafety@drexel.edu](mailto:biosafety@drexel.edu)) for full review and approval.

1. For information on Risk Group classification of specific human etiologic agents, refer to Appendix B of the NIH Guidelines.
2. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules are available in [HTML](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm#_Toc3457031) and [pdf](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) formats.
3. For information on experiments involving recombinant nucleic acid technologies that require oversight, refer to Section III of the NIH Guidelines.