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UPDATES TO BIOSAFETY PROTOCOL DOCUMENTS & REVIEW PROCESSES

➢ COMMITTEE STRUCTURE CHANGES

As of March 7th, 2013, the Institutional Health and Safety Committee (IHBC) were replaced by two new committees, each with their own scope:

- **The Institutional Biosafety Committee (IBC):** The IBC will review biosafety protocols that fall under sections III-E of the NIH Guidelines for Recombinant and Synthetic Nucleic Acid Molecules (*NIH Guidelines*).
- **The Research Health and Safety Committee (RHSC):** The RHSC will review biosafety protocols that do not fall under the previously mentioned sections of the *NIH Guidelines*, but involve high risk infectious agents and/or non-human primates. The RHSC will also discuss university laboratory issues.

➢ *NIH GUIDELINES* CHANGES

On March 4th, 2013, a major revision to the *NIH Guidelines* went into effect. A summary of the changes are listed below:

- **Change of Title:** Page 1. "NIH Guidelines for Research Involving Recombinant or **Synthetic Nucleic Acid Molecules"**
- **Change of Purpose**: Section I-A. The purpose of the NIH Guidelines was recently revised to include:
  - Recombinant nucleic acid molecules
  - **Synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules - NEW**
  - Cells, organisms, and viruses containing such molecules
- **Revised Definition:** Section I-B. The definition of recombinant and synthetic nucleic acid molecules is now defined as:
  i. "Molecules that (a) are constructed by joining nucleic acid molecules and (b) can replicate in a living cell (i.e., recombinant nucleic acids);
  ii. Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or
  iii. Molecules that result from the replication of those described in (i) or (ii) above."
- **Section II-A-3:** Added two new paragraphs regarding risk assessment and synergistic effects of combining transgenes.
- **Section III-A-1-a:** Added two new paragraphs regarding drug resistant genes.
- **Section III-B-2:** Added a new section to allow experiments that have been previously approved under Section III-A-1-a as Major Actions to not be re-reviewed NIH/OBA if the determination is made by NIH/OBA that the experiment is equivalent to the originally approved experiment.

- **Section III-C-1:** Revised the definition of human gene transfer experiments:
    - "…Human gene transfer is the deliberate transfer into human research participants of either:
        1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
        2. **Synthetic nucleic acid molecules or DNA, or RNA derived from synthetic nucleic acid molecules, that meet any of the following criteria:**
            - **(a) Contain more than 100 nucleotides; or**
            - **(b) Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or**
            - **(c) Have the potential to replicate in a cell; or**
            - **(d) Can be translated or transcribed."**
- **Section III-F: Exempt Experiments. Added/revised the following:**
    - Section III-F-1: ***(New)*** "Those synthetic nucleic acids that:
    - can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section."
    - Section III-F-2: ***(Revised)*** "Those that are not in organisms, cells or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes."
    - Section III-F-7: (***New)*** "Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA."
    - Renumbered Sections III-F-1 through III-F-8.
- **Section IV-A:** Added a paragraph to the Policy Section.
- **Appendix B-I:** All serotypes of Adenovirus-Associated Viruses are considered to be Risk Group 1 agents. Previously, only serotypes 1 – 4 were listed.

➢ REVIEW & NOTIFICATION PROCESS CHANGES

- Three-year renewals, new protocols, and annual updates are due on the **10th of the month** before their expiration date (ex: protocol expiring May 2nd, 2013 is due on April 10th).
- Principal Investigators and designated alternate contacts will be sent email notifications to remind them to submit three-year renewals and annual updates:
    - 90-Day Notice
    - 60-Day Notice
    - 30-Day Notice
    - 10-Day Notice & Termination Warning
    - Termination Notice (sent the day of protocol expiration)

DOCUMENT CHANGES

Due to the before-mentioned changes, various documents, forms, and trainings have been modified or created:

- **New Documents:**
  - IBC Standard Operating Procedures
  - IBC Charter
  - RHSC Standard Operating Procedures
  - RHSC Charter
  - IBC & RHSC 2013 Meeting Schedule
  - IBC & RHSC Review Process Flow Chart
  - rDNA Experiments Covered by the NIH Guidelines
- **Revised Documents:**
  - Biosafety Training
  - Biosafety Protocol Guidelines
  - Biosafety Notice of Intent Form
  - Biosafety Notice of Intent – Supplemental Table for rDNA
  - Biosafety Protocol Annual Update, Amendment & Termination Form
  - Biosafety Protocol – Recombinant & Synthetic Nucleic Acid Molecules Questions for Protocol Amendments & Annual Renewals
  - Biosafety Protocol – Reviewer's Form
- **Summary of Changes in the Revised Documents:**
  - Replaced Recombinant DNA with Recombinant & Synthetic Nucleic Acid Molecules (rDNA)
  - Updated content/questions to reflect changes in the NIH Guidelines
  - Updated content/questions to reflect changes in EHSO processes
  - Updated documents to include information on the two committees (IBC & RHSC)
  - Changed "Annual Renewal" to "Annual Update"