P&F PROJECT PROPOSALS INVOLVING HUMAN SUBJECTS - Application Resources

For the preparation of a Joslin Diabetes Center (JDC) P+F application, JDC Investigators will work as usual with the Office of Sponsored Research's Pre-Award Administration Team, and follow the normal grant application preparation deadlines and other procedures. Investigators from other institutions who are preparing a JDC P+F application will follow, prior to submission, the procedures at their home institution.

This section is intended to point to resources that assist Investigators to:

1) Determine whether or not a proposed P+F project needs to be designated in the application as "human subjects research;"

2) Determine whether or not a proposed P+F human subjects research project needs to be designated in the application as a "clinical trial;"

3) Understand the additional application requirements for projects that are "human subjects research" and/or "clinical trials."

***Please Note*: Prior Approval for P&F Projects Proposing Studies Posing More Than Minimal Risk to Human Subjects**

All selected P&F projects that will support clinical trials or studies of more than minimal risk to human subjects MUST receive prior, written approval from NIH prior to P&F award. Whether a clinical trial or study is minimal risk should be verified by the institution's IRB; however, minimal risk is often defined as:

"A clinical trial or study where the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

For a clinical trial or study that is more than minimal risk, the Joslin institutional business official must provide the following materials to the NIH Program Official and Grants Management Specialist prior to award of the P&F project:

- PI Name and Position/Title
- Project Title
- Brief description of the study protocols that address risks and protections of human subjects, including the project purpose/aims, intervention(s), outcomes, and eligible population with sample size
- Data and Safety Monitoring Plan

Resources to assist Investigators:

Is the proposed project "human subjects research?"

a) This NIH site (link below) offers a wide spectrum of information useful to investigators and institutions when applying for grants relating to human subject research, including definitions, and decision-tree type questionnaires.

https://humansubjects.nih.gov/

b) For JDC Investigators, the JDC Committee on Human Subjects policy documents CHS-050 and CHS-051 (on the Joslin intranet) describe for JDC Investigators how Joslin determines whether a project involves "human subjects research," whether a project is exempt from review, and related JDC procedures.

Is the proposed project a "clinical trial?"

c) This NIH site (link below) offers comprehensive information useful to investigators and institutions when applying for grants for human subject research projects that might involve clinical trials; covering definitions (including 'minimal risk'), and decision-tree type questionnaires.

https://grants.nih.gov/policy/clinical-trials.htm

NOTE: P+F projects selected for funding that are determined to be a clinical trial with greater than minimal risk to participants, will required approval from NIH before initiation.

How to answer the questions on the PHS Human Subjects and Clinical Trials Information form?

d) Below is a link to the current NIH Application Guide for Research applications. It contains detailed guidance on the PHS Human Subjects and Clinical Trials Information form.

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/research-forms-e.pdf