IRB Member Guidance on IRB Review of Study Resources

The IRB must assess study resources to ensure that they are adequate for the protection of human subjects in research. This assessment goes into the IRB’s determination that the study meets the regulatory conditions of approval (e.g., risks to subjects are minimized). Study resources may include some or all of the following: the adequacy of research funding, adequacy of staffing, the location of the research, investigator qualifications, service referral, etc. The exact resources considered adequate for human subject protection are study specific. For example, the location of the research may not be at issue if the study is a registry or chart review only study, but would be of importance in studies where medical interventions or subject interactions (questionnaire/survey research or behavior research) are to occur. In cases where medical records are being collected for the research study, key personnel’s access to the medical records and whether they are Aura-owned medical records should be considered.

Within the Aurora research submission process, information is collected to assist the IRB in their assessment of resource adequacy relative to the following topics:

Location of the research activities is appropriate to minimize risks – both physical and psychosocial (e.g., privacy and/or confidentiality) – to subjects.

- Will the research be done in an Aurora hospital or clinic, or a non-Aurora hospital or clinic? Aurora hospitals are JCAHO accredited institutions. Aurora clinics have standards established by the institution that address the care and safety of patients. “Other” locations to consider include: clinic or office hallway, private office, home or residential environment, school classroom, clinic waiting room.
- Are clinical facilities adequate to execute the protocol requirements?
- Is adequate/appropriate equipment available to conduct the study?
- Are appropriate emergency procedures/equipment/services available

Principal Investigator (PI) training/expertise – necessary clinical and research privileges/training have been secured and are appropriate to perform/oversee the research. It can be assumed that the PI has completed IRB required research training prior to the review of the research.

- Questions relative to required clinical privileging are part of the submission application.
- A CV of the PI is obtained as part of the submission process, and is provided to the Primary Reviewer.
- Number of research studies that are open to subject enrollment, and are under the oversight of the PI. This information will be generated by the RSPP office and included with the submission packet.
- For novel technologies and/or the potential for increased risk of mortality and/or morbidity, the IRB should evaluate whether the clinical investigator’s previous specific experience in this field and with the test article are appropriate. The IRB should consider whether new medical credentials are necessary.
- Are support services (e.g., translation services, genetic counseling, psychological counseling, referrals to other services) available/adequate?

Research staff resources/training

- Appropriate number of research/clinical staff to carry out study procedures – this should be considered by reviewing the Delegation of Authority log included with the submission packet.
- Research staff is qualified by training and experience to carry out the research procedures delegated to him/her (clinical privileges, research training/experience). It can be assumed that all key personnel have completed IRB required research training prior to the review of the research.

Pharmaceutical and device controls – includes consideration of storage, handing and dissemination of investigational drugs, biologics, placebos and devices.

A listing of the specific study procedures and the risks to subjects, and whether these risks are appropriately minimized

Does the study design and protocol monitoring adequately minimize the risks to subjects?

Is there adequate funding for the study? Especially for investigator-initiated research, the IRB should consider whether the funding is adequate. Funding source is listed on the submission application.