



From The Director

In human subjects research, investigators have the primary responsibility for protecting the rights and welfare of the research participants and are responsible for complying with federal and state regulatory statutes and complying with all applicable provisions of UNLV human research policies and procedures. It is important that research be conducted according to the IRB approved protocol while complying with all IRB determinations.

Obtaining and documenting the informed consent of each subject or each subject's legally authorized representative, unless the IRB has waived these requirements is obligatory as is ensuring that each potential subject is aware of the nature of the research and participation. Investigators should provide a copy of the IRB approved informed consent document to each subject or the subject's legally authorized representative at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained for at least 3 years after the completion of the research and according to institutional policy.

This edition of the OPRS Newsletter will serve as an additional resource for information on informed consent. The information is the second of a four part series that began with the September 2008 issue.

The OPRS office is committed to providing a supportive, meaningful and expeditious service to assist researchers in the IRB review process. We look forward to your suggestions for future publication topics.

Brenda Durosini
OPRS Director



Informed Consent

Informed consent refers to the voluntary choice of an individual to participate in research based on accurate and complete information of, among other things, its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate.

Informed consent is not a single event or just a form to be signed. Rather, it is an ongoing process that takes place between the investigator and the subject.

The basic concepts of the consent process include:

- full disclosure of the nature of the research and the subject's participation, adequate comprehension on the part of the potential subject, and
- the subject's voluntary choice to participate.

General Requirements

- Informed consent must be prospectively obtained from the subject or a legally authorized representative of the subject (if allowed by state law).
- Information must be conveyed in language that is understandable to the subject or the subject's legally authorized representative.
- The subject must be given sufficient opportunity to consider whether or not to participate.
- Consent must be sought only under circumstances that minimize the possibility of coercion or undue influence.
- Informed consent may not include any exculpatory language. For example, subjects must not be made to give up legal rights or be given the impression that they are being asked to do so.

Comprehension

Even though the IRB has approved a consent procedure, it is the investigator's responsibility to ensure that each potential subject is aware of the information and to take the appropriate steps necessary to gain that comprehension of the study.

Individuals may not be involved as research subjects unless:

- they are aware of the information that has been provided and informed consent has been obtained, or
- the IRB has approved a waiver for informed consent of the subject.

Upcoming Protocol Due Dates

Social Behavioral IRB

February 12

Biomedical IRB

February 24

Social Behavioral

March 19

Biomedical IRB

March

Upcoming Cyber IRB Trainings

Feb. 3rd

10am to 11am

Feb. 4th

11:30am to 12:30pm

Feb. 9th

2pm to 3pm

Feb. 12th

10am to 11am

Feb. 17th

12pm to 1pm

Feb. 19th

11:30am to 12:30pm

Feb. 23rd

11am to 12pm

Feb. 25th

12pm to 1pm

To Register Contact OPRS at:

702.895.2794

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

FDH 330 - M/S 1047

Elements of Informed Consent

Federal regulations detail specific elements of information that must be provided to each research subject unless the IRB has approved a waiver or alteration of these requirements. Basic elements of informed consent include a:

- statement that the study involves research, an explanation of the purposes of the research, the expected length of the subject's participation, a description of the procedures to be followed, and identification of procedures which are experimental in nature;
- description of any reasonably foreseeable risks or discomforts to the subject;
- description of any benefits, to the subject or others which may reasonably be expected from the research;
- disclosure of appropriate alternative procedures or courses of treatment, if any, that are available that might be advantageous to the subject;
- a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

Basic elements of informed consent also include:

- For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments, are available to the subject if injury occurs and if so, what that may consist of or when further information can be obtained;
- An explanation of whom to contact for pertinent questions about the research and research subjects rights.
- An explanation of whom to contact in the event the subject experiences a research-related injury;
- A statement that participation is voluntary and refusal to participate will not result in penalty or loss of benefits to which the subject is otherwise entitled and the subject may withdraw at anytime without penalty or loss of benefits to which the subject is entitled.

Research and Procedures

The information provided to subjects should:

- make clear that the activity involves research and describe the overall experience that will be encountered;
- explain the procedures, including any parts that are experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues); and
- include the expected length of time it will take for study visits or scheduled procedures, as well as the total expected length of participation.

Risks

All reasonably foreseeable risks, discomforts, inconveniences, and harms that are associated with the research activity should be described. Investigators should be forthcoming about risks and not understate or gloss over reasonably foreseeable risks. If additional risks are identified during the course of the research, the consent process and documentation will require revisions, and subjects previously consented may need to be re-contacted and informed of the additional risks.

Benefits

Any benefits to subjects or others that may reasonably be expected from the research should be described. Investigators should be frank about benefits and not overestimate or magnify the possibility of benefits to the subject. If there is no reasonable expectation of benefit, the subject should be told this. Payment to subjects should not be listed or described as a benefit of participating in the research.

Alternatives to Participation

If appropriate, alternatives to participating in the research project that might be advantageous to the subject should be described. Investigators should be reasonably specific about describing the nature and type of available alternatives to participation if appropriate.

Confidentiality Protections

Federal regulations require that subjects be told the extent, if any, to which confidentiality of research records identifying the subject will be maintained. For example, sponsors, funding agencies, regulatory agencies, and the IRB may review research records. Some studies may need sophisticated encryption techniques to prevent confidentiality breaches or may need a Certificate of Confidentiality to protect the investigator from being compelled to release (e.g., under subpoena) subjects' names or identifiable private information.

Compensation for Injury

If research-related injury (i.e., physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk, an explanation must be given as to whether any compensation and treatment will be provided to an injured subject. If so, the compensation and treatment should be described, or the subject should be told where further information may be obtained. Federal regulations do not limit injury to only "physical injury."

The regulations prohibit:

Requiring subjects to waive or appear to waive any of their legal rights, and leading subjects to believe they are waiving their rights. Consent language regarding compensation for injury must be selected carefully so that subjects are not given the impression that they have no recourse to seek satisfaction beyond the institution's voluntarily chosen limits.

Contact Persons

The regulations require that the subject be provided with information on who to contact to answer questions about the research and the rights of research subjects. Subjects must also be informed of whom to contact in the event of any research-related injuries.

This information must be explicitly stated and addressed in the consent process and documentation.

A single contact person is not likely to be sufficient to answer all questions. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects may best be referred to persons not on the research team. These questions may be addressed to OPRS.

Voluntary Participation

The regulations require statements regarding voluntary participation and the right to withdraw at any time. Subjects must be informed that:

- participation is voluntary
- participation may be discontinued at any time
- there is no penalty or loss of benefits for refusing to participate or discontinuing participation.