



From the Director

I am pleased to announce, with the support of the VP for Research and Graduate Dean, Dr. Ron Smith and the AVP for Research, Dr. Stan Smith, OPRS has moved forward with plans for an electronic protocol submission process. This new electronic system, named CyberIRB®, will allow researchers to submit all IRB applications and paperwork to OPRS electronically.

The online submission of new, requested revisions, modifications and continuing review of protocols will assist in streamlining the IRB process for investigators. To ensure that the electronic submission process is rolled out with minimal flaws, OPRS will beta test the program with various departments. Beta testing should begin September 2008 and is slated to go live October 2008. To ensure an effortless transition to the electronic process, OPRS will be providing weekly workshops, graduate classroom electronic protocol submission instruction, as well as taking requests for electronic instruction to be presented during faculty department meetings. Please see workshop schedule found in this newsletter and on the OPRS website.

This system will provide many obvious benefits for UNLV researchers:

- online application will overcome geographic barriers
- better security for confidential information
- one version of IRB application in one location
- improved accuracy of information submitted
- consistent, complete access to application data
- easier process to revise/modify existing protocols
- reduced potential for error
- reduced time for application screening by OPRS prior to IRB review
- virtual elimination of the re-keying of information
- reduction in paper use
- all of the above benefits will contribute to an overall faster turnaround for IRB application submission

Additional information will be provided as we continue to move forward.

Brenda Durosini
OPRS Director



IRB Decisions to Approve, Requests Revisions, Table or Disapprove

The UNLV Institutional Review Boards (IRBs) provide oversight for research activity conducted by the institution's researchers. They have the responsibility to insure and safeguard the rights and welfare of human subjects who participate in research activities conducted by UNLV investigators. To this end, the Board is obligated and authorized by university policy, federal and state statutes to:

- Ensure that subjects are adequately informed of the nature of the study;
- Ensure that subjects' participation is voluntary;
- Ensure that the benefits of a study outweigh its risks;
- Ensure that the risks and benefits of the study are evenly distributed among the possible subject populations;
- Suspend human subject activity that violates regulations, policies, procedures, or an approved protocol, and report such violation and suspension to the Institutional Official; and
- The IRB(s) will review, and have the authority to approve, table to require revisions of the protocol or disapprove all research activities, including proposed changes in previously approved human subject research.

Research involving human subjects must be reviewed by the IRB:

- Before research activities begin;
- Before making any changes to an approved protocol;
- If the research activity will continue past the approved date; and
- When concerns or noncompliance are reported

Upcoming Protocol Due Dates

Social Behavioral IRB

August 14th

Biomedical IRB

August 26th

Social Behavioral IRB

September 11th

Biomedical IRB

September 23rd

Cyber IRB

Submittal Workshops
To better assist the campus community in the transition to electronic submittal, OPRS will host weekly workshops for faculty and students. The workshops will run an hour and investigators will receive hands on experience using the CyberIRB software. Please be advised that paces are limited. For more information and/or to reserve a seat, please contact Jon Basilio at: jonathan.basilio@unlv.edu or call: (702) 895-2794

Workshop Schedule:

Mon. Sep. 9th @ 11 am
Tue., Sep. 18th @ 12 pm
Wed., Sep. 24th @ 11 am
Mon., Oct. 6th @ 2 pm
Tue., Oct. 14th @ 10 am
Wed., Oct. 22nd @ 10 am
Thu., Oct. 30th @ 12 pm
Wed., Nov. 5th @ 12 pm
Thu., Nov. 13th @ 10 am

Contact OPRS at: 702.895.2794

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

FDH 518 — M/S 1047



Research activity can begin only after an Approval Notice has been issued to the PI from OPRS.

Approval - All stipulations for the protection of human subjects have been met. An “approve” decision on new research (or a modification in research protocol), signifies that the IRB is accepting oversight (or continued oversight) of the research and allowing the research to go forward as approved. The PI is notified by written correspondence of the decision.

Revisions Request - Minor revisions are required before the IRB can finalize approval of research activity. PIs must respond in writing to IRB stipulations and recommendations within 60 days from the date of notice. Additional time may be requested. If response is not received within the time allotted, the protocol will be administratively closed.

Table - Additional information is necessary before the IRB can render any decision on the research activity. A “table” action removes the research protocol from IRB consideration in order that additional information or clarification can be obtained from the PI. The PI is notified by written correspondence of the decision. The IRB Chair, Board member or Staff may also communicate with PI to address reasons for tabling the item. The investigator may be requested to appear before the IRB. As noted above, a two month time frame for receipt of information applies.

Disapprove - Most decisions to “disapprove” involve research subject safety and/or scientific validity. This decision signifies that the IRB is rejecting oversight of the project as submitted, and the research activity is not allowed to begin. When the IRB disapproves a modification to an already approved research activity, the modification cannot be implemented, but the previously approved activity may continue. The PI is notified by written correspondence of the decision. The IRB Chair, board member or staff can work with the PI to assist him/her in resubmitting the protocol.

OPRS Staff

Jon Basilio, BS

Administrative Assistant III

Office Manager; CITI certification coordinator; Provides triage for questions and concerns relating to human subjects research; Assists with special projects

Christa Esparza

Compliance Coordinator

Coordinates with Social/Behavioral and Biomedical Administrators in the protocol triage process; ProIRB® and CyberIRB® electronic submission systems specialist; Processes Approvals, Continuing Reviews, and Modifications

Josi Dos Santos, BA

Compliance Administrator

Conducts initial review of Social Behavioral Sciences protocols and related materials to identify regulatory, legal or ethical issues; Serves as the liaison between researchers and the Social Behavioral Sciences IRB through meetings and written correspondence; Coordinates IRB meetings and maintains IRB records for federal compliance and inspection; Provides assistance in audits and non-compliance functions

Cindy Lee-Tataseo, BS, CIP, CIM

Sr. Compliance Administrator

Facilitates the Biomedical Sciences IRB; Ensures research is conducted in compliance with federal laws, regulations, policies and guidelines; Provides initial review and evaluation of Biomedical Sciences research protocols and assists researchers with intricate issues of research compliance; Serves as human research compliance educator, providing workshops and presentations to graduate research classes, faculty, and others as requested; Lead investigator for audits and non-compliance issues

Brenda Durosinmi, BGS, MPA, CIP, CIM

Director/IRB Administrator

Provides oversight for the UNLV human research protection and compliance program for all UNLV campuses to ensure a culture of research compliance; Responsible for the administration of the Biomedical and Social and Behavioral Sciences IRBs; Serves as the authority with expert knowledge of federal and state regulatory statutes and university policies and procedures for human subject research; Implements educational training and outreach programs to members of the UNLV research community; Develops and updates IRB policies and procedures; Represents the UNLV human research protection and compliance program through presentations and publications at regional and national meetings; Supervises the administrative and clerical functions of research compliance