Capturing IRB Protocol-Proposal Congruency

For NIH research involving human subjects at Just-In-Time (JIT)

The Office of Grant and Contract Administration (GCA) in partnership with the Human Research Protection Program (HRPP) is formalizing the protocol/proposal congruency process in order to better comply with 45 CFR 46.103(f).

The new process which will be effective as of June 16, 2014:

- Applies ONLY to NIH proposals at Just-in-Time (JIT);
- Is designed to capture all Human Investigation Committee (HIC) or Human Subjects Committee (HSC) approved protocols associated with an NIH proposal, prior to submission of Just-In-Time (JIT) documentation; and
- Allows for protocol number(s) and congruency date to be recorded in a central location, reducing administrative burden for Department Business Offices (DBO).

In support of the congruency process, a new form has been created to capture all protocol(s) associated with a NIH proposal and to document the date of congruency. The form, located on the HIC and HSC websites, will be:

- Prepared by the NIH proposal’s Principal Investigator (PI),or by Protocol PI(s);
- Sent with the relevant protocol submission documents to the Human Investigation Committee (HIC) or Human Subjects Committee (HSC) in order to conduct a congruency review; and
- Routed to GCA in advance of submitting the required JIT documents.

Note: GCA will no longer need or request HIC or HSC approval letters for NIH JIT submissions.

Three auditorium information sessions to review this process change and introduce the new form are scheduled for:
- Tuesday, June 10, 2014 from 12:00pm – 1:00pm in TAC N107
- Monday, June 23, 2014 from 12:00pm – 1:00pm in the Brady Auditorium
- August, date to be determined

Users can sign up for these opportunities through TMS by clicking here or by going to:


Questions

For questions for how this impacts the GCA NIH JIT process, please contact either Laura Kozma (laura.kozma@yale.edu) or Cynthia Kane (cynthia.kane@yale.edu).