



Institutional Biosafety Committee

Policies and Procedures

September 2011

CONTENTS

IEM8 (BER)G6 13 (W.D.H.C.3) 4.40637E12 01120

1. INTRODUCTION 2.1

- 1.1 UNLV Institutional Biosafety Committee Roles and Responsibilities 2.7
- 1.2 The Foundation for IBC Review: The NIH Guidelines

2. OVERSIGHT OF BIOLOGICAL RESEARCH AT UNLV

- 2.1 Jurisdiction of UNLV IBC
- 2.2 Reporting Relationships
- 2.3 Scope of Authority of UNLV IBC
- 2.4 IBC Approval or Disapproval or Revision Decisions
- 2.5 Notification to RAC, NIH/OBA or Other Agencies of Approvals, Suspensions or Terminations, and Serious or Continuing Non-compliance
- 2.6 Serving as the IBC for an Unaffiliated Entity
- 2.7 Cooperative Research
- 2.8 Research Conducted on UNLV Campus by Other Universities without UNLV Faculty as Co-Investigator

6. CRITERIA FOR UNLV IBC REVIEW AND APPROVAL OF RESEARCH

6.1 General UNLV IBC Review

6.2 Additional Requirements for Select Agent Studies

6.3 Additional Requirements for Biosafety Level 3 Studies

6.4 Additional Requirements for Studies involving Vertebrate Animals

6.5 Additional Requirements for Studies involving Humans

6.4 Gen41diq (i)co6 (ew)4 (or)d4 -0c 0 Tw 3.39 0 Td(())TjEMC /LBody 4MCID 20 B

1. INTRODUCTION

The University of Nevada, Las Vegas (UNLV) is committed to protection of our faculty, staff, students and community through careful analysis of all biological research occurring at or affiliated with UNLV. The University recognizes and accepts responsibility, which it shares with its investigators and other researchers for determining that research involving biological materials meets or exceeds all federal, state, and local regulations.

These policies and procedures are intended to serve as a guide for registration for investigators and their staff who conduct research involving potentially hazardous biological materials. While these policies and procedures provide a general overview of the biological review process and the main regulatory requirements designed for human and environmental protection, the field of biosafety and biosecurity is continually evolving. Investigators should refer to the UNLV Institutional Biosafety Program for more in-depth information about biosafety. They should also ensure that they and their staff understand the information contained herein and follow any mandatory requirements, obtain additional information on any regulatory requirements or expectations relevant to their specific research, and contact the Institutional Biosafety Committee (IBC) with any questions they may have. As UNLV policy evolves, and rules change, the information will be updated. Please make sure you have the latest information by checking the IBC Website: <http://www.unlv.edu/Research/IBC/>.

1.1 UNLV Institutional Biosafety Committee Roles and Responsibilities

Under *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* UNLV must establish an IBC that meets certain requirements and follows specific criteria for reviewing and approving Recombinant DNA Research. The IBC is required to

- conduct an independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research;
- assess the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research;
- ensure that all aspects of [Appendix M](#) of the *NIH Guidelines* have been appropriately addressed by the Principal Investigator;
- ensure that no research participant is enrolled in a human gene transfer experiment until the RAC review process has been completed,

to the IBC, explaining why he or she believes the project should be approved or continued. However, a final IBC decision to require modifications in, disapprove, suspend or terminate a project is incontrovertible. No other committee or official (University or Federal) can override these IBC decisions. Further, no committee or person can approve an investigator to conduct any research that the IBC has not approved.

2.5 Notification to RAC, NIH/OBA or Other Agencies of Approvals, Suspensions or Terminations, and Serious or Continuing Non-compliance

The IBC is required under the NIH Guidelines to ensure that the Principal Investigator submit certain protocols to the RAC for approval. It also must certify certain approvals and notify NIH/OBA regarding certain actions and activities. The IBC acts on behalf of the institution to certify the compliance of the project with the UNLV IBC Policies and Procedures to the relevant federal regulatory agencies and sponsors of the research, as applicable, and will provide such certifications to the principal investigators for forwarding to the applicable agency.

In the case of a suspension or termination, the IBC will consult with the Vice President for Research and Graduate Studies. The IBC will notify the funding agencies of the decision of the IBC.

Should the IBC receive a report of noncompliance with IBC policies or procedures or federal guidelines or regulations, the IBC will inform the Vice President for Research and Graduate Studies. If it appears that a project has been initiated without required IBC approval, or that other serious violations may have occurred, the IBC will require the investigator to suspend all activity at once. The IBC then implements procedures for investigating, remedying, and reporting noncompliance.

2.6 Serving as the IBC for an Unaffiliated Entity

Generally, the IBC reviews only research conducted at or involving UNLV employees, sponsorship, or information. However, on occasion, such as where another entity that does not have an IBC is the recipient of a grant under which UNLV faculty will be conducting the research (under a subcontract/award), the UNLV IBC may agree that it can serve as the IBC for the grantee. Where the UNLV IBC agrees to this arrangement, a memorandum of understanding (MOU) will be drafted and then signed by UNLV Vice President for Research and Graduate Studies and the IBC Chair to permit the UNLV IBC to act as the review committee.

2.7 Cooperative Research

Cooperative research projects are those which involve more than one institution. In the conduct of such projects, each institution is responsible for biosafety

appropriate.

The Vice President for Research and Graduate Studies will appoint members to the UNLV IBC so that it will be sufficiently qualified through the experience and expertise of its members to review all biohazardous research at UNLV.

3.1.2 Terms

In general, UNLV IBC members are appointed for three-year terms. If a member is chosen to become the Chair, his or her term is extended as necessary. At the discretion of the Vice President for Research and Graduate Studies, memberships may be renewed.

3.1.3 Appointments

The Associate Vice President for Research is responsible for ensuring the appropriate composition of the UNLV IBC. To determine what expertise is needed, and who might be recommended to be appointed, he/she solicits recommendations for appointments from UNLV IBC members as well as the Chairs and Deans within UNLV schools and colleges. In addition, as he/she deems appropriate, the Associate Vice President for Research may solicit self-nominations from the faculty and full-time staff.

The Vice President for Research and Graduate Studies is the appointing authority for all IBC membership positions. Where a new community member is sought, the Vice President for Research and Graduate Studies will receive recommendations from the Associate Vice President for Research, knowledgeable UNLV faculty or may choose an alternative method of securing nominations. Solicitations for new members will highlight the desired qualifications based on gaps in the expertise of the UNLV IBC noted by IBC members or the Associate Vice President for Research. The Vice President for Research and Graduate Studies can appoint new members at his or her discretion.

3.2 Non-Voting Members

Members of UNLV staff or faculty may serve as non-voting members of the UNLV IBC should it be decided that such persons would be of assistance to the UNLV IBC in conducting their duties. A non-voting member cannot be counted in the quorum and cannot vote, but can participate in discussions and deliberations. The Vice President of Research and Graduate Studies may appoint a non-voting member who will serve for only as long as requested.

3.3 Consultants

The UNLV IBC may invite consultants to participate in discussions and deliberations on particular projects where they believe that additional expertise

would assist in reviewing a particular protocol. The UNLV IBC Chair has the

4.1 Committee Meetings/Deadlines

IBC meetings are generally held during each quarter and as needed when research protocols require a vote. Protocols must be received two (2) weeks prior to the scheduled meeting of the full committee.

4.2 IBC Meeting Agenda

The Associate Vice President for Research prepares an agenda for each IBC meeting, listing all protocols that will be reviewed at the upcoming meeting (new and continuing), any adverse event reports to be reviewed by the committee, the projects that have been approved because they are exempt from the guidelines, and any other items for discussion.

4.3 IBC Meeting Procedures

Approvals of all protocols (all projects other than exempt) will be conducted only at convened meetings at which a majority of the members of the IBC are present. Any IBC member who is involved in any way in a research project being reviewed, or who has any other potential for conflict of interest, may not participate in the discussions or deliberations (other than to provide information as requested), nor vote on it. The IBC policy is to have such member leave the room during deliberations. When the Chair has a potential conflict of interest, he/she will designate someone to temporarily chair the meeting.

4.4 Actions that the IBC May Take at Meetings

UNLV IBC members will discuss each project and vote to approve or disapprove the project or proposed modification to an already approved project, or to defer a

decision until revisions are implemented, additional information is provided, or further expert review is obtained (including invitation of consultants). Under certain circumstances, if minor revisions in the submitted documents are required or a missing document of minor importance is to be obtained, the IBC may delegate the chair to subsequently issue an approval of the project on behalf of the IBC, upon completion of these tasks.

4.5 IBC Meeting Minutes

The office of the Associate Vice President for Research will prepare the IBC minutes of each meeting. The minutes will include the following information: 1) attendance; 2) actions taken by the IBC; 3) the number of members voting for, against, and abstaining in the decisions; 4) the basis for requiring changes in a project, or disapproving, suspending or terminating a project and 5) summary of the discussion of issues of concern and their resolution.

4.6 IBC Notification of Meeting Decisions

After each UNLV IBC meeting, the chair will notify the principal investigator in writing of the outcome of the review. The investigator will be informed, in writing, of whether the project was approved, whether it requires revisions before approval may be granted, whether additional information is needed from the investigator before approval can be voted upon, or whether it was disapproved (in sufficient detail for the investigator to understand). The investigator will also be informed at the time of approval, in writing, when an application for extension is due.

4.7 Time Sensitive Protocols

Normally, protocols must be received at least two weeks prior to the committee meeting at which they will be reviewed. This allows assigned reviewers enough time to conduct a thorough review prior to the scheduled meeting of the full committee.

On certain occasions, however, some protocols require a rapid response due to extenuating circumstance that fall beyond the control of the Principal Investigator.

5. LEVELS OF IBC REVIEW: EXEMPT, FULL COMMITTEE REVIEW

Not all research requires review and approval by the IBC. Some research is "exempt" under federal regulations, but may still be reviewed according to UNLV policy. This

6. CRITERIA FOR UNLV IBC REVIEW AND APPROVAL OF RESEARCH

6.1 General UNLV IBC Review

The *NIH Guidelines* detail the following specific items that must be reviewed for recombinant DNA research. These items must be reviewed on any submitted protocol including those for infectious agents, biological toxins and human materials:

- An independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research;
- An assessment the facilities, procedures, practices, and training and expertise of personnel involved in the research;

In addition, the reviewer should assure that the protocol meets requirements specified in the *UNLV Institutional Biosafety Program*

the protocol. The supervisor of laboratory animal care will report any animal care concerns at the IBC meeting during review of the protocol.

7.2 Required Reporting of Adverse Events and Problems

A “serious adverse event” is any event occurring at any dose that results in any of the following outcomes: death, a life-threatening event, in-patient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization also may be considered a serious adverse event when, upon the basis of appropriate medical judgment, they may jeopardize the human gene transfer research subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

An adverse event is “associated with the use of a gene transfer product” when

training and safety measures may be required.

7.3 Additional Measures to Monitor Active Research Projects

In its discretion, and depending upon the perceived risk of the research, an IBC may require more active monitoring of a research project. The IBC can make this determination during their initial review of the research project.

To remain active, all non-exempt protocols must be reviewed no less than every three years. The IBC may require more frequent reviews if it considers that more oversight is necessary due to the nature of the study or degree of risk. The investigator will be informed in the original approval notice when the next review must be obtained, and may be reminded prior to expiration of the approval period (at least one month ahead of time). However, it is the explicit responsibility of the

investigator to ensure that his/her project is approved fctove2o 7 (e)4 (a()-1)-2 (s)(e)4 ()(e)4 ()(e)4 () bc 0.0(e)4 (w)4 ()(e)4c- 2 (f)5pp9e2vies-2 10 (ht(y)20 (b)-10 (e)4 (be))f ub2 (r)3 (a)4 ve2ee1 1 pn-

the public all IBC meeting minutes and any documents submitted or received from funding agencies which the latter are required to make available to the public.

8.3 IBC Member Records

Curricula vitae of active members of the IBC will be maintained in the files of the office of the Associate Vice President for Research, and will be updated in content as necessary. Each member's membership term status will be monitored and updated, as necessary.

9. EVIDENCE OF TRAINING

All Investigators are required to complete the Laboratory Specific SOPs included in the UNLV Biosafety Program prior to initiation of research for their respective