UNIVERSITY OF ARKANSAS

University of Arkansas – Fayetteville Institutional Biosafety Committee Procedures Manual

Office of Research Compliance
Institutional Biosafety Committee

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I. Introduction

The University of Arkansas (UA) Institutional Biosafety Committee (IBC) is a committee appointed by the provost. The IBC recommends policies providing oversight of research and/or teaching activities involving the use of recombinant and synthetic nucleic acid molecules (rDNA); microorganisms; biological toxins; bloodborne pathogens; human and nonhuman primate materials; and transgenic plants and animals that ensure compliance with the *NIH Guidelines* (https://provost.uark.edu/committees/ibc.php). This manual serves as a reference for the campus community and explains the function of the IBC related to how it operates, and it lays out instructions for helping with the safe and appropriate conduct of research on the University of Arkansas campus. Sections of the manual describe and explain the various aspects of the review process and regulatory requirements. Investigators and IBC members should familiarize themselves with the contents of this manual.

Successful biological research depends on effective collaboration among investigators, the campus biosafety officer (BSO), and the IBC working together to navigate the complexities of regulations and laboratory safety requirements.

II. Institutional Authority of the IBC

The University of Arkansas (UA) Institutional Biosafety Committee (IBC) is a university committee formed by the provost, who serves as the institutional official (IO), and falls under Research & Innovation within the Research and Development unit led by the Vice Provost for Research and Innovation. The IBC operates directly from the Office of Research Compliance, which is headed by the Director of Research Compliance.

III. Purpose of the IBC

Institutional Biosafety Committees were established under the *NIH Guidelines* specifically for the review of research involving recombinant or synthetic nucleic acid molecules (https://osp.od.nih.gov/biotechnology/institutional-biosafety-committees/). The UA IBC reviews and votes on the approval of protocols involving recombinant and synthetic nucleic acid molecules, , Risk Group (RG) 2 and Risk Group (RG) 3 microorganisms as defined in the *NIH Guidelines*, biological toxins, bloodborne pathogens, human and nonhuman primate materials, mammalian tumor cell lines, transgenic plants, and transgenic animals. In addition, the IBC advises the chancellor and the provost on issues relating to biological safety.

IV. Research and Activities Requiring IBC Review and Approval

The IBC reviews and approves biologically related activities that include research and teaching. The UA IBC defines potentially biohazardous materials to include all infectious organisms (bacteria, fungi, parasites, and viruses) which can cause disease in humans, animals, or plants, or cause environmental or agricultural impact. The IBC will also capture information on materials that may harbor infectious organisms, such as human or

primate tissues, fluids, cells, or cell cultures. All human and NHP materials are subject to IBC oversight; other mammalian cell cultures are subject to oversight under certain conditions described in Section V-A of *Policy on Institutional Biosafety Committee (IBC) Review and Approval*. Potentially biohazardous materials include (but are not limited to) all the categories below. Projects involving material(s) included in any of these categories must be submitted for IBC approval prior to initiating the project.

- Recombinant and synthetic nucleic acid molecules (rDNA)
- Genetically modified organisms including, but not limited to:
    - Animals, plants, invertebrates, and/or other organisms created by UA employees or in/on UA property
    - Transgenic field trials, any genetically modified organisms to be introduced into the environment, including planting of deregulated items in the field (by UA personnel and/or on UA property)
    - Field testing of plants engineered to produce pharmaceutical and industrial compounds
- Any organisms, or agents requiring federal permits (including but not limited to APHIS, CDC, EPA, and FDA)
- Pathogens/infectious agents (human, animal, plant, and other)
- Human and nonhuman primate cells, including all cell lines, tissue, blood and potentially infectious fluids
- Work with animals or vectors known or suspected to be reservoirs of Risk Group 2 or 3 infectious agents when such work increases potential exposure risks to personnel or other animals
- Oncogenic viruses used in conjunction with animals

V. Governing Principles of the IBC

The IBC operates based upon the following regulations/guidelines:

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*), April 2016 update.
- *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) (Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH)), 5th edition.
- Policy on Institutional Biosafety Committee (IBC) Review and Approval (UA Office of Research Compliance).
- University of Arkansas Biological Safety Manual (Office of Environmental Health & Safety).

VI. Duties and Responsibilities

A. Principal Investigators and Laboratory Supervisors

Principal Investigators (PIs) are primarily responsible for the people and activities in their laboratories. They are responsible for implementing an appropriate biological safety program specific to their projects.

Prior to the commencement of any project, the PI must submit a protocol to the IBC if approval is required. During the course of a project, if personnel changes, or if there are any modifications, the PI must notify the IBC coordinator to initiate the committee review process. After submitting a new protocol, the PI must attend the next scheduled IBC meeting to present the project and answer questions from the IBC. Also, after submitting a modification or renewal, the PI must be available to attend the next scheduled IBC meeting to answer questions, if requested by the IBC chair, BSO, or other IBC member.

PIs must notify the IBC if purchasing the following:

- Plasmid(s) not previously approved
- Transgenic materials

B. Laboratory Workers, Postdocs, Students, and Individuals

Whoever works in the laboratory in a technical (rather than purely administrative) capacity is defined as a laboratory worker, whether the person is a faculty member, student, intern, visiting scholar, or volunteer. These individuals are required to appear on a protocol(s) submitted by the responsible PI to the IBC before working a project that is subject to IBC approval. In the case of laboratory workers and students, protocols are to be submitted with the professor or mentor as the PI; laboratory workers and students will be listed in the personnel section of the protocol. In the case of postdocs, protocols are to be submitted with the professor or mentor as the PI; however, the postdoc can be listed as co-PI.

C. University Leaders (Deans, Chairs, and Directors)

The responsibility of these individuals is the following:

- Require that prior to initiation of research, each investigator using rDNA, Risk Group 2 or 3 microorganisms, or human blood and tissues with characterized agents at Risk Group 2 or 3, contact the Office of Research Compliance for information related to appropriately completing the necessary forms required for IBC review and approval.

D. The Institutional Biosafety Committee (IBC)

On behalf of UA, the IBC has the following functions:

- Review and vote on approval of all protocols involving: rDNA regardless of funding source; Risk Group 2 or 3 microorganisms as defined in the *NIH*

Guidelines; biological toxins; bloodborne pathogens; human and nonhuman primate materials; transgenic plants; and transgenic animals.

- Assess the containment levels required for proposed research involving any of the materials listed above.
- Assess the adequacy of facilities; Standard Operating Procedures (SOPs); and training of the Principal Investigator and other laboratory personnel to conduct the proposed work.
- At the request of UA researchers, the IBC may review; provide guidance on; and vote on approval of additional protocols not involving the materials listed above.
- Keep abreast of mandated guidelines and other sources of best practices to ensure continued institutional compliance.
- Serve as a resource for investigators conducting any research subject to review by the IBC.
- Make recommendations to the Office of Research Compliance and/or the Office of Environmental Health & Safety regarding biosafety concerns.
- Report to the provost and to the NIH Office of Science Policy any significant problems or incidents of noncompliance with the *NIH Guidelines* and any significant, research-related accidents or illnesses.
- Determine the necessity for health surveillance and prophylaxis for personnel conducting biological research projects.
- Review any proposed additions or changes to the *University of Arkansas Biological Safety Manual*.
- Periodically review departmental inventories of rDNA, cell culture lines, and biological agents and toxins.
- Respond to reports of significant violations or accidents and report any such occurrence involving rDNA to the NIH Office of Science Policy.
- Review and approve any protocol changes that are required for IBC approval.

The IBC can be reached at (479) 575-2671 or ibc@uark.edu.

E. The Biosafety Officer (BSO)

The BSO has the following functions:

- Provide consultation and technical guidance for the safe handling of biological agents and toxins, assisting in the development of safety and exposure plans and training programs.
- Provide advice regarding the disinfection of facilities and equipment and assist in the disposal of infectious waste.
- Periodically review and recommend updates of the *University of Arkansas Biological Safety Manual* to the IBC.
- Review needs and make recommendations regarding selection, purchase, and certification of biological safety cabinets (BSCs) and other related safety equipment.

- Maintain a record of agents used, their classification, location and the names of the principal investigators.
- Audit laboratories for compliance with the approved standards and policies of the University of Arkansas.
- Enforce the policies of the University of Arkansas to the extent necessary to ensure the safety of the campus community and area citizens.
- Review and provide recommendations on all protocols to the IBC for final consideration.

F. The Office of Environmental Health & Safety (EH&S)

EH&S has the following functions:

- Review (initial and at regular intervals) physical facilities and containment equipment for compliance.
- Coordinate with Facilities Management (FAMA) to correct, modify, and/or repair facilities when necessary.
- Review Standard Operating Procedures (SOPs) for compliance with proper biosafety practices.
- Provide general guidance about health and safety standards.
- Ensure that biohazard, sharps and glass wastes are properly transported outside of laboratory buildings and are treated and disposed of properly after removal from laboratories per applicable regulations.
- Maintain list of approved biosafety laboratories with review dates and results.
- Conduct bloodborne pathogens training, as well as other necessary biological laboratory training.

VII. Authority of the IBC

A. Scope defined

The UA IBC has the authority to approve, require modifications in, or disapprove all research that falls within its jurisdiction as specified by both the federal regulations and institutional policy.

B. Authority to approve, modify, or disapprove protocols based upon consideration of biological safety aspects

The UA IBC approves protocols for three years. After three years the protocol must be renewed if the investigator wishes to continue the project.

C. Authority to require progress reports from investigators and oversee the conduct of the study

Any approved research or protocol is subject to continuing UA IBC review. Each protocol will be resubmitted every three years if the project is to continue.

D. Authority to approve/disapprove modifications

All modifications to currently approved research protocols and other activities such as personnel changes or plasmid addition are required to have IBC review and approval prior to implementation. Modifications are submitted as highlighted text within the protocol. A minor addition such as adding students is handled by approving it in a returned e-mail and placing a copy of that e-mail in the physical and electronic files. Other minor additions like adding appointed personnel are sent to the chair and BSO only. All other modifications are sent out for full committee review.

The modification approval is only good until the end of the original approval period. For example, if a protocol's original approval is May 24, 2018, it will have an expiration date of May 23, 2021. Any modification approved during this period will last until May 23, 2021.

E. Authority to suspend or terminate approval of a protocol

The UA IBC has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IBC's requirements or that has been associated with unexpected serious consequences. Any suspension or termination of approval shall include a statement of the reason(s) for the IBC's action and shall be reported promptly to both the principal investigator (PI) and unit head. Information concerning noncompliance or perceived noncompliance with the *NIH Guidelines* or UA policies or procedures may be brought forward by any person and the IBC must recommend appropriate action.

VIII. Membership of the IBC

A. Number of members

According to the *NIH Guidelines*, an institution's IBC must be composed of no fewer than five members who collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology, the capability to assess the safety of research with recombinant or synthetic nucleic acid molecules, and the ability to identify any potential risk to public health or the environment. At least two of these individuals must not be affiliated with the institution except for their membership on the IBC (IV-B-2-a-(1)).

B. Represented areas

The UA IBC consists of a plant/plant pathogen/plant pest containment expert, animal containment expert, two community members, a graduate student, a physician from Pat Walker Health Center, a chair, a human gene transfer expert, as well as the following ex officio members: biosafety officer (BSO), director of research compliance, and CLAF manager.

C. Qualifications of members

The IBC has sufficient expertise among the members to be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, recognized guidelines, applicable laws, and standards of professional conduct and practice.

D. Diversity of members

The UA IBC is sufficiently qualified through the experience, expertise, and diversity of the members, to promote respect for its advice and capability to assess the safety of recombinant DNA research and teaching and to identify any potential risk to workers, public health, or the environment. The IBC consists of two members from the community, who are not affiliated with the University of Arkansas. They represent the interest of the surrounding community with respect to health and the protection of the environment. Per *NIH Guidelines*, membership consists of professors with expertise in plants, plant pathogens, plant pest containment principles, animals and animal containment principles.

IX. Management of the IBC

A. Chair

i. Selection and appointment

Committee members seek nominations of individuals currently serving on the IBC. If a current member accepts the nomination, then the name is forwarded to the provost for approval and appointment. For a chair not currently a member of the IBC, the provost selects and appoints the individual. The chair serves a three-year term and may be reappointed. The chair is also a voting member; however, if s/he has a protocol for review before the committee, s/he must recuse him/herself from the vote. If the chair is unavailable for a scheduled meeting, any member may be a substitute. If the chair is unavailable for a period exceeding three months, another member will be asked to serve in the role for the duration of the absence.

ii. Duties

The chair directs the IBC meetings in accordance with institutional and federal requirements. S/he works closely with the RSCP director, BSO, IBC coordinator, IBC members, and investigators to ensure that research and other activities involving regulated or potentially biohazardous materials are conducted safely and in accordance with all applicable federal, state, and institutional regulations, policies, and procedures. The chair is the designated signatory for the IBC and conducts all IBC meetings. The chair may delegate signatory duties to the BSO. The chair counts toward a quorum at meetings and also votes.

iii. Removal

The provost may remove or replace the IBC chair.

B. IBC members

i. Selection and appointment

Members are appointed by the provost. University of Arkansas faculty members appointed to the IBC will serve a three-year term and may be reappointed for an additional three-year term. Appointments to the committee typically begin with the beginning of the fiscal year (July 1) and end with the ending of the fiscal year three years later (June 30). Community and graduate student IBC members will be appointed for a one-year term and may be reappointed for additional one-year terms. There is no limit to the number of terms a member may serve on the University of Arkansas Institutional Biosafety Committee. A committee member rotating off the IBC is encouraged to submit a recommendation for his/her replacement.

ii. Duties

University of Arkansas IBC members are responsible for ensuring that all research and other activities utilizing regulated or potentially hazardous biological materials are reviewed and approved in a manner consistent with federal, state, and local laws, regulations, guidelines and institutional policies.

iii. Removal

The provost may remove or replace any IBC member(s).

X. Conflict of Interest Policy

A. Financial Conflict of Interest

By University of Arkansas policy, investigators or other personnel with decision-making roles must disclose to the university potential financial conflicts of interest. Following review and determination that an investigator's potential conflict of interest cannot be eliminated, a plan for reducing or managing the conflict will be implemented. When the conflict of interest involves work with biohazardous materials, the IBC will be consulted in development of the proposed plan to minimize the potential adverse consequences of the conflict. The IBC may impose conflict management strategies more but not less stringent than those recommended by the Office of Research Compliance.

B. Non-Financial Conflict of Interest

i. No selection of IBC members by investigators

The PI cannot seek to influence IBC members when reviewing his/her protocol. Additionally, any IBC member must recuse him/herself from a review if s/he has any real or apparent conflict of interest.

ii. Prohibition of participation in IBC deliberations and voting by investigators

Reviews of protocols will be conducted with objectivity and in a manner to ensure the exercise of independent judgment of each member. Members may not participate in a vote by the IBC on actions concerning projects or activities in which they have an active role or conflict of interest. Failure to abide by these provisions may be cause for removal of a member from the IBC. IBC members must not vote on a protocol if they are investigators on the protocol or have any other conflict of interest with any person or entity connected to a protocol. The IBC member must make any conflict of interest known to the IBC Chair. The member may provide information to the IBC if requested. The fact that a protocol is submitted by another investigator from an IBC member's department does not, in and of itself, constitute a conflict of interest.

XI. Functions of the IBC

A. Conducting initial and continuing reviews

The UA IBC is responsible for the review and approval of all projects (whether funded externally or internally) involving regulated or potentially biohazardous materials conducted under the auspices of the University of Arkansas regardless of funding source.

B. Reviewing and approving changes/modifications to research activities

All modifications to currently approved research are required to have IBC review and approval prior to implementation. Protocol forms with the highlighted modification(s) are submitted to the IBC coordinator who then distributes to the IBC for review and approval. The modification approval is only good until the end of the original approval period. For example, if the original protocol is approved on May 24, 2018, it will have an expiration date of May 23, 2021. Any modification(s) approved during this time will last only until May 23, 2021.

C. Ensuring that changes in approved research are not initiated without IBC review and approval [except where necessary to eliminate apparent immediate hazard(s)

There are situations where a serious or unexpected adverse event requires an immediate change to a protocol in order to relieve an apparent immediate hazard. In these situations, the PI may implement a change necessary to protect humans or the environment. Investigators are encouraged to contact the IBC if this type of situation arises prior to implementation of the protocol change.

XII. Operations of the IBC

A. Scheduling of meetings

The IBC meets monthly, unless there are no protocols to be reviewed. Monthly meetings take place during the second Thursday beginning at 2:15 p.m. in the conference room (107) of MLKG, unless otherwise specified. IBC meetings are open to the public (unless proprietary information is discussed, which will occur in an executive session) and meeting dates are published on the Office of Research Compliance website.

B. Pre-meeting distribution of IBC review materials to members

Seven calendar days prior to a meeting the IBC coordinator will send each committee member the items to be reviewed prior to the next scheduled monthly meeting. The items include the following:

1. Agenda
2. Previous month's minutes
3. Protocols (new and any modifications or renewals being reviewed by the full committee, with the PI present)
4. Additional meeting related documents

C. Review process

i. Description of the review process

The UA IBC is responsible for the review and approval of all projects involving potentially biohazardous materials conducted under the auspices of the University of Arkansas regardless of funding source (external or internal). The IBC will consider all information presented within the biosafety protocol forms. The IBC may request additional information and/or clarification from the researcher.

ii. Review

Pre-IBC Review: Upon receipt of a protocol, the IBC coordinator will check the protocol for completeness of non-technical information such as signature, date, and appropriate biosafety level (BSL). If additional information is required, the PI will be notified. Complete protocols will be scanned and held for committee review. One week prior to the scheduled IBC meeting, protocols will be sent to each member for review.

Committee Review: The PI of each protocol appearing on the agenda is asked to attend the meeting to present the project to the IBC. Committee members engage PIs by asking questions and making comments. At the conclusion of each protocol discussion, the IBC chair entertains a motion based on four possible outcomes: approve, conditional approval contingent upon information/clarification, revise and resubmit, and disapprove.

- **Approve:** Voting members present at the meeting vote by majority assent to approve as written or, again with majority assent, with specific conditions imposed by the IBC. The coordinator will e-mail a Protocol Approval Letter to the investigator.

- **Conditional Approval Contingent upon Information/Clarification:** The IBC determines that the information provided in the protocol is sufficient to allow evaluation, but the protocol requires additional information or clarification. The PI is notified at the meeting, as well as via e-mail, of minor changes or stipulations required. The PI must submit a revised protocol, with the suggested changes/information, to the compliance coordinator. Once the response is received from the PI, the chair and BSO will review if needed. If the information provided is complete and satisfactory, the protocol will be filed, and an approval letter will be sent to the PI. If the information provided is not complete and unsatisfactory, either the chair or the BSO can refer the protocol to the full committee for review at the next scheduled meeting. In any case, the project cannot be initiated prior to receipt of the protocol approval letter.

  The IBC will hold a protocol that falls within this category for six months for the PI to meet the requirements for approval. After six months the protocol may need to be resubmitted to the IBC. The final decision rests with the IBC chair.

- **Revise and Resubmit:** In this case, the committee concludes from initial reading that the protocol provided insufficient information to the committee to fully deliberate and make a final determination, or the protocol, as submitted, remains unclear in major areas. The committee is requesting a revision of the protocol in order to document compliance with regulations and policies. The PI is notified at the meeting, as well as via e-mail. The notice will be sent to the PI asking for revision and resubmission of the protocol. This notice will list the protocol deficiencies which must be addressed. Depending on the degree of revision required and the seriousness of the issues, the PI will be advised that the revised protocol will be reviewed at the next scheduled meeting. The revised protocol must be sent to the compliance coordinator. The coordinator will distribute the revised protocol to the entire committee.

- **Disapprove:** This outcome is usually the result of the PI submitting a protocol which contains information or procedures

which the IBC feels that it cannot approve. The PI will be informed of the IBC's decision during the meeting and a Protocol Disapproval Notice will be sent to the PI informing him/her of the outcome of the review, as well. The notice will contain the reasons for disapproval and suggestions that may result in approval if the PI wishes to submit a new protocol. If the PI wishes to revise the proposed project, a new protocol is required, and a new protocol number will be assigned.

Emergency Review: The IBC chair may agree to expedite the review of a particular protocol when extenuating circumstances warrant. To do so s/he will convene an *ad hoc* meeting of the IBC after the entire protocol is sent to all committee members.

D. Voting requirements

i. Quorum required

A quorum of five voting members is needed.

ii. Full voting rights of all reviewing members

All members, excluding the BSO, RSCP director, and CLAF manager, have one vote.

iii. No proxy votes

No proxy votes are allowed.

iv. Prohibition of conflict of interest voting

IBC members must not vote on a protocol if they are investigators on the protocol or have any other conflict of interest with any person or entity connected to a protocol.

v. Alternates

Each IBC member may have a designated alternate approved by the provost. Alternates attend meetings when members are on leave and not active on the IBC for at least one semester. During an alternate's tenure on the IBC, s/he reviews all protocols, participates in all discussions, and votes on all protocols.

E. Communication from the IBC

IBC actions that occur during the meetings are conveyed to the PI before s/he leaves and also in writing by the IBC coordinator within one to two working days. Communications include approval, conditional approval contingent upon information/clarification, revise and resubmit, or disapproval.

F. Appeal of IBC decisions

If an IBC protocol is disapproved, the reason(s) for disapproval will be conveyed to the PI in writing. The investigator may request the IBC to reconsider by responding in writing within 10 working days and may request an opportunity to appear before the IBC. The IBC's decision upon appeal is final.

XIII. IBC Record Requirements

A. IBC membership roster

Each year the Office of Research Compliance will submit to NIH-OSP (Office of Science Policy) a copy of the membership roster and curriculum vitae demonstrating the qualifications of each committee member.

B. Written procedures and guidelines

Written IBC procedures and guidelines are contained in the *UA Biosafety Manual* and in the *Policy on Institutional Biosafety Committee (IBC) Review and Approval*. For a copy of these documents, please visit the EH&S (https://enhs.uark.edu/) or RSCP (https://research.uark.edu/units/rscp/) websites.

C. Minutes of meetings

The IBC coordinator will take minutes at each meeting of the IBC. The minutes will contain:

1) Members present
2) Others present (researchers/guests)
3) Summary of discussions
4) Motions made and seconded
5) Record of voting

D. Retention of records

All protocols reviewed, and related materials will remain on file in the Office of Research Compliance for three years after the conclusion of the protocol. The IBC maintains a database of all proposed and active protocols. Files are paper and electronic. Meeting minutes remain on file as a record of the committee's activities. Policy guidance and forms will be disseminated from and stored at RSCP until replaced by new and/or revised documents.

E. Communication to and from the IBC

The biosafety protocol forms are available on the RSCP website (https://research.uark.edu/units/rscp/biological-safety.php). Any questions regarding IBC review or the content of this manual should be directed to the IBC coordinator at (479) 575-2671 or ibc@uark.edu. The IBC coordinator works closely with researchers, the IBC chair, BSO, and RSCP director regarding IBC decisions and requests for additional information.

To reach the IBC regarding biosafety matters, visit the RSCP website (https://research.uark.edu/units/rscp/) and select the appropriate staff member, either the director or the IBC coordinator, who will provide assistance. If the communications include comments on IBC actions, those comments (and IBC response) will be forwarded to NIH Office of Science Policy as specified in Section IV-B-2-a-(7) of the *NIH Guidelines*.

F. Public access to IBC meeting minutes

The public may request copies of meeting minutes by e-mailing or writing to the director of research compliance or the IBC coordinator. A copy of the minutes will be provided within five working days. If the records request cannot be fulfilled within that time period, a reply to the request will be sent within five working days to explain the situation and provide a target day for compliance with the request. The Freedom of Information Act Exemptions 4 (5 U.S.C. § 552(b)(4)) and 6 (5 U.S.C. § 552(b)(6)) will apply, and minutes may be redacted as permitted in the exceptions. Redacted items include but are not limited to personnel records, details of bona fide or applied research, and proprietary information.

XIV. Investigator Information Provided to the IBC

A. Form 1: General Information

A PI applying for IBC approval for research or teaching activities needs to submit a completed Form 1: General Information. The form can be found by visiting https://research.uark.edu/units/rscp/biological-safety.php.

B. Biosafety Protocol Forms for rDNA, infectious agents, animal studies, toxins, and notification to Pat Walker Health Center, as needed

In addition to the Form 1: General Information, and depending upon the nature of the work, the PI will complete forms requesting information related to recombinant DNA (rDNA), Risk Group 2 or 3 infectious organisms, studies with toxins, human or nonhuman primate materials, animals, transgenic plants, mammalian tumor cell lines, or notifying Pat Walker Health Center of potential exposure of laboratory personnel to Risk Group 2 or 3 infectious organisms.

C. Requests for modifications in activities and/or personnel after initial approval

All major modifications to currently approved protocols are required to have IBC review and approval prior to implementation. Minor changes that do not increase the risk to workers, the community, and/or the environment may be processed as an administrative approval. A minor addition such as adding students can be handled by approving it in a returned e-mail and placing that e-mail in the physical and electronic files. The minor addition of adding appointed personnel is

sent to the chair and BSO only. Adding a plasmid(s) to a previously approved protocol is sent to the full IBC for a three-day review period and then forwarded to the chair and BSO for a two-day review and approval period. When plasmid approval is granted, the RSCP director is notified so the MTA (Material Transfer Agreement) can be signed. All other modifications go out to the full committee for a full week review process and after the week, the modifications are forwarded to the chair and BSO for final approval. The chair and BSO send approval via e-mail. For all approved protocol modifications, the protocols are scanned, saved, and hard and electronic copies are filed.

D. Notification of protocol expiration

Two months prior to the expiration of an approved protocol, the PI will receive an e-mail notifying him/her of the upcoming expiration of the protocol. Investigators desiring to continue their research are responsible for completing new biosafety protocol forms and returning them to the IBC coordinator in time for review before the expiration date. The investigators are responsible to keep biosafety protocol forms current regardless of whether they receive an expiration notice or not. If the PI does not respond by the expiration date, a termination letter will be sent. At this time all work on the project must be discontinued.

E. Reports of unexpected adverse events

All unanticipated/adverse events should be reported to the IBC in writing as well as any actions taken on the part of the researcher as a response to the adverse event. *NIH Guidelines* require that the PI report any significant events to the IBC and NIH-OSP (Office of Science Policy) within 30 days. For urgent situations, the BSO should be notified as soon as possible for further instructions.

F. Student research

Research conducted by students and that involve biological materials, whether dissertation, thesis, or other research projects, should be supervised by a faculty advisor and submitted to the IBC for review. IBC review and final approval should take place during the proposal stage of the dissertation, thesis, or research project. The IBC cannot approve a project ex post facto.

XV. IBC Information Provided to the Investigator

A. Monthly meeting reminder

One week prior to the next scheduled IBC meeting, each PI with a protocol to be reviewed during the meeting will receive an e-mail reminder that contains the following information:

- Meeting day/date
- Meeting time
- Meeting location

- Meeting agenda

B. Notice of protocol expiration

Two months prior to the date a protocol is to expire a letter stating so will be sent to the PI via e-mail. The PI has two options- renew the protocol or terminate the protocol.

C. Appropriate notification letters

i. New protocol

No more than five days following the IBC approval of a new protocol, a new protocol approval letter constructed on official University of Arkansas Office of Research Compliance letterhead will be sent to the PI. The letter includes the current date, the investigator's name, the IBC chair's name, the protocol number and title, and the protocol start and expiration dates.

ii. Modification

After the appropriate committee review process, a modification approval letter constructed on official University of Arkansas Office of Research Compliance letterhead will be sent to the PI. The letter includes the current date, the investigator's name, the IBC chair's name, the protocol number and title, date of modification request, and the protocol start and expiration dates.

iii. Renewal

After the appropriate committee review process, a renewal approval letter constructed on official University of Arkansas Office of Research Compliance letterhead will be sent to the PI. The letter includes the current date, the investigator's name, the IBC chair's name, the protocol number and title, date of renewal request, and the protocol start and expiration dates.

iv. Termination

An investigator receives a termination letter in two instances. One, after a renewal notice is sent by the IBC coordinator and the investigator responds that s/he wishes to terminate the protocol. Two, if an investigator does not renew his/her protocol within the two-month renewal period, a termination letter is sent following the protocol's expiration date. A termination letter constructed on official University of Arkansas Office of Research Compliance letterhead will be sent to the PI. The letter includes the current date, the investigator's name, the IBC coordinator's name, the protocol number and title, and the process for registering the protocol if it expires and the PI wishes to continue the project.

XVI. Sources

https://arkansasag.gov/resources/foia/

https://enhs.uark.edu/_resources/documents/biosafety-manual.pdf (*University of Arkansas Biological Safety Manual*)

https://osp.od.nih.gov/

https://osp.od.nih.gov/biotechnology/nih-guidelines/

https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf

https://provost.uark.edu/committees/ibc.php

https://vcfa.uark.edu/policies/fayetteville/rscp/ (*Policy on Institutional Biosafety Committee (IBC) Review and Approval*, April 2018)

https://c.ymcdn.com/sites/www.arkansaspress.org/resource/resmgr/files/FOIHandbook_18thEd.pdf (*The Arkansas Freedom of Information Handbook*)

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