



## Office for the Protection of Research Subjects

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### From the Director

Welcome to the first of monthly newsletters brought to you by OPRS. It is the mission of OPRS to provide human research compliance guidance and support for UNLV researchers and the Institutional Review Boards (IRBs) to assist in safe-guarding the rights and welfare of research participants. To that end, the newsletters will provide information to assist researchers in submitting human subject research protocol applications to the UNLV IRB, as well as provide information to assist researchers in becoming familiar with the IRB review process. The newsletter will disseminate important announcements, IRB meeting information and educational session availability. It will also provide information on federal, state and institutional regulations, schedules of events and other information pertinent to making IRB review a supportive, meaningful and expeditious process. We look forward to a growing readership, your comments and suggestions.

Brenda Durosinmi  
OPRS Director

### “What happens to my IRB protocol package when I send it to OPRS?”

One question we often hear is “What happens to my IRB protocol package when I send it to OPRS?” This issue will give a brief overview of the review process.

**Please Note:** Investigators are required to submit an application for IRB review prior to initiating a human subject research project. The protocol application package must be complete before IRB review can begin. Periodically IRB forms change. Make sure the most current form is being used by downloading it from the OPRS website.



### Screening Process

Once a complete protocol package has been received, it is assigned an IRB protocol number and entered into the ProIRB® Database. All applications are screened by OPRS staff. If the application is incomplete, or otherwise not fully prepared for review, it may be returned to the investigator or additional information may be requested via e-mail. The IRB Chairs will determine whether the project is eligible for exempt or expedited review (minimal risk studies), or requires full board review (research involving greater than minimal risk or vulnerable populations).

### Exempt/Expedited Studies

If exempt or expedited review is appropriate, the OPRS staff may e-mail the investigator with requests for additional clarification or material prior to final approval. The investigators must satisfactorily respond to all requests from the Chair for revisions or clarification. When the Chair determines the study is procedurally sound and all required revisions have been made, s/he approves the project and determines the interval for the next continuing review.

### Full Board Studies

At the full board meeting, the IRB will discuss the project's purpose and design, considers the risks and potential benefits of the research, and reviews the Informed Consent Document, instruments, advertisements, and any other submitted materials. If the IRB requires revisions prior to approval of the study, the investigator will be notified. If the IRB decides to table a study, the project must be reviewed by the full board at a subsequent meeting.



### Revisions Request

The investigator will have 2 months to submit requested revisions. Additional submittal time can be requested by the investigator if needed. The protocol will be administratively withdrawn if no response is received from the investigator within 2 months.

### Approval

Once the IRB approves the protocol, the PI receives notification of approval via e-mail. Hardcopies of the approval documents are sent to the PI via campus mail.

#### Upcoming Protocol Due Dates

##### Social Behavioral IRB

July 10th

##### Biomedical IRB

July 22nd

##### Social Behavioral IRB

Aug 14th

##### Biomedical IRB

Aug 26th

#### Open House

Open House is held each Friday to answer protocol specific questions. Please contact OPRS for times.

#### Coming Soon

2009 IRB Protocol Due Dates & Meeting Schedule

• Fall Workshop Schedule

• PowerPoint Training Presentations available on the OPRS website

#### Next Issue

IRB Decisions to Approve, Require Revisions, Table or Disapprove

• OPRS Staff Functions

Contact OPRS at:  
**702.895.2794**

<http://research.unlv.edu/OPRS/>

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