

Human Research News

January 14, 2013: Important OHRPP Updates

Improved OHRPP Website

Click [here](#) to view the completely revised OHRPP website. The website has an updated look and improved navigation to make information more accessible. E-mail sfriend@research.ucla.edu if you have any other suggestions about making the website more useful to you and your team.

Simplified Procedures for Disbursement of Gift Cards, Bruin Card, and Cash

The Office of Business and Finance Services and the OHRPP have coordinated their efforts to simplify the procedures for disbursement of gift cards, Bruin Cards and cash to research subjects. Click [here](#) for a description of this revised process. This link also includes a link to the [Research Human Subjects Payment Form](#). This form may be completed online and submitted via the web to Business and Finance Services.

IMPORTANT NOTE: This simplified process encourages investigators to use one of the preferred gift cards, though you may request other cards. If you would like to provide an opinion about which of the cards should be preferred, please complete this [survey](#) the end of the week, January 19th.

webIRB Enhancements for Improved Handling Amendments

On February 2nd webIRB will deploy a series of enhancements to improve its functionality. The enhancements include, but are not limited to, improving the handling of amendments to currently approved protocols. There are two key features to this improvement:

1. The need to "link" amendments to continuing review ("CR") applications will be removed. Although an amendment may still be submitted and reviewed at the same time as a CR, the "link" feature will no longer be required or available.
2. webIRB will no longer accept more than one amendment ("parallel amendments") at one time. By doing this, the need to "link" amendments is not required and the entire amendment process will work more smoothly.

Please e-mail webIRBhelp@research.ucla.edu or call (310) 825-5344 or (310) 825-7122 if you have any questions.

Biomedical Consent Form Standard Statement Reminders

Researchers who use the "greater than minimal risk" consent form template should note the following two changes. Although these changes were first promulgated in November of 2011 when the [UCLA Consent Form Standards and Sample Language for Greater than Minimal Risk Studies \(Biomedical Focus\)](#) were rolled out, IRB members and staff note that many investigators fail to follow these standards and, therefore, approvals of their studies are unnecessarily delayed:

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Financial Interest Statements:

The previous version of the consent form template included a “PI Disclosure section” on the first page. In keeping with national standards, that paragraph is no longer required. Rather, the revised template addresses potential conflicts of interests differently in the following two ways:

1. The entity funding the study should be included at the end of the section “WHY IS THIS STUDY BEING DONE?” (or in the “INTRODUCTION”). “This study is being funded by....”
2. Financial Interests Statements are described on page 22 on the [Standards](#) document and are included in a latter section of the consent form that has the major heading of “WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?” The subheading is “Researcher Financial Interests.” You can also see Recommended Consent Form Language in [UCLA OHRPP Policy and Guidance on Investigator Conflict of Interest](#).

Radiation Risks Statements:

Page 11 of [the above document](#) provides simplified standard wording to describe the risks of radiation in the following three circumstances when the procedures involving radiation are:

1. **Standard of Care Radiation Exposure Risks:** Since the radiation procedures used in this study are all standard of care, the amount of radiation you will receive is the same as that for similar patients who are not participating in this study. Therefore, you will not be exposed to any additional radiation for participation in this study.
2. **Non-Standard of Care Radiation Exposure Risks:** You are exposed to radiation on a daily basis, both from natural (sun and earth) and manmade sources. The estimated radiation dose that you will receive as a participant for this type of research has been compared to the limits allowed for a radiation worker. This limit is low and is not expected to be harmful. The person obtaining your consent can answer any questions you have, and provide detailed written information about the amount of radiation resulting from this study.
3. **Radiation Exposure Risk Statement for Studies Requiring Radioactive Drug Research Committee (RDRC) Review:** You are exposed to radiation on a daily basis, both from natural (sun and earth) and manmade sources. In addition to the radiation that you may be exposed to as part of your clinical care, you may potentially receive [[describe e.g., XXX PET CT scans](#)] in a year while participating in this study.

The US Food and Drug Administration (FDA) has set radiation limits for participants for this type of research. The dose you will receive in this study is low and below these limits and is not expected to be harmful. The person obtaining your consent can answer any questions you have, and provide detailed written information about the amount of radiation resulting from this study. Please inform your researcher if you have been exposed to radiation as a result of any other research studies.

The lengthier more technical description of the risks that is provided to investigators along with MRSC and/or RDRC approval is **not** to be included in the consent form but, rather is for use by the investigator and available to the subject if the subject asks for that level of detail.

Pages 9 through 12 provide additional sample language to describe, for example, the risks related to CT and PET scans, MRIs, as well as the use of contrast agents, among other risks.