HUMAN SUBJECTS RESEARCH NEWSLETTER
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Children Reaching Legal Age of Consent While Enrolled in a Protocol

When a child who was enrolled in research with parental or guardian permission subsequently reaches the legal age of consent to the procedures involved in ongoing research, the subject's participation in the research is no longer regulated by the requirements of 45 CFR part 46.408 regarding parental or guardian permission and subject assent.

The researcher should seek and obtain the legally effective informed consent, as described in 45 CFR 46.116, for the now-adult subject for any ongoing interactions or interventions with the subjects. This is because the prior parental permission and child assent are not equivalent to legally effective informed consent for the now-adult subject.

As long as the participation continues to meet the regulatory definition of "human subjects research" (for example, it involves the continued analysis of specimens or data for which the subject's identity is readily identifiable to the researcher), then it would be necessary for the researcher to seek and obtain legally effective informed consent of the now-adult subjects.

However, the IRB could approve a waiver of informed consent under 45 CFR 46.116(d), if the IRB finds and documents that the required conditions for a waiver of consent are met. Complete and submit the "Request for Waiver of Informed Consent" form to the IRB for this determination.

The IRB has created a consent template for "Continued Participation in a Research Study" that should be used for consenting the now-adult subjects. This consent form is essentially a continuation cover consent that explains why they are being consented at this time. A copy of the originally signed parental permission and assent (if applicable) should be attached to this continuation consent form and presented to the now-adult subject. The HIPAA authorization must also be obtained at this time. Subjects should be reminded of their right to withdraw from the study including: (a) their right to revoke HIPAA authorization, to the extent that such authorization is revocable under the terms of the informed consent and the authorization signed by their parents or guardian; and (b) their right to revoke any other right granted in the study, (e.g., rights with respect to use of tissue samples) to the extent it would be revocable by their parents or guardians were they still minors.

Reimbursements to Subjects

Did you know that research subject payments are 1099-misc reportable? Both UVM and FAHC require that you obtain the research subject's social security number for this purpose. Subjects should be informed that they will need to provide their social security number to you so that they may be paid. They also should be made aware that if payments are excess of $600 that they may have to claim this money on their taxes.

The IRB will be reviewing specifically how you are obtaining the number and transmitting the number to the respective procurement offices. The IRB may contact the applicable institution's Information Security Office to assist with ensuring that the proposed process is acceptable.

What we do know from the UVM Information Security Officer is that researchers should not use internet survey tools to capture the social security number as the security of the number cannot be guaranteed.

ClinicalTrials.gov
Registration Follow-up

Did you realize that after you have successfully registered your clinical trial on ClinicalTrial.gov, you are required to report periodically on your progress and provide final results?

See the following article "Reporting "Basic Results" in ClinicalTrials.gov" at http://chestjournal.chestpubs.org/content/136/1/295.full?sid=5bf6541b-d31a-4bc2-9460-35a4a3172186 for additional information.

Here is an excerpt from the article:

"In general, the law requires study sponsors or designated principal investigators (PIs) [called "responsible parties" in FDAAA 801] to report summary results information for interventional studies of drugs, biological products, and devices within 1 year of completing data collection for the prespecified primary outcome, regardless of sponsor or funding source. Results data are submitted online through the PRS and are displayed with the corresponding registered summary protocol information at ClinicalTrials.gov.[9] Results submission may be delayed under certain circumstances described in the law. Noncompliance could result in penalties specified by the law, such as the withholding of NIH grant funding and civil monetary penalties of up to $10,000 a day. (See http://prsinfo.clinicaltrials.gov/fdaaa.html for more information on reporting requirements)."

It is our understanding that some investigators are beginning to receive email reminders of the requirement to update the record with outcomes. Pay attention to these emails and update your results to avoid the serious consequences noted above.

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See the article below for a reminder on how to register a study on ClinicalTrials.gov:

(From the Human Subjects Research Newsletter Edition - Winter 2008)

CLINICAL TRIALS REGISTRATION: WHAT YOU NEED TO KNOW!

There are two different clinical trial registry mandates:

1) International Committee of Medical Journal Editors (ICMJE)
- Required as a ***condition for publication*** of trial results
- Clinical research studies must be entered in a public registry before any subject enrollment
- See definition of clinical trial in the link below

2) FDA
- Enacted as ***law with penalties***
- See link below for types of trials requiring registration and timing of registration
- Types of trials have recently expanded and number of data elements increased

Where should a clinical trial be registered? Who is responsible? What is the process for registering a clinical trial? Who do I call if I have questions?

For answers to the above, see: Clinical Trials Registration Information *(scroll through the update instructions)*

Form and Template Changes

We have recently completed a review of our forms and have made quite a few changes. The Common Protocol Cover form, in particular, was substantially changed. Click here for a highlighted version (not for use). When you are ready to submit a new protocol you can find a clean version on our forms site. Some of the changes made to this form were also applicable to other submission forms so we made those changes as well. If you have questions about these new questions, please contact our office.

Remember to obtain the forms from our forms website **each** time you need to complete one. Do not download and then reuse the same forms as they will become outdated as soon as you download them. The IRB will return outdated forms if the disparity from the old to the new results in inability to conduct a review.

We have also updated our "Consent with Guidance" template with the following:
- Tissue or data sharing
- Subject compensation
- Clinical Trials Registration

Changes to the Protocol Sponsor and Consent Forms

Many times new protocols are submitted identifying a sponsor when the actual funds have not yet been received. Although this identification is necessary, it presents a problem with regards to the proposed consent document. When the proposed consents that include the sponsor are approved, we have been assuming the funding will be forthcoming. Since the rollout of InfoEd, it has become clear that while the intention is to secure the funding as soon as possible, the investigator may decide to start work prior to receipt of funding. This results in an incorrect consent form being used.

To this end we have modified our Common Protocol Cover form to ask whether you intend to enroll subjects prior to securing the funding. If you do want to enroll subjects, then you cannot list the sponsor in the consent. You must insert your department if that is who is providing funding in the interim. You will then need to submit a Request for Amendment form to indicate a funding change and to revise your consent form to include the sponsor. If you do not intend to begin enrollment prior to receipt of funding, then we can approve the consent with the sponsor included. The same would be true when the funding has ended. You will need to submit an amendment to make us aware of the funding change. If you intend to continue subject enrollment, you will also need to revise your consent form to change the sponsor back to departmental funding.

Protocol Closure or Request to Reopen a Closed Protocol

Investigators have the responsibility to formally close a study once it is completed or discontinued. A protocol can only be considered completed once all subject interventions are complete, all follow-up has ceased, and the data analysis is final. **Notification must be done by completing a continuing review form. This provides the opportunity for the researcher to summarize all the activities into a final report. Researchers cannot use an amendment form to close a protocol.**

If the investigator needs to reopen a protocol and it has been less than one year after closure, a completed continuing review form must be submitted for review and approval. If the study is billable, it will be invoiced for this review regardless of the amount of time that has passed. If the study has been closed for greater than one year, a new protocol submission is required. If the study is billable, the protocol will be invoiced at the time it is re-reviewed.

Note: If the investigator is leaving the institution, it is the investigator's responsibility to contact the IRB to discuss their institutional status in regards to ongoing research activities and to close or appropriately transfer protocols before their departure. If this is not accomplished prior to leaving the institution, all protocols may be administratively closed by the IRB. See above requirements if a protocol needs to be reopened after an IRB administrative closure.

Happy Thanksgiving from the RPO Staff

Submission of Clarifications

When you are replying to a Committee request for clarification, additional materials, or revising a previously submitted form, please make it clear in your return submission to the office that it is a response and not a new submission. We have discovered recently that we have been duplicating submissions in our database because it is unclear that the submission is a response to the Committee versus a new submission. Please help us by including a cover memo with any response materials.

Thank you.

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