U-MIC TRANSCRIPT
Umbrella Projects

OHRP regulations and guidance specify that IRB review is not required for projects lacking immediate plans for involvement of human subjects. "Certain types of applications and proposals **lack definite plans** for the involvement of human subjects either because **the specific human subject activities have not yet been fully developed**, or because **human subject research was not anticipated** at the time of the application. In such cases, the application or proposal need not be reviewed by the IRB prior to an award (see 45 CFR 46.118 and 46.119).

Before releasing funds for research involving human subjects, granting agencies typically ask for documentation of IRB review and approval. Some agencies, including National Institutes of Health (NIH), ask for documentation of IRB approval before finalizing a funding agreement even if the funding will not directly or immediately support any specific human subjects research. For instance, IRB approval may be requested for a training grant, program project, or center grant where the money will be distributed among various studies; or for a project that will eventually involve human subjects, but this "will depend upon completion of instruments, prior animal studies, or purification of compounds." http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.118

These projects are commonly referred to as “umbrella projects” or “dry applications.” To submit an umbrella or dry application in eResearch, select the application type "Projects lacking immediate plans for involvement of human subjects, their data, and/or their specimens."

Umbrella applications may be reviewed using an "Expedited review procedure." This means that review may be conducted by an individual, such as an IRB Chairperson or other qualified Board Member.

Umbrella applications, particularly center grants or program project grants, that do not anticipate an human subjects research component may be able to "Terminate" after the grant is finalized. Umbrella applications that do anticipate a future human subjects research component must apply for and receive IRB approval prior to beginning the research. This may be accomplished by either amending the existing "umbrella application" to become a "Standard" application, or by creating a separate Standard application.

Posted: 5/29/2013