IBC FAQs

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Couldn't find your answer here?
Email the IBC Administrative Staff and we will be happy to help you.

1. **What is the Institutional Biosafety Committee?**

   The UCLA Institutional Biosafety Committee (IBC) was established as the local review body responsible for oversight of all research and teaching activities involving the use of biohazardous materials and recombinant/synthetic nucleic acids. The IBC is a faculty-led committee appointed by the UCLA Vice Chancellor for Research (VCR) and consists of experts in various fields, including biosafety, human gene transfer, infectious diseases, recombinant DNA, animal containment, plant containment, and occupational health. Additionally, there are two non-affiliated members who serve on the committee and represent the interests of the surrounding community. The IBC is responsible for reviewing and approving Biological Use Authorization (BUA) applications. The IBC also establishes, monitors, and enforces policies and procedures involving biohazardous materials and recombinant/synthetic nucleic acids to meet applicable federal, state, local and institutional regulations and guidelines.

2. **What does BUA stand for?**

   BUA stands for Biological Use Authorization. This is sometimes used interchangeably with the terms “IBC Protocol” and “IBC Application.”

3. **What are Recombinant and Synthetic Nucleic Acid Molecules?**

   Recombinant and Synthetic Nucleic Acid Molecules (referred to as r/sNA) are defined by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) as:

   i. molecules that a) are constructed by joining nucleic acid molecules and b) that 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.

You may also want to refer to this Fact Sheet for additional information on synthetic nucleic acid molecules.

4. What is OSP?

The NIH Office of Science Policy (OSP) advises the NIH Director on matters of significance to the agency, the research community, and the public, with an eye toward promoting progress in the biomedical research enterprise through the development of sound and comprehensive policies.

OSP's various offices and programs work on a wide range of issues including biosafety, biosecurity, genetic testing, genomic data sharing, human subjects protections, the organization and management of the NIH, and the outputs and value of NIH-funded research. This is accomplished through a wide range of analyses and reports, commentary on emerging policy proposals, and the development of policy proposals for consideration by NIH, the Federal government, and the public. By monitoring research and through consultation, coordination, and analysis, the office develops policies related to:

- The conduct of clinical trials using recombinant and synthetic nucleic acids,
- Biosafety for NIH supported research,
- Biosecurity, including oversight of dual use research, and
- Registration of new stem cells lines for NIH funded research.

5. What is RAC?

The Recombinant DNA Advisory Committee, or "RAC," is a federal advisory committee that provides recommendations to the NIH Director related to basic and clinical research involving recombinant or synthetic nucleic acid molecules. RAC proceedings and reports are posted to the OSP website to enhance their accessibility to the scientific and lay public.

All human gene transfer studies must be assessed locally to determine if review by RAC is warranted. Human gene transfer research often raises scientific, medical, ethical, and social considerations worthy of special attention and public discussion. Some of these issues arise from the fact that the techniques being used are relatively new and their risks and benefits are not well characterized. The RAC performs an in-depth examination of the issues associated with this technology in a setting where public input and comment is encouraged.

6. What research/teaching activities require Institutional Biosafety Committee (IBC) Approval?

The Institutional Biosafety Committee is charged under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) and UCLA Policy with oversight of all research and teaching activities involving:

- Recombinant/synthetic nucleic acid molecules (r/sNA), as covered by the *NIH Guidelines*
- Infectious agents that can cause disease in healthy humans and/or significant environmental or agricultural impacts, as covered by the BMBL
- Select agents and toxins, as covered by the CDC DSAT regulations
- Human and nonhuman primate materials, as covered by the Cal/OSHA Bloodborne Pathogens Standard
- Genetically-modified animals and whole plants, as covered by the *NIH Guidelines*

At its discretion, the IBC may also review protocols involving animals or animal specimens known to be reservoirs/vectors of zoonotic diseases.

7. Are there activities that do not require IBC review?

Yes. Section III-F and Appendix C of the *NIH Guidelines* detail experiments that are considered "exempt" and do not require IBC review. Among these "exempt" activities are:

1. Purchase or transfer of genetically-modified rodents that require ABSL-1 containment. Refer to #8 below for additional information.
2. Generation of ABSL-1 genetically-modified rodents via breeding, meeting certain exclusion criteria (see Appendix C-VIII of the *NIH Guidelines* for these criteria). You may also refer to #8 below for additional information.
3. Activities that involve only the *in vitro* use of nucleic acids (i.e., PCR, synthetic double stranded RNA) and do not involve the cloning and propagation of r/sNA in cells or organisms.
4. r/sNA derived entirely from extrachromosomal elements of certain bacterial organisms propagated and maintained in those bacterial organisms (refer to *NIH Guidelines* Appendix C-VI for a list of these organisms).
5. Experiments using the following host-vector systems in small (<10 liter) volumes (excluding those which may have hazardous or eukaryotic viral genome region segments):
    - *E. coli* K-12
    - *Saccharomyces cerevisiae* and *Saccharomyces uvarum*
    - *Kluyveromyces lactis*
    - *Bacillus subtilis* or *Bacillus licheniformis*

Refer to NIH Guidelines Exempt Experiments FAQ for additional information.

8. **Does my genetically modified animal need to be registered with the IBC or is it exempt?**

   Non-Rodents: All genetically modified non-rodent animals (both vertebrate and invertebrate) are subject to the *NIH Guidelines* and require IBC registration. This includes genetically-modified fish, flies, worms, etc.

   Rodents: Certain genetically-modified rodents are exempt from IBC registration. In general, if your response is NO to the following questions, your rodent strain is exempt from IBC registration:

   For Parental Rodent Strains:
   1. Was this strain(s) created at UCLA or contracted out by UCLA?
   2. Was this strain(s) created using a viral vector?
   3. Does the genetic modification confer expression of any microbial pathogen genomic region?
   4. Is the genetic modification hazardous in any way as to potentially require BSL-2 containment or higher (e.g., Does the genetic modification confer expression of a toxin)?

   If crossing two different genetically modified rodent strains:
   1. Do the parental lines or the resultant offspring require BL2 or higher containment?
   2. Were these animals created with non-replicative viral vectors such that more than one-half of the viral genome from a single family of viruses will be present in the parental strain or in the subsequent crosses of these strains?
   3. Were any of the parental transgenes under the control of a gammaretroviral LTR [e.g., MLV, MoSCV)]?

   If in doubt, please email ibc@research.ucla.edu to determine whether IBC registration is needed.

9. **I've determined that my work involving recombinant or synthetic nucleic acids is Exempt from the *NIH Guidelines* – do I still need to submit to the IBC?**

   You do not need to submit a BUA; however, you will need to contact the IBC administrative staff to confirm that your work is exempt from IBC review. Please submit a brief summary of the project and the materials to ibc@research.ucla.edu.

10. **What does the IBC look for when reviewing a research project? Does this include a scientific or ethical review?**

    When reviewing projects involving r/sNA and biohazardous materials, the IBC is evaluating whether the activities can be conducted in a manner that will ensure protection

of personnel, the general public, and the environment. The IBC is not responsible for the scientific or ethical review of the project, except in cases where the scientific design of the study contributes to public health or environmental risks and/or requires potentially unsafe or risky practices. In those cases, the IBC may require modifications that would reasonably mitigate the risk without impacting the research outcomes.

Specifically, the IBC considers the following items when reviewing a research project:

1. Does the PI have sufficient expertise to oversee the safe conduct of the research?
2. Is the proposed Biosafety Level appropriate for the work?
3. Does the proposed location(s) meet the requirements for the assigned Biosafety Level?
4. Will the work be conducted using appropriate biological safety practices and equipment?
5. Is there a potential for environmental release or public exposure? If so, how is this risk mitigated?
6. If any deviations from the Institutional Biosafety Plan are proposed, are there Standard Operating Procedures (SOPs) in place outlining these deviations?Are personnel properly trained, including general EH&S trainings and lab-specific training?
7. Is hazard communication provided to all personnel who are at reasonable risk of exposure to biohazardous or r/sNA materials?
8. Have occupational health considerations been addressed, including vaccinations and medical surveillance, when appropriate?

11. How do I submit a project for IBC review?

If you are eligible to be a PI on a Biological Use Authorization (BUA) (see FAQ 12), you may register with the IBC by completing an online BUA application through SafetyNet.

12. Who can be a Principal Investigator (PI) on a Biological Use Authorization (BUA)?

Principal Investigators must either meet the criteria for PI eligibility as defined in UCLA Policy 900 or identify a Faculty Sponsor who meets the PI eligibility criteria. Any exceptions to this requirement are also described in UCLA Policy 900, section III.C., Exceptions. Certain exceptions may be made on a case-by-case basis, with approval by the IBC Chair.

13. How long does it take for a BUA to be approved?

The review time varies based on the type of application. Certain applications may be eligible for review via Designated Member Review (DMR), while other applications may require Full Committee Review.

On average, new and renewal BUAs requiring Full Committee Review take about 4 weeks to be approved; however, based on when the application is submitted, the review time may be longer. Amendments to existing BUAs may be processed faster depending on the changes that are being made. Administrative amendments such as personnel and funding changes can typically be approved within 48 hours.

The Committee meets twice per month to review BUAs that require Full Committee Review. Please check the submission and review schedule for dates. Most BUAs are completed in one review cycle; however, if there is insufficient information available to conduct a risk assessment, a BUA may be deferred to the next meeting, which would delay the overall time from submission to approval.

14. What is Designated Member Review (DMR)?

Certain applications may be eligible for review outside of a convened meeting via a process called Designated Member Review (DMR). Examples of applications that are eligible for DMR include the use of primary human materials (e.g., blood, body fluids, tissues, etc.) and the generation of genetically modified rodents that can be contained at BSL1. IBC members are designated as reviewers based on the scope of the BUA. Once a BUA has been reviewed and approved via DMR, it will be "ratified" by the Full Committee at the next convened meeting.

15. What is the review process after the electronic submission of a BUA?

Figure 1. BUA Review Diagram

Figure 1 shows the process by which a BUA is reviewed and approved. When a BUA is submitted, the following events occur:

1. **SPECIALIST REVIEW:** The IBC Administrative Staff perform a pre-review of the application. At this point, the PI cannot edit the BUA.
2. **CLARIFICATION REQUESTED:** Once pre-review is complete, the PI and PI Proxy will receive an email indicating that action is needed on his/her part. The PI or PI Proxy will need to login to SafetyNet and provide a response to each of the pre-review comments, as well as update the BUA as requested. At this point, the BUA is editable. After all changes have been made, the BUA must be submitted by the PI (PI proxies may not submit).
3. **SPECIALIST REVIEW:** Once the PI responds and the pre-review comments have been satisfactorily addressed (this may take several iterations), the IBC Administrative Staff will either (a) assign the BUA to the agenda for the next

convened full IBC meeting, (b) assign the BUA to an IBC member if eligible for DMR, or (c) move the BUA directly to the REVIEW COMPLETE step below if eligible for Administrative Review. At this point, the PI cannot edit the BUA.

4. **COMMITTEE REVIEW:** At the fully convened meeting, the BUA will be discussed and the Committee can take the following actions:
    - **BUA Approved as written.**
    - **BUA Approved pending clarification.** The application is returned to the PI for revisions and the PI's responses will be reviewed by the IBC Administrative Staff and/or via Designated Member(s).
    - **BUA Tabled pending clarification.** The application is returned to the PI for revisions and the PI's responses will need to come back before the Full Committee for further review.
    - **BUA Disapproved.** The application is not approved in its current state and may not be re-submitted to the IBC.
5. **POST REVIEW:** Following the Full Committee Review, the PI and PI Proxy are notified of the IBC's decision and advised of any necessary clarification or revisions.
6. **MODIFICATIONS REQUIRED:** The PI or PI Proxy is instructed to login to SafetyNet to modify the application. At this point, the BUA is editable. After all changes have been made, the BUA must be submitted by the PI (PI proxies may not submit). The modifications will either be reviewed by SPECIALIST REVIEW (if Approved) or COMMITTEE REVIEW (if Tabled).
7. **REVIEW COMPLETE:** Once the requested modifications have been addressed, the final approval letter will only be issued after confirmation that all listed personnel have completed required trainings and all locations have been inspected by the EH&S Biosafety Division. At this point, the PI cannot edit the BUA. The BUA may only be edited with an amendment submission.

When a BUA is submitted to the IBC that is eligible for Designated Member Review (DMR, as defined in FAQ 14), SPECIALIST REVIEW and CLARIFICATION REQUESTED are followed by REVIEW COMPLETE.

16. How can I check on the status of a BUA submission?

Figure 1. BUA Review Diagram

In your SafetyNet Inbox, select the BUA application in question. Basic information regarding the application will appear along with a diagram, similar to the one in Fig. 1

above. The dark blue field represents the state. The arrows represent the possible next steps. Below is a definition of each step.

Pre-Submission = The BUA has not been submitted yet for review. You are still able to edit the BUA in this state.

Specialist Review = The BUA has been submitted for pre-review and is no longer editable. A Specialist (IBC Administrative Staff, Biosafety Officer, or other reviewers as applicable) is in the process of reviewing the application.

Clarification Requested = The BUA is editable in this state. The PI needs to address the comments and questions that are noted.

Committee Review = The BUA has been assigned to a Full Committee Review meeting and is no longer editable.

Post-Review = The Committee has reviewed the BUA and made a determination to a) Approve the BUA as written, b) Approve the BUA pending clarification, c) Table the BUA pending clarification, or d) Disapprove the BUA.

Modifications Required = The BUA is editable in this state. The PI needs to address the comments and questions that are noted.

Review Complete = The BUA is completed/approved and is no longer editable.

17. When do I need to amend an Approved BUA?

PIs must submit all changes to their BUA for review and approval by the IBC. The approved BUA must accurately reflect the materials, operations, locations, and personnel active in the lab at any time. Unless specified otherwise, the proposed changes must not be implemented until the PI receives a written approval notice from the IBC. The types of changes that require an amendment to the BUA are:

1. Change in Principal Investigator
2. Change in personnel
3. Change in hosts (microbial, in vitro or in vivo)
4. Change in procedures
5. Change in facility containment level or usage
6. Addition of new facilities
7. Addition of new materials (as described in the Scope section of the Plan)
8. Modification of previously approved materials (e.g., new inserts to be used with previously approved viral vectors, etc.)

18. How do I amend an Approved BUA?

In your SafetyNet inbox, go to the Submissions tab. Select the BUA that you would like to amend. In the "My Current Actions" column, click the "Create Amendment" button. For approved BUAs that have been migrated into SafetyNet, all fields in the smartform will need to be completed, not just those fields that are being updated. The system will not allow you to submit until all fields are complete.

Changes to materials, procedures, etc. that do not impact the overall risk assessment may be eligible for review outside of the full committee via Designated Member Review (DMR) (refer to FAQ 14). If there are major changes to the work that impact or potentially impact the risk assessment, the amendment may instead need to go through the Full Committee Review process. Administrative changes (e.g., funding, personnel) may be reviewed and approved by the IBC Administrative staff only.

19. How long is the BUA approval period?

Approval of BUAs involving the use of non-exempt r/sNA or biohazardous materials is valid for a period of three years, unless a shorter duration is requested by the IBC. In order to maintain continuity of approval, PIs must submit a renewal BUA for IBC review before the three year approval lapses. At least 90 days prior to the expiration date, you will receive an automated email reminding you of the upcoming expiration date. A link to SafetyNet will be provided in this email along with instructions on submitting a renewal BUA.

20. How do I submit a renewal application?

BUAs need to be renewed every three years, or sooner is a shorter approval period was given by the IBC. When it is time to submit a renewal application, you will receive an email notification from SafetyNet. Currently, the renewal function is not active in SafetyNet. Therefore, to submit a renewal application, you will need to make a copy of the BUA that is expiring to serve as the renewal application. You may do this by going to your SafetyNet inbox. In the Submissions tab under My Active BUAs, select the BUA that you would like to renew/copy. In the "My Current Actions" column, select "Copy Submission." You will be prompted to enter a name for the new submission. Depending on the size of the submission, copying it may take several minutes; therefore, the new submission may not appear in your inbox immediately.

If this is the first time you are using SafetyNet for this BUA, you will be working off of a "shell" that was migrated over from the old paper application system to SafetyNet. This "shell" will only have the basic information filled in; as a result, you will need to enter all information into the copied submission as if this is a new application rather than a renewal application. You may refer to the old paper form, which has been uploaded to the Supporting Documents page of the BUA, when transferring over this information.

21. Do I need to register my biological toxin? What do I need to do if I am working with a Select Toxin even at exempt quantities?

Only Select Toxins require IBC approval. This includes all quantities of Select Toxins, even quantities that are well below the CDC permissible amount. Non-select toxins, such as diphtheria toxin and pertussis toxin, do not require IBC approval; however, other clearances may be required. For additional information, please visit the EH&S webpage on Biological Toxins.

22. Is IBC approval required for the use of immortal/established human cell lines?

Yes. Research and teaching activities involving the use of human-derived materials (i.e., blood, blood components, tissues, cells, secretions) are subject to the Cal/OSHA Bloodborne Pathogens (BBP) Standard and require IBC approval. It is impossible to test human cells, including established cell lines, for all BBP/adventitious agents. Therefore, UCLA's policy is the following:

Human and nonhuman primate cells and tissue cultures (including immortalized/established cell lines) must be handled in accordance with the Cal/OSHA Bloodborne Pathogens (BBP) Standard and under BSL2 containment and practices for cell culture experiments and ABSL2 containment and practices when these materials are used in animal experiments. These experiments require IBC approval prior to initiation of work. Additionally, BBP training is required for all employees who can reasonably anticipate exposure to human-derived materials. This training is required both at the time of initial work assignment and annually thereafter. Information about BBP training can be obtained at: WorkSafe

Certain well-established human cell lines may be eligible for an exemption from the containment portion of this policy and may be downgraded to BSL1/ABSL1 if the following criteria are met:

- ATCC or similar vendor has designated the cell line as BSL1.
- The cells have been tested and deemed free of hepatitis viruses, HIV, Epstein-Barr virus, papovaviruses, and herpesviruses. The results to these tests must be provided to the IBC and testing must be performed every three years (coinciding with the 3-year IBC review).
- There is an extremely low possibility of the cells being exposed to other pathogens/biological materials that could result in contamination of the cell line (i.e., there may not be any other BSL2 or higher materials or cells handled in the facility).

All requests for an exemption to this policy must be reviewed and approved by the IBC prior to downgrading the cells to BSL1.

23. How do I complete the Research Summary section in SafetyNet?

When completing Question 1 in this section, please keep the following items in mind:

- Nonhuman primates include monkeys, prosimians and apes.
- Some human materials are exempt from IBC registration and do not need to be documented in the BUA. Examples include saliva, feces and urine if there is no visible blood and they are not known/suspected to be infectious.
- For a list of Select Agents and Toxins, please refer to http://www.selectagents.gov/SelectAgentsandToxinsList.html.
- Human gene transfer is defined as the deliberate transfer of recombinant or synthetic nucleic acids into humans.
- Zoonotic diseases are infectious diseases of animals that can naturally be transmitted to humans. Transmission occurs when an infected animal or an intermediate species (vector) comes into contact with humans. Examples of zoonotic animals include nonhuman primates (monkeys, prosimians and apes), bats, raccoons, wild-caught birds, etc. Examples of arthropods that are vectors of zoonotic diseases include mosquitoes and ticks.
- Check the box next to "Genetically Modified Animals" for all genetically modified mammals, rodents, insects, worms, and fish.

24. What should I do if I can't find the location I'm looking for in the list provided?

When searching for a location, you must either search for the building name (e.g., CHS) OR the room number (e.g., 22-222). Searching for a combination of building name and room number (e.g., CHS 22-222) will not produce any results. When searching for a room number, remember to use dashes when appropriate. For example, when looking for CHS 22-222, the room number needs to be entered as "22-222" rather than "22222".

Please also keep in mind that building names have been abbreviated in SafetyNet. Below is a list of these abbreviations. Searching for the full building name will not produce any results.

If after following these rules, you are still unable to find a location, please contact ibc@research.ucla.edu.

Abbreviated Building Names:

- CHS = Center for Health Sciences
- BSRB = Biomedical Sciences Research Building
- CNSI = California NanoSystems Institute
- DSERC = Doris Stein Eye Research Center
- DVRC = Doheny Eye Institute; Doheny Vision Research Center
- ENG = Engineering

- JSEI = Jules Stein Eye Institute
- LSB = Life Sciences Building
- MRL = MacDonald Research Laboratories
- MSB = Molecular Sciences Building
- REED = Reed Neurological Research Center (RNRC)
- REHAB = Westwood Outpatient Rehabilitation Clinic
- RRUMC = Ronald Reagan UCLA Medical Center
- TLSB = Terasaki Life Sciences Building

- The following locations are designated as CHS in SafetyNet:
  -
  - Brain Research Institute (BRI)
  - Neuropsychiatric Institute (NPI)
  - Marion Davies Children's Health Center (MDCC)
  - School of Public Health
  - School of Dentistry
  - Semel Institute for Neuroscience and Human Behavior
  - Vivarium

25. What should I do if I can't find the agent I'm looking for in the list provided?

Most agents are available in the pre-populated list. If you are unable to find an agent, try using a wildcard (%) before or after the word or portion of the word for which you are searching. For example, when searching for lentivirus, try typing %lenti or lenti% in the search field. Some abbreviations may not be recorded in the pre-populated list, so also try searching for the full term rather than the abbreviation.

If you are still unable to find an agent in the list provided, please email ibc@research.ucla.edu.

26. What should I do if I'm unable to find an individual in the SafetyNet personnel list?

If you are unable to find personnel in the list provided, please email ibc@research.ucla.edu with the individual's full name, email address, department, and 9-digit University Identification Number (UID). It typically takes 24 hours to add a new person to the personnel list.

27. How do I check if my personnel have completed the required trainings to be listed as an approved user of biohazardous materials?

Personnel may log onto WorkSafe to check their own training record. Each individual may also view and sign up for upcoming trainings in WorkSafe. Currently, there is not a function by which Lab Managers and Principal Investigators can view the training

records for all individuals in their lab. This functionality is being developed and should be available to the research community in the near future. Please contact the EH&S Training Team at EHST@ehs.ucla.edu to obtain a copy of training records.

28. How do I assign a PI Proxy in SafetyNet?

Only the PI can assign a PI proxy. A PI proxy has the ability to edit a BUA, but does not have the ability to submit. If you have multiple BUAs, you will need to assign a proxy for each individual BUA. You may assign multiple proxies for each BUA.

To assign a PI proxy, go to your SafetyNet inbox. In the Submissions tab, select the BUA for which you would like to assign a PI proxy. In the "My Current Actions" column, select "Assign PI Proxy" and select the individual(s) you would like to assign as proxy.

29. How do I allow others to view my BUAs in SafetyNet?

In SafetyNet, you can manage who is able to view your BUAs. This is referred to as your Guest List. Only the PI can manage the guest list. Those who are on the guest list will have read-only access to the BUA. If you have multiple BUAs, you will need to manage the guest list for each individual BUA.

To manage your guest list, go to your SafetyNet inbox. In the Submissions tab, select the BUA for which you would like to manage. In the "My Current Actions" column, select "Manage Guest List" and select the individuals you would like to have read-only access to your BUA.

30. How do I ensure all BUA correspondence are sent to my Lab Manager, Administrative Assistant, etc.?

In SafetyNet, you can manage who (in addition to the PI) will receive correspondence regarding the BUA by assigning a Primary Contact. Only the PI can assign a primary contact. The primary contact will have read-only access to the BUA, unless they are also assigned as a PI proxy. If you have multiple BUAs, you will need to assign a primary contact for each individual BUA. You may only assign one primary contact per BUA.

To assign a primary contact, go to your SafetyNet inbox. In the Submissions tab, select the BUA for which you would like to assign a primary contact. In the "My Current Actions" column, select "Assign Primary Contact" and select the individual you would like to serve as the primary contact for that BUA.

31. Do you have any SOPs for common procedures that I can use?

Common SOP templates are available here.

32. Where can I find additional information concerning the IBC and EH&S Biosafety?

IBC Administrative Office: ibc@research.ucla.edu or 310-794-0262 (x40262)
EH&S Biosafety: biosafety@ehs.ucla.edu or 310-206-3929 (x63929)
IBC website: http://ora.research.ucla.edu/RSAWA/IBC/Pages/index.aspx
EH&S Biosafety website: https://www.ehs.ucla.edu/research/bio

33. Where can I access the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*)?

Click to Link to the NIH Guidelines
Click for Link to FAQs and other guidance from the NIH Office of Science Technology (OSP)

34. Where can I access the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)?

Click to Link to the BMBL

35. Where can I find additional information concerning synthetic nucleic acids?

IBC Requirements for Synthetic Nucleic Acid Molecules
NIH Guidelines Synthetic Nucleic Acid FAQ

36. Where can I find additional guidance in determining the appropriate Risk Group for microbial agents?

1. American Biological Safety Association Risk Group Database: http://www.absa.org/riskgroups/index.html
2. CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL): http://www.cdc.gov/biosafety/publications/bmbl5/
3. Public Health of Canada MSDSs for biological agents: http://www.phac-aspc.gc.ca/msds-ftss/

37. How does the IBC assess whether a human gene transfer study needs to be reviewed by NIH RAC?

Effective April 27, 2016, NIH Recombinant DNA Advisory Committee (RAC) review of individual human gene transfer protocols is only required for cases in which the IBC or IRB determines that a protocol would significantly benefit from RAC review, and has been determined to meet one or more of the following criteria:

- The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk; or

- The protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value; or
- The proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies involved to evaluate the protocol rigorously.

Following the assessment by the UCLA IRB and IBC, a letter will be issued to the PI which indicates the outcome of these assessments. For multi-site studies, if another site has already conducted this assessment, the determination letter should be provided to the UCLA IBC. In these cases, UCLA's IRB and IBC do not need to perform another assessment.

When the PI registers the study with NIH, the written assessment letter from the IRB and IBC needs to be provided. Therefore, the IBC review will need to take place prior to registration with NIH. The PI will then need to submit documentation to the IBC that the study has been registered with NIH prior to the final IBC approval letter being issued.

If the IRB or IBC determines that RAC review is warranted, the RAC review must be conducted prior to the IBC re-reviewing the BUA so that this review can be taken into consideration when the IBC conducts their risk assessment.

Please refer to this fact sheet for additional information.

Couldn't find your answer here?
Email the IBC Administrative Staff and we will be happy to help you.