

 <b>Office of Research Integrity - Human Subjects</b>			<b>SOP #:</b> ORI(HS)-3.06
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Approved By: ORI Executive Director	*Signature on file	Date:	<b>Date First Effective:</b> 01/25/2017
Approved by: Biomedical Chair	*Signature on file	Date:	
Approved by: Social Behavioral Chair	*Signature on file	Date:	<b>Revision Date:</b>

## SOP 3.06 - Institutional Review Board (IRB) Appointments and Membership

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### 1. Objective

The purpose of this SOP is to describe the administrative structure of the Institutional Review Boards (IRB) at UNLV and the appointment process for IRB chair, co-chairs, and members.

### 2. General Description

An IRB is a board established by a local institution to protect the rights and welfare of human subjects recruited to participate in research activities under the auspices of the institution. There are regulatory and institutional requirements for appropriate membership on the IRBs.

Federal regulations (45 CFR 46) require a specific minimum IRB membership composition. The Office of Research Integrity and university officials also have an obligation to evaluate the effectiveness and representativeness of IRBs on a regular basis.

### 3. Roles & Responsibilities

Execution of SOP: Institutional Official (IO), Office of Research Integrity –Human Subjects (ORI-HS) Staff, and the IRB

#### **Institutional Official Responsibilities**

The Vice President for Research has appointed the Associate Vice President for Research to serve as the IO in accordance with the provisions of UNLV's Federal Wide Assurance (FWA). The IO is authorized to act for the institution and assumes overall responsibility for compliance with the FWA. The IO appoints chairs, co-chairs, and members of the IRBs.

#### **ORI-HS Responsibilities**

The Executive Director provides recommendations to the IO for chairs and co-chairs of the IRBs.

#### **ORI-HS Responsibilities**

The Office of Research Integrity-Human Subjects (ORI-HS) is responsible for ensuring IRB composition that meets the requirements of 45 CFR 46 and of this SOP. ORI-HS submits changes to in membership to the US Office of Human Research Protection (OHRP) and serves as the primary point of contact regarding the UNLV FWA. The ORI-HS also is responsible for preparing appointment letters in a timely manner for the IO's signature and member acceptance.

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### **IRB Chairs' Responsibilities**

The IRB Chairs and co-chairs are responsible for providing advice on membership and serving as IRB members. IRB Chairs and co-chairs report to the Executive Director, ORI. IRB Chairs and co-chairs provide expedited reviews in addition to managing full board meetings as described in the SOPs on expedited review and IRB meeting management. IRB Chairs and co-chairs are also responsible for delegation of expedited review to other members of the IRB on an as needed basis.

### **IRB Members' Responsibilities**

IRB members are responsible for serving as active participants in the IRB process including providing suggestions to the IO when membership replacement decisions must be made. IRB members are also responsible for disclosing all Conflicts of Interest that could impact their role as a board member.

### **Role of Office of General Counsel**

A representative from the Office of General Counsel serves as a non-voting member on the IRBs. The role of General Counsel is to provide guidance on ancillary legal matters, such as the legal definition of a child, to ensure IRB compliance with applicable federal, state, and NSHE laws and regulations.

## **4. Procedures**

UNLV maintains two IRBs: the Social/Behavioral IRB and the Biomedical IRB. Membership for the IRBs and for chairs and co-chairs is determined based on both federal requirements and institutional factors.

### **Federal Requirements for IRB Membership**

Federal requirements (45 CFR 46.107) specify IRB membership practices including:

Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

1. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
2. Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

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3. Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
4. No IRB may have a member participate in any IRB review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Conflicting interests are further described in the SOP on conflicts of interest.
5. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

#### **Appointment of Chairs and Co-Chairs**

IRB chairs and co-chairs are appointed by the IO for one-year renewable terms, upon recommendation by the Executive Director, ORI. Appointments are made in writing, and acceptance of the position is also indicated in writing. The Executive Director, or designee, is responsible for soliciting recommendations from a variety of sources and for preparing the recommendations for submission to the IO. Care is taken to ensure that changes in board chairship do not disrupt the functioning of the board. Chairs and co-chairs are appointed for one year terms. UNLV has no limit on the number of terms IRB chairs or co-chairs may serve. The IO may remove a chair or co-chair prior to the completion of a one year term.

1. Individuals under consideration for appointment as an IRB Chair must meet the following requirements: completion of human research protections training; recent experience as a voting IRB member (or comparable experience) for at least one year prior to nomination as IRB Chair; display of adequate knowledge of ethical principles, professional standards, federal regulations, and other applicable law, through IRB meeting attendance and participation; and demonstration of professional competence necessary to review specific research activities.

#### **Appointment of IRB Members**

Members are appointed to the IRBs by the Institutional Official based on recommendations of the IRBs, ORI, the ORI-HS, and administrative representatives such as deans, associate deans, and chairpersons of departments that conduct human subjects research. Care is taken to ensure that membership is representative of various units and perspectives while not becoming overwhelmingly large. UNLV IRBs generally will have more than the minimum number of members to ensure adequate and efficient reviews, as the Institutional Official deems appropriate. Appointments are made in writing, and acceptance of membership is also indicated in writing. Changes in board membership are congruous with the functioning of the board.

1. Scientific members of UNLV IRBs generally will have had experience in research involving human subjects, and will be recruited from among active, tenured or emeritus members of the faculty of UNLV academic units.
2. Nonscientific members will have as their primary focus a non-scientific area such as law, ethics, human or patient rights. Nonscientific members may be recruited from among the active members of the faculty, full-time UNLV staff, or community. This member also represents the general perspective of participants and must be present at greater than 50% of the convened meetings held.
3. Community members will be knowledgeable about the local community and willing to discuss the issues and research from the community perspective. They are chosen from the southern

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Nevada vicinity and neither they nor their immediate family members may have any affiliation with UNLV. Unaffiliated members must attend greater than 50% of the convened meetings held.

4. Alternate voting members are appointed for one year terms.. Such alternate members will have similar qualifications and experience to regular members. Alternate members may be called upon to serve where regular members will be absent from a meeting and there will be less than a quorum at an upcoming meeting. Alternate members will have voting rights and be counted in a quorum only when they replace the respective regular member.
5. Members of UNLV staff or faculty may serve as non-voting members of UNLV IRBs should it be decided that such persons would be of assistance to UNLV IRB in conducting their duties. A non-voting member cannot be counted in the quorum and cannot vote, but can participate in discussions and deliberations.

### **Terms**

In general, UNLV IRB members are appointed for one-year terms which may be extended as needed.

Memberships may be renewed indefinitely at the discretion of the Institutional Official.

Members may be removed from the committee by the IO if there are excessive absences, if the member is disruptive at board meetings, does not contribute to the discussions at the meetings, if conflicts of interest arise, or if other serious issues would impede the IRB review process.

### **Notification to OHRP of Changes in IRB Membership**

The ORI-HS will notify OHRP in writing of changes to UNLV IRB membership within 90 days of the change to the board. Each IRB membership may be updated independently.

The ORI-HS first verifies the data currently on file with OHRP with includes the Head Official with the institution, the IRB Administrator, and the IRBs included on the FWA.

When adding members, the ORI-HS administrator must include the name, sex (M/F), earned degree(s), whether they are a scientists or non-scientist, their primary scientific or non-scientific specialty, the affiliation with the institution(s), and any comments.

Alternate members are also named and the specific member they are alternate for is detailed.

The changes are submitted to OHRP, who files the paperwork.

### **Evaluation of IRB Chairs, Co-Chairs, and Members**

IRB Chairs, Co-Chairs, and members are evaluated on an annual basis, at the end of the fiscal year. IRB Chairs, Co-Chairs, and members self-evaluate themselves on a variety of objective and subjective criteria (i.e., number of meetings attended, preparedness for meetings)using an online survey, and responses are received by the Executive Director, ORI. Aggregate data from the self-evaluations are reported to both IRBs during their regularly convened meetings and to institutional officials. . The information is also used by the IO and Executive Director to identify areas of education needed for IRB chairs and members.

### **Evaluation of IRB Staff**

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The evaluation of IRB Staff is conducted by the Executive Director, ORI on an annual basis, in accordance with UNLV bylaws. Additionally, IRB staff are evaluated on a number of objective and subjective criteria related to workload (i.e., number of determinations, number of protocols proceeded). Completed evaluations are also provided to the Associate Vice President of Research.

## **5. References**

45 CFR 46, describes membership requirements for the IRBs.

SOP 5.05 Expedited Review

SOP 5.07 Additional Decisions Available to the IRB

Evaluation tool for IRB chairs and members

Appointment/Reappointment letters for IRB chairs and members