INSTITUTIONAL BIOSAFETY COMMITTEE

SUMMARY OF GUIDELINES for RESEARCH INVOLVING INFECTIOUS AGENTS or RECOMBINANT DNA MOLECULES.

Any research in this institution involving infectious agents, fresh human tissue or recombinant DNA must be reported to the Institutional Biosafety Committee (IBC) for review. Work with recombinant DNA must be conducted in accordance with the revised Guidelines issued by the Department of Health and Human Services (Federal Register, July 5, 1994, Separate Part IV) http://www4.od.nih.gov/oba/rac/frnotices/1994_guideline_action.htm a copy of which is also on file in the Research Development Office (Room 1254 WH). This summary is intended to assist investigators in preparing documents for review by the IBC and should not be taken as a substitute for careful reading of the Guidelines.

CONTAINMENT: All work with infectious agents must be carried out with appropriate containment measures. The Recombinant DNA Guidelines include a Classification of Microorganisms on the Basis of Hazard (Appendix B), which should be used to determine the level of containment required for a given organism. Fresh human blood, body fluid or tissue requires Biosafety Level 2 (BSL-2) containment. Containment procedures are described in Health and Human Services Publication No.(CDC)93-8395, "Biosafety in Microbiological and Biomedical Laboratories", 4th Ed., which is available on line: http://bmbl.od.nih.gov/. A hard copy is also available in the Research Development Office (Room 1254 WH). **Work with any microorganisms or infectious agents must be carried out under at least BSL-1 containment procedures (See pages 17-19 of CDC 93-8395)**. For work with organisms classified as BSL-2 or higher (pages 19-26), the IBC will conduct a site visit of the facilities to be used. To avoid delays with grant submissions, **application to the committee for approval must be made at least one month in advance of the grant deadline**. Failure to do so will jeopardize your ability to submit a complete grant application.

Experiments involving recombinant DNA are discussed in Section III of the Guidelines, as follows:

III-A. Experiments that require Institutional Biosafety Committee approval, review by the Recombinant DNA Advisory Committee (RAC) that advises the Secretary of HHS, and NIH Approval before initiation.

1) Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally;
2) Experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects.

III-B. Experiments that require NIH and Institutional Biosafety Committee approval before initiation.

1) Experiments involving the cloning of toxin molecules with LD_{50} of less than 100 nanograms per kilogram body weight.

III-C. Experiments that require Institutional Biosafety Committee approval before initiation.

1) Experiments using human or animal pathogens (Class 2, Class 3, Class 4, or Class 5 Agents (see Section V-A) as host-vector systems.
2) Experiments involving the use of infectious animal or plant DNA or RNA viruses or defective animal or plant DNA or RNA viruses in the presence of helper virus in tissue culture systems.
3) Experiments involving whole animals.
4) Experiments involving whole plants.
5) Experiments involving more than 10 liters of culture.

III-D. Experiments that require Institutional Biosafety Committee notice simultaneous with initiation.

1) Experiments involving the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus.
2) Experiments involving whole plants (not covered in III-C.4).

III-E. Exempt Experiments. The following recombinant DNA molecules are exempt from the NIH Guidelines and registration with the Institutional Biosafety Committee is not required:

1) Those that are not in organisms or viruses.
2) Those that consist entirely of DNA segments from a single non-chromosomal DNA source, though one or more of the segments may be a synthetic equivalent.
3) Those that consist entirely of DNA from an eukaryotic host including its indigenous plasmids or viruses when propagated only in that hose (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.
4) Those that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
5) Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically reviewed by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C-1-b (1)-©. See Appendices A-1 through A-VI for a list of natural exchangers that are exempt from the NIH Guidelines.
6) Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-©.) as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C for other classes of experiments that are exempt from the NIH Guidelines.

NOTE: Notwithstanding paragraph III-E, above, the Upstate IBC requires that all experiments involving recombinant DNA be reported to the committee for review.

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