

**SEATTLE CHILDREN'S RESEARCH INSTITUTE
OPERATING POLICIES / PROCEDURES**

DEPARTMENT:	Institutional Biosafety Committee
POLICY NUMBER:	IBC-014
REPLACES:	IBC-14 (6/7/06)
EFFECTIVE DATE:	10/15/08
REVISION DATE:	10/15/08
POSTED FROM:	Exempt per RIA-01-14.2.3

TITLE: Exempt Applications

SUMMARY:

Any rDNA application that meets the criteria for exemption from the *NIH Guidelines* will be reviewed by the IBC Chair. The IBC Chair shall inform the investigator that the work is exempt and BL-1 containment applies. The IBC Chair must inform the IBC at the next convened meeting of any exempted applications.

POLICY/PROCEDURE:

014-1 Upon receipt of a complete application for any of the following classes of experiments, the IBC Chair shall provide the IBC Chair a complete set of application materials:

- 014-1.1 Those that are not in organisms or viruses (*III-F-1*);
- 014-1.2 Those that consist entirely of DNA segments from a single non-chromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent (*III-F-2*);
- 014-1.3 Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means (*III-F-3*);
- 014-1.4 Those that consist entirely of DNA from a 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)(*III-F-4*);
- 014-1.5 Those that consist entirely of DNA segments from different species that exchanges DNA by known physiological processes, though one or more segments may be a synthetic equivalent. See Appendix A of the *NIH Guidelines* for a list of natural exchangers that are exempt (*III-F-5*), and/or;

- 014-1.6 Those that do not present a significant risk to health or the environment (*III-F-6*) as follows (may be updated as determined by the NIH Director):
- 014-1.6.1 rDNA molecules containing less than one-half of any eukaryotic viral genome (all viruses from a single family being considered identical) that are propagated and maintained in tissue culture, with the exceptions listed in Appendix C-I-A of the *NIH Guidelines*;
 - 014-1.6.2 *Escherichia coli* K-12 Host-Vector Systems with the exception of those experiments listed in Appendix C-II-A of the *NIH Guidelines*;
 - 014-1.6.3 *Saccharomyces* Host-Vector Systems with the exception of those experiments listed in Appendix C-III-A of the *NIH Guidelines*;
 - 014-1.6.4 *Bacillus subtilis* or *Bacillus licheniformis* Host-Vector Systems which does not revert to a spore former with a frequency greater than 10^{-7} may be used for cloning DNA with the exception of those experiments listed in Appendix C-IV-A of the *NIH Guidelines*;
 - 014-1.6.5 Extra-chromosomal elements of those gram positive organisms listed in Appendix C-V of the *NIH Guidelines* with the exception of those categories listed in Appendix C-V-A of the *NIH Guidelines*, and;
 - 014-1.6.6 The purchase or transfer of transgenic rodents for experiments that require BL-1 containment.

014-2 If the IBC Chair considers that the application meets the criteria for exemption, they shall prepare a letter to the investigator stating that the experiment is exempt from IBC review. A copy of this letter shall be forwarded to the President and the IBC file.

014-3 If the IBC Chair considers that the application fails to meet the criteria for exemption, they shall refer the application back to the IBC Chair for assignment to expedited or full review.

014-4 The IBC Chair shall inform the IBC, at the next convened meeting, of any exempted applications, a record of which shall be contained in the IBC Minutes.

Submitting Office: Institutional Biosafety Committee

Approved by:

\\s\ David Moore 10/15/2008
IBC Chair | Director, Research Technical Operations

\\s\ James B. Hendricks, PhD 10/15/2008
President, Seattle Children's Research Institute