UNIVERSITY of CALIFORNIA • IRVINE
Human Research Protections Program
News Brief

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DID YOU KNOW...

Although the IRB prefers to receive the signatures of the Lead Researcher, Department Chair and Faculty Sponsor (when applicable) in hard copy, the IRB will now accept faxed or scanned and e-mailed signatures.

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AAHRPP Update

The much anticipated site visit by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) (4/21-4/23) was a success! Thank you to the 60+ investigators, research staff, UCI Administrators, IRB and COIOC Members, and ORA staff for taking the time out of their busy schedules to participate in the site visit. The site visitors reviewed 100+ protocol files and examined over 1300+ pages of internal HRPP documentation.

The site visit team praised the IRB members' knowledge of the federal regulations and specifically mentioned the members' use of the flexibility within the federal regulations to facilitate human subjects research such as granting waivers of informed consent for minimal risk research. The site visitors were equally impressed with the investigators and research staff's knowledge and commitment to the protection of human subjects. Currently the IRB and the HRP staff are working to fix findings that were mentioned by AAHRPP at the 4/23 closeout session and the written report. None of the findings appeared to be major; all are very "fixable" through a change in policies and procedures or through a written plan. UCI is required to respond to AAHRPP by June 23, 2008.

UCI will be notified of its accreditation status after the September 2008 AAHRPP Council Meeting where we hope that UCI will again be granted the top tier accreditation level - Full Accreditation.

Emergency Use of a Test Article

Emergency Use is defined as the **one-time** (per institution) **use of a test article** (an investigational drug, biological product, or medical device) for a patient in a **life-threatening situation** where **no standard acceptable treatment** is available and there is **not sufficient time to obtain IRB approval** [21 CFR 56.102(d)].

Emergency Use **does not** require prior IRB review and approval. At UCI, we recommend that the treating physician notify the IRB prior to the emergency use of a test article. The IRB will work with physicians to make sure patients are treated as soon as possible and in accordance with federal regulations. The physician is required to submit the **Emergency Use of a Test Article form to the IRB within 5 business days after the emergency use** [21 CFR 56.104 (c)].

EMERGENCY WAIVER FOR USE OF A TEST ARTICLE

A physician who wants approval of an emergency use of a test article should first check the **Emergency Use of a Test Article web page** to see the list of drug, biological product, or medical device previously used at UCI in an Emergency Use situation. If the test article is not listed, contact the manufacturer to determine if the product can be made available (for one, specific patient) under the company's IND or IDE; or if the company declines or cannot be reached, the physician can contact the FDA for an emergency IND.

- For Drug Products - (301) 827-4570
- For Biological Blood Products - (301) 827-3518
- For Biological Vaccine Products - (301) 827-3070
- For Medical Devices - (301) 594-1190
- For Nights, Weekends, Holidays - (301) 443-1240

The FDA allows one-time emergency use of a test article. If the test article is listed on the UCI HRP web page, submit an IRB application for review and approval.

IRB Protocol Submission Deadlines for June Meetings:

- **IRB-B: May 28**
- **IRB-C: June 4**
- **IRB-A: June 11**

INFORMED CONSENT REQUIREMENTS

The treating physician is required to obtain informed consent of the patient or the patient's legally authorized representative, unless both the treating physician and a physician who is not otherwise participating in the clinical investigation certifies in writing per 21 CFR 50.23 (a). See the Emergency Use of a Test Article form. The IRB also has a emergency use consent form template available for use.

The paperwork and report filing required by sponsors, drug companies, and the FDA are the **responsibility of the UCI physician** requesting the emergency waiver of approval. Also, the data gathered as a result of an "Emergency Use" cannot be considered research data.

Please see the **Emergency Use of a Test Article web page** to obtain additional information about the process.

Clinical Research and Data Safety Monitoring Plans

All **clinical investigations**, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness and comparative trials (phase III), **involving greater than minimal risk to participants** (i.e., full Committee review) require, at a minimum, a data and safety monitoring plan to assure the safety and welfare of the research subjects.

Monitoring is commensurate with size and complexity of the study. Monitoring may be conducted in various ways or by various individuals or groups, depending on the size and scope of the research effort. Sometimes having a UCI-based data and safety monitoring board (DSMB) is sufficient; in other instances the establishment of an independent DSMB may be required.

For clinical investigations involving greater than minimal risk, a description of the Data Safety Monitoring Plan (Appendix S) is *now required* as part of the electronic IRB Application. The Plan should contain the following information:

1. A description of the composition of the board including the relevant experience of the Board, as applicable. For UCI initiated studies, the name, title and experience of the individual(s) are required.
2. An indication of how frequently the board or individual monitor will review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy.
3. An explanation of the process by which the board or individual monitor will make recommendations concerning the continuation, modification, or termination of the trial;
4. A description of the event(s) that would trigger an unscheduled review. Also stopping guidelines and un-blinding rules, when applicable.
5. List who will be *locally* monitoring and collecting information on adverse events and/or unanticipated problems (e.g., UCI Lead Researcher, Research Coordinator, etc.). Include the name, title and experience of the individual(s).
6. A description of the plan for annual reporting of the participants' safety, and the study's conduct, progress, and efficacy. At the time of Continuing Review, the investigator should provide documentation that the DSMB met and indicate any findings or recommendations made. For UCI initiated studies, the investigator should provide a copy of the annual report at the time of continuing review.

Forthcoming ORA/HRP Announcements

- **IRB e-Doc Depot**
- **New ORA website**

For more information on data and safety monitoring plans and board requirements, see the **Data and Safety Monitoring for Clinical Research** web page.

Pregnant Women and Fetuses

Research involving pregnant women, fetuses and human in vitro fertilization are subject to additional federal regulations that guide IRB deliberations on such studies. Investigators interested in studying pregnant women, fetuses and/or neonates are required to complete **Appendix B** when completing the electronic IRB Application or when requesting a modification to an IRB-approved study.

Research involving **pregnant women or fetuses** can be approved by the IRB if the following federal requirements are satisfied:

- Preclinical studies have been conducted, including studies on pregnant animals; clinical studies, that include non-pregnant women and provide data for assessing potential risks to pregnant women and fetuses
- Risk to fetus is caused solely by interventions or procedures that hold prospect of direct benefit for the woman or the fetus or
- If no benefit, risk to the fetus is not greater than minimal and the research develops important biomedical knowledge not obtainable by any other means.
- Any risk is the least possible for achieving the objectives of the research.
- Individuals engaged in the research will have no part in: 1) any decisions as to the timing, method, or procedures used to terminate a pregnancy, and 2) determining the viability of the fetus at the termination of the pregnancy; and
- No inducements, monetary or otherwise, will be offered to terminate the pregnancy.

Consent Signature Requirements

- The **mother's consent** is required when the research holds: the **prospect of direct benefit to the pregnant woman**, or the prospect of a **direct benefit both to the pregnant woman and the fetus**, or **no prospect of benefit for the woman nor the fetus but risk to the fetus is not greater than minimal** and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means;
- **Consent from the mother *and* father** is required when the research holds the prospect of **direct benefit solely to the fetus** (unless the father is absent, incompetent, unknown or the pregnancy resulted from rape/incest) .

Investigators proposing to conduct **research involving neonates** are also required to complete **Appendix D**.

For more information on research with see the **pregnant women, fetuses and neonates** and consent signature requirements see the **Vulnerable Subject Populations** web page.