Change to the threshold for collection of subjects’ social security numbers for reimbursement

Effective immediately, you only need to collect a social security number for any reimbursements totaling greater than $25. This includes cash, gifts, tokens, and gift certificates. For protocols previously approved without this threshold, submit an amendment and revised consent to make this change.

Sponsor Invoicing and Continuing Review

We are finding it increasingly difficult to invoice for “ongoing” industry sponsored research as the sponsor contact information changes and we are not being informed. To help address this problem, we have added a section to the continuing review form for completion.

This will help us avoid wasting time chasing this information down each year looking for the most current invoicing information.
Clarification on the Child Consent Policy from last Newsletter

We received a couple of calls in regards to protocols in which minors were enrolled with the parents’ permission, for a one-time procedure or set of procedures. In one case, the procedure was minimal and the child was never seen again. The question was: Did the IRB expect the PI to collect consent from the now adult in this case. The answer is No in this scenario.

The researcher should only 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.

Unanticipated Problems Revisited and Revised 2012

At the national PRIM&R meeting in November, RPO staff attended sessions regarding unanticipated problems (UAPs), protocol deviations/noncompliance, and adverse event reporting. The IRB is required under 45 CFR part 46 to submit to the Office for Human Research Protections (OHRP) any UAPs. OHRP considers UAPs, in general, to include any incident, experience, or outcome that meets all the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

OHRP recognizes that it may be difficult to determine whether a particular incident, experience, or outcome is unexpected and whether it is related or possibly related to participation in the research. OHRP notes that an incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.

Diagram of the Relationship between Unanticipated Problems and Adverse Events*


As you can see, the UAPs that are ultimately reportable to OHRP are just a subset (“B”). The IRB wants to see all incidents falling into “B” and “C” and will ultimately make the decision as to whether the unanticipated problem is further reported to OHRP. Over time, we have reduced the number of non-reportable adverse events that are submitted to our office. However, we haven’t had a clear way to allow for reporting and documentation of deviations/noncompliance,
Unanticipated Problems Revisited and Revised (continued)

interim findings, or other possible scenarios that may affect risk to subjects ultimately resulting in a change to the protocol procedures or consent form.

To that end, we have consolidated our local adverse event report form and our deviation form into one form. The new form “Unanticipated Problem Potentially Involving Risks to Subjects or Others Report” provides examples of the types of incidents that might occur and for which the IRB would need to be notified.

We have also revised the current “New Safety Information” form to only allow for new safety information that does not negatively affect risk to subjects or others. We continue to want to receive this new information, (which most of the time comes in the form of an updated IDB or DSMB reports), so you will now use the revised form “New Safety Information Not Affecting Risk to Subjects”. Having this information will allow us to have a complete safety picture for a given protocol. Remember, though, if it affects risk, you need to fill out the “Unanticipated Problem Potentially Affecting Risks to Subjects or Others Report.”

We have updated Section 9, Unanticipated Problems Reporting, of the Research Manual and created a new and improved power point presentation that resides on our forms page.

This change also necessitated a revision in our current continuing review forms to be in alignment with the UAP form questions. So please be sure to use the most current continuing review forms.

Below are a few additional points to bring to your attention.

- Going forward, RPO will provide acknowledgement of all safety submissions whether changes are required or not. This will help close the loop for you as the investigator and the IRB will be able to formally document the review of these types of submissions.
- Any adverse events that do not meet the criteria for submission to the IRB will be returned to you (this is not different). They will be sent back to the contact via an email PDF and the IRB copy will be discarded.
- Do not submit Study Progress Reports as they do not provide any additional safety information. If your sponsor requires that you submit the progress report, it is more appropriate to be sent along with a continuing review.

This change has been in the works for quite some time. The forms have been vetted by several research coordinators and acknowledgements of receipt have been going back to contacts for a few months now. As always, other changes or tweaks may be necessary as we implement these new forms. Please do not hesitate to contact me at Donna.Silver@uvm.edu or give me a call at 6-5040 with any feedback. I will present these changes to the VCCR group on April 11 at noon. Please review the materials and bring your questions.