Scientific Review and the IRB

A key component of an Institutional Review Board (IRB) review is considering scientific merit as a function of protecting the rights and welfare of human subjects. Excerpts of Federal regulations 45 CFR 46.111 and 21 CFR 56.111 are quoted below to support review of the scientific basis for the proposed research when evaluating the risks and benefits associated with the proposal. Research that is not scientifically sound and cannot achieve its stated objectives may not be considered ethical research. The IRB evaluates whether the design of the research protocol is sound and minimizes risks to participants.

> "(1) Risks to participants are minimized: (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
> (2) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result."

Note that research protocols that qualify for exemption from federal regulations per 45 CFR 46.104(d) do not require scientific review.

With this in mind, there are several options researchers and the IRB may use to ensure the scientific merit of research submitted to the IRB for review:

1. **For research previously subjected to full peer review (e.g., reviewed by a study section, grant committee or grant agency):** No additional internal scientific review is required. This assumes that the actual research study submitted to the IRB was peer reviewed in its current form. Note the IRB may request a copy of the proposal as part of the review processes.
2. **For social, behavioral and educational research (all levels of review) that is "no greater than minimal risk":** Scientific review is the responsibility of the college, school, department, or faculty advisor.
3. **If research is determined to be "greater than minimal risk"* the UCCS IRB reserves the right to request information about the scientific review process, or to require a scientific review on a study-by-study basis:** These reviews are not designed or intended to serve as a peer review intended to maximize scientific quality, but designed to meet regulatory criteria outlined above with regard to human subjects protection. The review may be performed by members of the IRB reviewing the study, and is based on **45 CFR 46.111**.
    a. If the IRB does not believe it has the appropriate expertise to review a particular study, then it will call upon the help of an outside consultant with the appropriate expertise.
4. Fewer than 1% of studies reviewed by the IRB in a given year are determined to be "greater than minimal risk."

Additional information regarding the components of reviewing scientific merit can be found in the Standard Operation Procedures for the Institutional Review Board.