# HUMAN SUBJECTS RESEARCH NEWSLETTER
## COMMITTEES ON HUMAN RESEARCH
SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
ISSUE 39, SUMMER 2013


### Helpful Reminders

We have developed two new automatic reminders that we hope will be helpful. There are two scenarios when the Committee releases a protocol approval when not all criteria have been met. In one case, the Committee is concerned about the risk to subjects and wants information regarding outcomes as quickly as possible and the other case is when the grant while intending to involve human subjects, doesn't involve them at the time of initial review.

**Additional Safety Reporting for High Risk Protocols**

The Committee always has the option to require more frequent reporting if there is concern about the risks to subjects. Typically we have requested either a three or six month continuing review. What we have found, however, is that there has been no enrollment during these shorter cycles. Creating, submitting, and reviewing shorter continuing review periods, creates extra work for everyone. Therefore, in lieu of more frequent continuing review, the Committee will now determine at time of initial review what information they need more frequently and request that that information be submitted (e.g. after 1 subject, 10 subjects, or 2 months). Monthly notices will be sent to the contact person with that specific requirement. The information requested should be sent in as soon as possible. The information will then go to the Safety Subcommittee for review and a decision about continued additional reporting. Once the Committee is comfortable with the risks, the reminders for information will cease. If you have any questions about these reminders, contact the office.

**Projects Yet to Be Developed**

Certain types of applications may involve human subjects (within the funding period) but definite plans are not included in the application or protocol. These applications may not need to be reviewed by the Committee before an award can be made by DHHS or another federal agency. Examples of this may include activities such as research training programs, pilot, or developmental projects in which human subjects' involvement will depend upon development of instruments or pre-clinical animal studies.

No human subjects may be involved until the project has been reviewed and approved by the IRB and certification of approval submitted to the funding agency.

The Committee will now send reminders on a bi-annual basis to help you to remember that this is a requirement. Once all of the human subject research activity has been submitted, the reminders will cease.

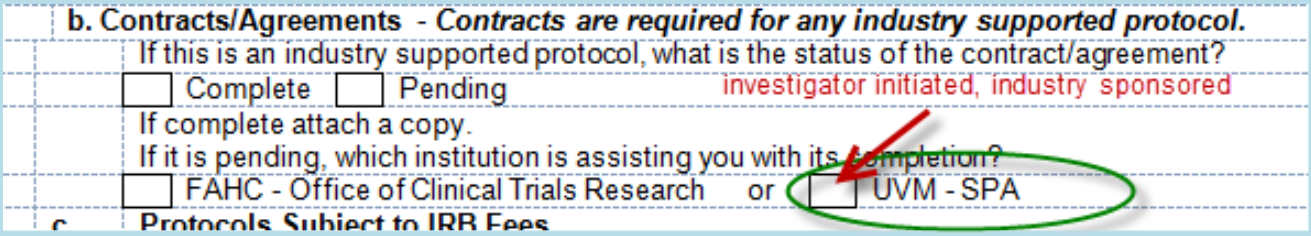
### A Year Later - Update on Revised Safety Policy

Things are going well with the safety submissions. In general we are receiving what we should be receiving and those that are not are usually caught at time of continuing review and submitted at that time. One thing I would reiterate is that if you have submitted a FAHC Safe report, you need to attach a copy of that report to the IRB submission. This assists the Committee with their review of the event or incident.

## Specifics on Who Handles Investigator Initiated Grants and Whether They are IRB Billable

According to the FAHC/UVM Affiliation Agreement, **any investigator initiated protocols with external funding of any type** needs to be handled through Sponsored Projects Administration (SPA) not the Office for Clinical Trials Research (OCTR). SPA will assist in determining what type of contract/agreement is necessary and work on the PI's behalf in negotiations. If the protocol is deemed billable, the invoicing/payment process is handled by the IRB and SPA Post-Award areas not FAHC's Financial Edge System.

We have revised our protocol cover form to help make you think about which entity should be assisting you with your contracts/agreements. If you have checked "SPA", this will trigger the invoice.




## Manual For Human Subjects New Version March 8, 2013

**Summary of Changes Since 03/12 Version**

4.A.1. Is the activity in which you will be engaged RESEARCH? (addition of flow)

4.A.2. Assessing whether there are "HUMAN SUBJECTS" in research (addition of flow)

7.A. "Full" Committee Review (additional text added to this section)

7.E. Review of Research Involving Secondary (Existing) Data Sets (new section pending)

7.F. Coordination with Other Compliance Committees/Divisions (new section)

8.B. Legally Effective and Prospectively Obtained Informed Consent and Documentation of Consent (entire section completely rewritten)

8.B.3. Requirements for Preparing Consent Forms and HIPAA Authorizations in Foreign Language (entire section rewritten)

8.C. Data Management Guidance (new section pending)

8.C.5. Grant Proposals Lacking Definite Plans for Involvement of Human Subjects (new NIH requirements see section)

8.C.8. Changes to the Scope of a NIH Awarded Project (new NIH requirements see section)

9.C.4. The Request for Modification / Amendment to Approved Protocol Form (new NIH requirements see section)

9.D. Notice of Protocol Closure or Request to Reopen a Closed Protocol (entire section rewritten)

11.C. Prisoners (entire section rewritten)

11.D. Children (new text regarding Wards of the Statue in this section)

11.E. Non-English Speaking Individuals (new section)

11.F. Cognitively Impaired Individuals (rewritten)

13. Multi-Institutional Research Studies (entire section rewritten)

Attachment D: List of Identifiers – New attachment