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Ethical Guidelines on the HRPP website:

- The Belmont Report
- Nuremberg Code
- Declaration of Helsinki

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UNIVERSITY of CALIFORNIA • IRVINE

Human Research Protections Program

News Brief

AAHRPP Reaccreditation Update

UC Irvine completed the self-assessment of its Human Research Protections Program (HRPP) and the **application has been submitted for reaccreditation** with the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP).

AAHRPP will conduct a site visit in Spring/Summer 2008 during which **interviews will be scheduled with investigators**, University officials, IRB members and staff selected by AAHRPP. Information about the site visit will be shared with the research community as the details become available.

In preparation for the interviews, the Office of Research will increase its **education and outreach** efforts to assure investigators, research coordinators, IRB members and staff understand their roles and responsibilities in UC Irvine's HRPP. Stay tuned for more details in early 2008!

Belmont Report Basics

In 1974, the National Research Act was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify **basic ethical principles that should underlie the conduct of biomedical and behavioral research** involving human subjects, as well as develop specific guidelines by which researchers should abide.

Accordingly, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued "**The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.**"

The Belmont Report states, "These three [principles] are comprehensive...and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to **understand the ethical issues inherent in research involving human subjects**. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The **objective is to provide an analytical framework** that will guide the resolution of ethical problems arising from research involving human subjects."

1. Respect for Persons (be respectful)

- Individual Autonomy
- Protection for those with reduced autonomy

The first principle is represented through the **informed consent process**. Respect for persons requires that subjects enter into the research voluntarily and with adequate information. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others.

2. Beneficence (be nice)

- Maximize benefit and minimize harm

The second principle is best represented through the 7 criteria of IRB approval defined in Federal regulations (45 CFR 46.111 and 21 CFR 56.111). The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and IRB members are obliged to give forethought to the **maximization of benefits and the reduction of risk** that might occur from the research investigation.

3. Justice (be fair)

- Equitable distribution of research costs (risks) and benefits

The third principle is represented through the fair recruitment and selection of research subjects. Researchers address this important principle by describing the method in which subjects are selected and recruited, as well as if the costs, compensation, risk and benefit are appropriately distributed.

Modifications (Amendments) to Approved Research

The Basics

Per Federal regulations, once a human research study has received IRB approval, any subsequent changes to the study must be reviewed and approved by the IRB prior to implementation (except when necessary to avoid an immediate, apparent hazard to a subject). At UCI, **a change to an IRB-approved research study is called a modification or amendment.**

In accordance with the regulations, a modification request must be submitted to the IRB prior to implementing any change to the study and **must be approved by the IRB *before* the change is implemented.**

To request approval of a proposed modification, investigators complete and submit an [electronic Modification \(e-MOD\) Request](#).

The Level of IRB Review

A modification/change to an approved human research study will generally be reviewed at the same level of review in which the study was first reviewed, i.e., expedited review or by the full Committee. The level of IRB review also is determined by the type of change proposed and how the change impacts the IRB's assessment of potential risks and benefits.

Minor Modifications:

A minor modification is a proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study. Generally, minor modifications qualify for expedited review.

Significant Modifications:

A significant modification is a proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Generally, significant modifications require full Committee review. Significant modifications that involve revisions to the consent document often require re-consenting currently enrolled subjects.

Examples of Minor Modifications

- Addition or deletion of study team members
- Addition of non-sensitive questions to un-validated survey or interview procedures
- Addition of or revisions to recruitment materials or strategies
- Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study (i.e., new procedures that fall under any of the expedited categories can usually qualify as minimal risk)

Examples of Significant Modifications

- Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.)
- Addition of research procedures that involve greater than minimal risk to subjects (e.g., addition of a new drug to a treatment regimen; addition of invasive procedures; change in route or frequency of drug administration, etc.)
- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation

The Office of Research Administration will be closed from

December 24, 2007 to January 1, 2008.

IRB Protocol Submission Deadlines for January Meetings:

- **IRB-B: December 17**
- **IRB-C: January 2**
- **IRB-A: January 9**

Filing a Closing Report When Research Concludes

Submitting a closing report is official notification to the Office of Research Administration that the study has concluded and that all study activities have ceased.

The report provides a summary of the research activities as well as serves as the final modification to the study. Additionally, the closing report helps to ensure that the IRB has accurate and complete records regarding institutional research activities. To submit a closing report, any member of the study team can access and create the [electronic Closing \(e-Closing\) Report](#); however only the Lead Researcher or Faculty Sponsor can officially submit the report.

When should a study be closed?

A study should be closed when **all** of the following apply:

- Subject recruitment and enrollment is complete (i.e., no new subject recruitment or enrollment are ongoing)
- All specimens, records, data have been obtained (i.e., no further collection of data/information from or about living individuals will be obtained)
- No further contact with subjects is necessary (i.e., all interactions or interventions are complete and no follow-up contact is necessary)
- Analysis of subject identifiable data, records, specimens are complete (i.e., use or access to subject identifiable data is no longer necessary. Note: this includes review of source documents by study sponsors).

Allowing a study to "discontinue", does not provide the IRB with a final report summarizing research activities. **It is the Lead Researcher's responsibility to submit a Closing Report**, which serves as the study's final modification.