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

Certain types of applications may involve human participants (within the funding period) but definitive plans are not included in the application or protocol ([45 CFR 46.118](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.118)). This type of application would include such activities as institutional grants, training grants, and projects in which human participants' 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 participants’ involvement will depend upon completion of significant pre-human participants 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 as a to-be-developed compilation of research being conducted under a specific grant. It does not constitute an actual IRB review of the risk/benefit ratio of protocols to be conducted under it.

*Future protocols must be submitted for IRB review and approval separate from this request. This is not an IRB approval for a protocol but a mechanism to allow funds to be distributed while the human subjects protocol is under development.*

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| 1. Principal Investigator’s name |  |
| 1. Grant Title |  |
| 1. SPA Funding Proposal # |  |
| 1. Provide a brief explanation of why human subjects research plans are not yet fully developed (or other reasons for submitting this form |  |

***\*Note: When human participant research activities are developed, you must submit an IRB protocol for review and approval prior to the research activities beginning. Except for research waived under § 46.101(i) or exempted under § 46.104, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Federal department or agency component supporting the research.***