Jan. 11, 1:00-2:15pm Faculty IRB Committee Meeting

Jane McCutcheon, Chairing; Minutes, Neil Charness

Jane noted that similar to the IRB Wizard project, the IRB Forms Project hasn't had a good response, with only 9 universities submitting consent forms. A variety of forms were submitted, including about 7 Social & Behavioral Forms, 8 Biomed, 7 Short forms. They fell along degree of formalism from very prescriptive to more informal. Examples included cases such as NYU biomed which started with what is in a research study and what it means, to cases such as Michigan State which detailed tax policy (we will not send to IRS, until $600).

Question: How do you track participation in multiple studies for tax purposes when the same person participates in multiple studies? Do you keep track of participant SSN numbers? Different institutions treat this topic quite differently. Some have good language on taxation issues. Some policies are overly restrictive.

On other topics, some policies have templates that are overkill, such as warning about pregnancy risks for participants in aging studies.

Risk explanation would be a good area to concentrate on for generating example form templates. Additional templates that are submitted include: genomics disclosure, child assent, consent, parental permission, debriefing, fMRi consent outlined specifically. We need to get more responses from institutions who have not provided. For those gathering such forms to submit, please rename your consent document to indicate institution and type of consent form. Try to find other institutions who would volunteer.

A suggestion was given that we might want to break down consent forms into modules. How would we structure a modular consent form? We could have base issues common to all forms and then secondary ones (e.g., pregnancy, risk).

Core Consent form should include elements of consent with places where details are important (e.g. risk in experimental biomedical studies be modular, with specific links to specific risks). Try to develop a single consent form for all studies that is tailored to specifics with modules, including which elements can be omitted for minimum risk, exempt studies.

Question: Can we start building the modular components from what we have? Yes and no. We need more examples. For instance, given the lunch talk by Menikoff concerning OHRP restructuring of the NPRM, it seems that we may need to take into account new exclusion, exemption provisions.

Question: Will forms be confidential when sent? Institutions may be unwilling to submit if they think they are being compared to other ones and will look bad. Documents are protected behind an NAS firewall.

Question: Can you find consent forms online, publicly accessible, and use them? We might be able to harvest them. Neil did a quick search and found about 2 million hits on google for "irb consent form" and links to universities such as Cornell, Stanford, others.

Question: Did we want to try to move forward by going through what we have and comment on them? We may not have enough now to represent the diversity. It was agreed that we should try to write a

single core consent form using core elements and use modules that could be plugged in depending on the study type for issues such as taxes, risk, blood draw.

Question: What if forms are not computerized? What about forms that you send home on paper? There are clever companies creating forms for smartphones. It would be wise to try to incorporate technology. Implementation can be discretionary about paper, or e-forms. There would need to be a printable version at the end stage when an IRB approves the study and form.

Members were advised to think about picking a module and send to Neil Charness & Jane McCutcheon