UNLV

Institutional Biosafety Committee

Policies and Procedures

September 2011

CONTENTS

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 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, Institutional Biosafety Committee approval (from the clinical trial site) has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained;
- for human gene transfer protocols selected for public RAC review and discussion, consideration of the issues raised and recommendations made as a result of this review and consideration of the Principal Investigator's response to the RAC recommendations; ensure that final IBC approval is

granted only after the RAC review process has been completed;
- ensure compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*; and
- Notify the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval.

The UNLV IBC also has the role of review and approval of all

- Human infectious agent research;
- Research involving human blood, cells, tissues and other potentially infectious human materials (OPIM);
- Research involving biological toxins; and
- Research involving select agents;
- Research involving exempt strains of select agents.

These activities cannot be carried out without prior IBC review and written approval.

1.2 The Foundation for IBC Review: *The NIH Guidelines*

The *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* were developed to assure proper oversight of recombinant DNA research at institutions receiving funding from NIH for recombinant DNA research. Since 1976 these guidelines have been updated and published in the federal register. The latest version of the guidelines is available through NIH on their website. Compliance with these guidelines is required for any institution that wants to retain NIH funding.

2. OVERSIGHT OF BIOLOGICAL RESEARCH AT UNLV

2.1 Jurisdiction of the UNLV IBC

The IBC is responsible for reviewing all biological research falling within the following categories:

- Research sponsored by UNLV both funded and unfunded;
- Research conducted by or under the direction of any employee or agent of UNLV in connection with his or her responsibilities, even if conducted elsewhere;
- Research conducted by or under the direction of any employee or agent of UNLV using any property or facility of UNLV,

These categories cover <u>all</u> research in which UNLV and its faculty, staff, and students may be involved.

The IBC must review research under the direction of any employee or agent of UNLV even if it will be conducted at another institution. In such situations, the

investigator and home institution remain legally responsible for the conduct of research at the other institution. Where another IBC also has jurisdiction over the research, the investigator should inform the UNLV IBC. The general policy of the UNLV IBC is to require submission of the project to the home IBC for review first, with submission to the other institution's IBC to follow. Final IBC approval at the home institution of the project as amended by the other IBC is required.

2.2 Reporting Relationships

The Vice President for Research and Graduate Studies is ultimately responsible for the oversight of biological research activities. The Institutional Biosafety Committee is responsible for overseeing the effective operation, policies, and compliance of the conduct of biological research at UNLV. No person or other committee--whether internal or external--can overturn an IBC decision to disapprove, terminate, or suspend a research protocol.

2.3 Scope of Authority of UNLV IBC

The UNLV Institutional Biosafety Committee has the following authority and responsibility over research at UNLV:

1. Review all research projects that will involve potentially hazardous biological materials prior to commencement of research;
2. Approve, disapprove, or require changes in all such research;
3. Notify federal government agencies and sponsors of approvals and disapprovals, or forward such notifications to investigators for submission as applicable;
4. Ensure prompt reporting by investigators to the RAC as well as any sponsoring agency of unanticipated problems involving risk to humans or environmental releases;
5. Ensure prompt reporting to the IBC by investigators of noncompliance with the IBC or federal policies or regulations, and report serious or continuing noncompliance to appropriate federal agencies;
6. Suspend or terminate a previously approved project and notify applicable agencies; and
7. Conduct continuing reviews of ongoing research as well as any other monitoring such research may require;

2.4 IBC Approval, Disapproval or Revision Decision

The IBC Chairperson notifies investigators by written document of approval, revisions, and disapprovals (or terminations), with enough detail to explain the decision to the investigator.

Should the IBC disapprove or terminate a research project, the principal investigator may request to present more information either in person or in writing

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

review. Cooperative research being conducted by UNLV faculty/student at another university or facility will include UNLV IBC as the approval authority for such research. In such cases, UNLV IBC will review documents presented by the other university or facility and may seek consultation with its legal representative.

2.8 Research Conducted on UNLV Campus by Other Universities without UNLV Faculty as Co-Investigator

All research conducted by other universities without a UNLV faculty member as co-investigator will be required to have a memorandum of understanding (MOU) with appropriate signatures on file with the IBC. No research may begin until all approvals have been obtained. The protocol package must be submitted with approval from the requesting organization's IBC.

3. IBC MEMBERSHIP

The UNLV IBC is comprised of regular voting members and non-voting members. The IBC may utilize, as they deem necessary, non-voting members and consultant reviewers.

3.1 Regular Voting Members

3.1.1 Composition

The IBC shall have at least six regular voting members, including the Chair. The Chair may also serve as the animal or plant expert. At a minimum, the membership of the IBC shall include:

- A Biosafety Officer (Biological Safety Officer) with expertise in biohazard practices, procedures and containment;
- A Microbiologist, with knowledge of infectious disease research practices;
- An Animal Expert with knowledge of and experience with recombinant DNA research involving animals and containment protocols for animals;
- A Plant Expert with knowledge of and experience with recombinant DNA research involving plants and containment protocols for plants, plant pathogens and plant pests;
- Two (2) Community Members unaffiliated with UNLV.

The Chair shall select an alternate for an absent member and assure, in so far as possible, that the diversity of the membership in attendance reflects the overall IBC membership.

If human gene therapy protocol(s) are submitted, the committee must obtain expertise in this area either through membership or consultation.
The UNLV IBC generally will have more than the minimum number of members to ensure adequate and efficient reviews, as the Vice President for Research and Graduate Studies deems

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 authority to invite such persons to participate. However, a consultant cannot be counted in a quorum, and cannot vote.

3.4 IBC Chair

The IBC will have a Chair chosen from the membership of the IBC, who is knowledgeable in biosafety, including the regulations, University and agency policies, and ethics relevant to such research. The Chair generally will serve for three-years. The Vice President for Research and Graduate Studies may in his/her discretion extend the term.

The Chair is responsible for conducting all meetings of the UNLV IBC. The chair is also responsible for reviews, delegating reviewers for protocols and initial reviews of adverse event reports. The Chair is responsible for ensuring that the IBC members are adequately informed about the requirements of the regulations for protocol review so that they conduct appropriate reviews.

The Chair will designate an appointee to serve in his/her absence. Whenever the Chair is not available, the designated appointee will assume the responsibilities of the Chair during the period of his or her absence.

3.6 Duties of IBC Members

Serving as an IBC member is considered to be an important role of faculty as well as an honor. It is recognized and appreciated that members serve in addition to their regular teaching, research and other service. Therefore, it is understood that on occasion a member may need to miss a scheduled IBC meeting. However, it is very important for continuity, scheduling, and well-rounded reviews that members attend IBC meetings. Membership is chosen based on the unique expertise that each member brings to an IBC. If a member cannot make a meeting, he/she should notify the IBC Chair in advance (two weeks before meeting) so that an alternate can be secured. Because members serve at the pleasure of UNLV, failing to regularly attend meetings or the lack of diligence in performing duties will result in removal of a member from the IBC by the Vice President for Research and Graduate Studies.

3.7 Notification to NIH/OBA of Changes in IBC Membership

The Associate Vice President for Research will notify NIH/OBA in writing of changes in UNLV IBC membership.

4. IBC MEETINGS

The IBC must meet once during each semester and will be convened as needed during semester breaks.

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. Protocols in this category may warrant a waiver of the required two-week submission period to allow a review by the IBC at the earliest regularly scheduled meeting or may require calling a meeting. In such cases, the protocol must be submitted with a memorandum explaining the circumstances giving rise to the request in enough detail that the request may be considered. The IBC Chair will make a determination whether the protocol qualifies for special handling and if it does, will advance the protocol to the next IBC meeting for early review or convene an IBC meeting. The investigator will be notified by the IBC Chair of the decision to grant or deny the request.

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 category of research is reviewed by the UNLV biosafety officer. Investigators are required to submit all potentially biohazardous research to the UNLV IBC to formally determine the category of research:

5.1 Exempt Research

Under the *NIH Guidelines* some recombinant DNA research is exempt. Exempt research is listed as the following:

- Those that are not in organisms or viruses.
- Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
- Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.
- Those that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment. See Appendix A: http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_A.htm.

  Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C: http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_C.htm

The research listed above and other categories detailed in section 5.3 of this document will be reviewed by the UNLV Biosafety Officer. He/she will make a recommendation approve, disapprove or require modification of the proposal to the IBC Chair. The IBC Chair will then send an official response to the Principal Investigator.

5.2 Full Committee Review

If the proposed research falls under the full-board review category detailed in section 5.3 of this document, all IBC members will be provided electronic copies of the protocol. All committee members will be expected to review the protocol

and submit questions to the IBC Chair or designee at least two business days prior to the next convened committee meeting. At that meeting, the Principal Investigator submitting the protocol must be available to answer questions (either in person or by telephone). The full committee will vote to approve, disapprove or require modification of the protocol. All experiments in the full-board review category require approval prior to initiation of the research.

5.3 Types of Research in Each Review Level

When protocols are submitted, they will be forwarded from the Associate Vice President for Research to the Biosafety Officer. The Biosafety Officer will determine which level the protocol should be reviewed at based on the following table:

Biosafety Officer Review	**Full-Board Review**
Exempt rDNA research as detailed by the *NIH Guidelines for Research Involving Recombinant DNA*	In vitro experiments using known BSL-2 agents
BSL-1 in vitro experiments where rDNA agents contain less than 2/3 of the genome of any animal virus	In vitro experiments using primary human material in combination with BSL-2 agents
Research involving established human cell lines not known to contain infectious agents	BSL-1 in vitro experiments where more than 2/3 of the genome of any animal virus is used
Research involving human sera or tissue from non-established or unknown sources	BSL-1 and BSL-2 in vivo experiments (IACUC approval required)
	Experiments using risk group 2 agents as host-vector systems
	Research involving human material likely to contain BSL-3 agents
	BSL-3 in vitro experiments
	BSL-3 in vivo experiments (IACUC approval required)
	Human gene transfer research (IRB approval required)
	Experiments using risk groups 2, 3, 4 or restricted agents as host-vector systems
	Experiments involving toxins or immune modulators
	Experiments involving use of infectious or defective DNA or RNA viruses in the presence of a helper virus in tissue culture systems
	Experiments involving viable rDNA-modified microorganisms tested in whole animals.
	Experiments involving plants infected with agents recognized to have potential for serious detrimental impact on managed or natural ecosystems
	Experiments involving greater than 10 liter volume cultures of rDNA containing organisms
	Biosafety Level change requests by the P.I. or any member of the IBC
	Any IBC research proposal requested to be brought before the Full-Board

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*.

6.2 Additional Requirements for Select Agent Studies

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules for the possession, use, and transfer of select agents and toxins (42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121) in the Federal Register on March 18, 2005. All research conducted at UNLV must first satisfy these regulations (or subsequent amendments) then may be submitted for review to the UNLV IBC. As part of this submission, documentation of approval by the appropriate federal agency must be attached. IBC reviewers of select agent protocols must take into account requirements of the above listed federal regulations.

6.3 Additional Requirements for Biosafety Level 3 Studies

All research conducted at Biosafety Level 3 must comply with the UNLV Biosafety Manual (and latest edition of the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories*). An assurance must be attached to all Biosafety Level 3 protocols detailing appropriate facilities and staff training for this type of research. All facilities shall be commissioned as BSL-3 laboratories. Appropriate protective devices (Biological Safety Cabinets, etc.) must be demonstrated as certified prior to approval of any such protocol.

6.4 Additional Requirements for Studies Involving Vertebrate Animals

All protocols involving biohazards and vertebrate animals must attach a copy of their UNLV Animal Care Protocol. For research involving vertebrate animals, coordination will be made during review of the protocol with the UNLV Animal Care and Use Committee to address any animal or biosafety issues involved with

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

Approvals for biohazard studies involving animals will be granted conditional approvals with the statement "This approval is for the biosafety portion of your protocol. You must maintain current animal care approvals during the entire project. If at any time your animal care protocol is discontinued or denied this IBC protocol is no longer approved".

6.5 Additional Requirements for Studies Involving Humans

For any research involving biohazards and human subjects UNLV IRB approval must be attached to the IBC protocol. Also, any involvement of recombinant DNA in human studies must be reviewed and approved by the RAC prior to initiation of the study as detailed in the *NIH Guidelines*. For research involving humans, coordination will be made during review of the protocol with the UNLV OPRS to address any human or biosafety issues involved with the protocol. The OPRS director will report any IRB concerns at the IBC meeting during review of the protocol.

Approvals for studies involving biohazards and humans will be granted conditional approvals with the statement "This approval is for the biosafety portion of your protocol. You must maintain current IRB approvals during the entire project. If at any time your IRB protocol is discontinued or denied this IBC protocol is no longer approved".

7. UNLV IBC MONITORING AND INVESTIGATOR REQUIREMENTS REGARDING RESEARCH IN PROGRESS

7.1 Amendments in Protocol

To obtain approval for proposed changes, investigators should submit an amendment form. The IBC will vote on major amendments to previously approved non-exempt projects during their meeting. Amendments to exempt projects and minor changes to non-exempt project will be reviewed by the UNLV Biosafety Officer. Minor changes include deletions of personnel, room changes (at BSL-2 or below), additions of qualified personnel and additional safety measures. Minor amendments may be approved by the IBC Chair based on the Biosafety Officer's recommendation in between meetings. Investigators <u>are not</u> permitted to implement any amendments without approval by the IBC except to eliminate apparent immediate hazards.

The date of approval of an amendment does not change the date by which the regularly scheduled continuing review of the project is to be completed.

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 there is a reasonable possibility that the event may have been caused by the use of that product.

An "unexpected serious adverse event" is any serious adverse event for which the specificity or severity is not consistent with the risk information available in the current investigator's brochure.

Any of these events or any event involving exposure of any person to infectious materials, biological toxins or human blood or OPIM must be reported within 5 days of the event in writing to the Chair of the IBC. Even if an adverse effect was anticipated by the protocol (and disclosed to a subject), <u>if the effect has changed in nature, severity, or frequency in the study</u>, this must be reported to the IBC. Required reporting also includes, but is not limited to, any procedural errors during the research, a breach in confidentiality or privacy, emotional disturbances, noncompliance with the regulations or IBC policies, or any other problems occurring during the research. Investigators should err on the side of caution when determining whether an event is reportable to the IBC. Life-threatening adverse events must be reported to the IBC within 24 hours.

Adverse event reports, when involving recombinant DNA, must be reported under the *NIH Guidelines*. Any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses must be reported to the appropriate institutional official and NIH/OBA within 30 days, unless the Institutional Biosafety Committee determines that a report has already been filed by the Principal Investigator. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

In the case of any adverse event involving hazardous biological materials, an IBC meeting will be called at the earliest date that a quorum will be possible. The IBC's review of adverse event reports will focus on reasons for exposures and any risks that may have changed. The IBC will determine if there is a need to revise the protocol and whether approval should continue. Also, increased monitoring,

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 for extension before expiration.

The principal investigator should submit a completed Protocol Renewal Form well in advance of the expiration date (minimum of 30 days). If approval for continuation has not been issued by the IBC prior to the expiration date, the investigator must terminate the research, and the project will need to be reviewed and approved as a new study.

The purpose of renewal review is to re-assess any safety risks based on the latest biosafety information. Modifications occurring during the three year period between reviews must be submitted via modification forms. In the renewal form Investigators should summarize the status of the study, and report any advancement or changes generally in the area under study that may impact the safety of continuing the study.

8. RECORD KEEPING

8.1 IBC Records

The Office of the Associate Vice President for Research maintains a file for each study, containing the following information: 1) research protocol(s) (all versions of the protocol are retained); 2) any approval documents from other committees or agencies; 3) notifications of IBC decisions, 4) records of protocol renewal activities, 5) reports on amendments and adverse events, and 6) correspondence between IBC and investigators of the project.

The files on a research project will be retained for at least three years after completion of the research.

8.2 IBC Meeting Records

Agendas and minutes of the IBC meetings are stored either on the computer or by hard copy and are kept indefinitely. Upon request, UNLV must make available to

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 projects. This document must be included in the IBC file. Additional documented training on the protocol may also be submitted for evidence of training.