**Grant Proposals Lacking Definite Plans for Involvement of Human Subjects**

Certain types of applications may involve human subjects (within the funding period) but definite plans are not included in the application or protocol (45 CFR 46.118). This type of application would include such activities as institutional grants, training grants, and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Regulations give federal agencies and their grantee institutions the discretion to allow a limited release of federal research funding to investigators without approval or exempt status. Conditions include:

* Human subjects involvement will depend upon completion of significant pre-human subjects development activities, or
* The award is for a clinical research network or consortium that plans to add new protocols over the course of the award, or
* The award is for funds that will be awarded to specific projects that will be selected and funded by the awardee (e.g., a pilot project program; some training grants).

*This form is recognized by the IRB only as a compilation of research being conducted under a specific grant. It does not constitute a review of the risk/benefit ratio of protocols to be conducted under it.*

*Those protocols (including informed consent documents) must be submitted for IRB review and approval separate from this request.*

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| **1.** | **PROJECT TITLE** | | | |
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| **2.** | **PRINCIPAL INVESTIGATOR INFORMATION** | | |
|  |  | | | |
|  | Principal Investigator (PI): |  |
|  |  | | | |
| **3.** | **Is this review request for** (check applicable) | | | |
|  |  | | | |
|  | **Individual Training Grant** (salary support only –research activities occurring under separate approved protocol(s)) | | | |
|  | **Program Project** (all research activities occurring under separately submitted protocols) | | | |
|  | **Grant when the research has yet to be developed.** (projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds.) | | | |
|  |  | | | |
| **4.** | **Provide a brief explanation of why human subjects research plans are not yet fully developed (or other reasons for submitting this form):** | | | |

***\*Note: When the human subject research activities are developed, you must submit a human subject protocol for review and approval prior to the research activities beginning.***