We're In The Money! Adding New Grants to Existing IRB Submissions

Emory IRB Webinars

5/9/2019

Topics to Cover

- Regulatory requirements associated with IRB review of grants
- The required information and documentation to include with submission
- Situations where it is more appropriate to submit a new study

When should you submit your grant to the IRB?

When to add?

Generally, no need for IRB review until "Just In Time" stage

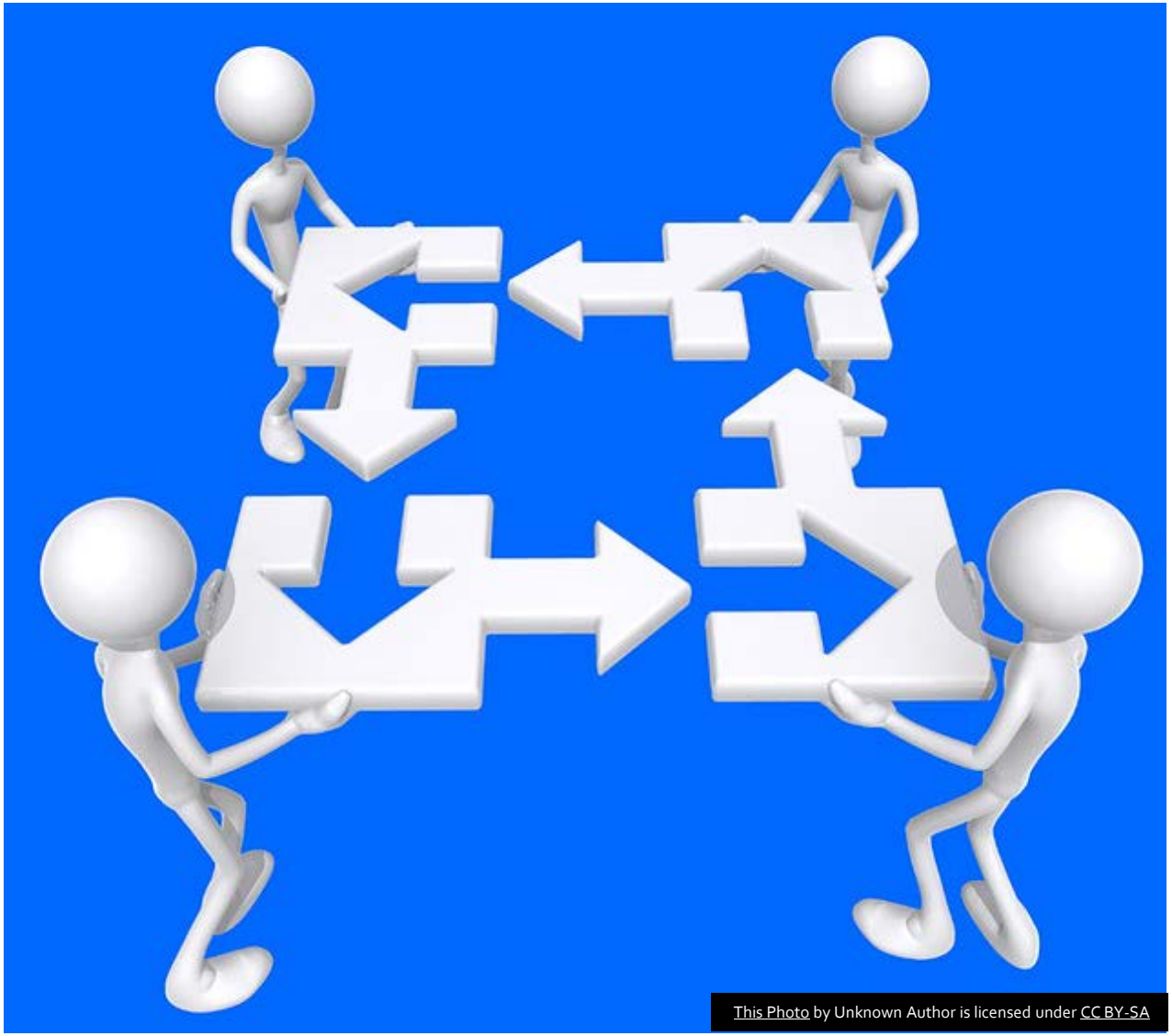
Rarely, a funding agency will require IRB approval with grant application

NOTE: Work with OSP analyst if IRB approval is pending – NIH normally accepts and issues award with restrictions

Requirements regarding grant funding and human subjects protocols

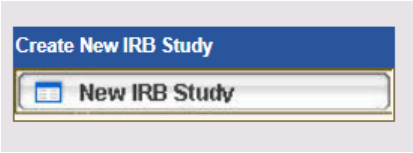
- NIH and other funding agencies require that the **institution certify** for each grant application that any human subjects research was reviewed and approved by an IRB.
- This means that an IRB must **review all human subjects activities** of every grant application
  - Not via simply receiving the grant application, but by having all activities **submitted as part of a protocol(s)** that follows IRB protocol guidelines.

Though the Revised Common Rule removed the grant-congruence from the IRB responsibilities, the Institution still needs to certify, which requires IRB input



Set Expectations

In general, expect new grants to require a new study submission.



What does the IRB need to review?

When Human Subjects Research is Not Yet Developed

- Grant may fund development work needed prior to "human subjects" phase.
- If NIH requires IRB "approval" while methods/instruments are not yet developed:
  - Submit to the IRB the grant with protocol that explains what is known and what is yet to be developed
  - No consent form needed if not feasible to be created yet
- Once specific methods and materials are developed for research with human subjects, submit an amendment before starting any HSR activity

When to submit grant as an amendment

- The aims and objectives of the grant align with the currently approved protocol
- Only minor changes are needed
- The PI of the existing IRB agrees to take responsibility for the work of the Grant PI (if different)
- The existing IRB-approved protocol is not a registry/repository designed to be used for other research studies
  - Repository studies are generally only for collection and storage, not use in specific research studies

Submitting the Amendment

Highlight relevant sections of the grant and protocol. *May* be done via adding an ancillary/substudy document instead of revising existing main protocol

Make sure any consent forms reflect the grant in the heading, HIPAA, and/or confidentiality sections

If the grant is federal, OHRP needs to be added to the Confidentiality or HIPAA sections

If NIH funding is being added for the first time, Certificate of Confidentiality language should be added (and old language about subpoena removed)

Attestation Statement

If applicable, explain what changes are being made to the consent form, smartform, and/or protocol to align with the grant. *Be sure the IRB application includes 'Changes to Protocol' and not just 'Changes to Funding'* ***or***;

Indicate in writing that you have reviewed the current protocol and consent and smartform and found they did not require any changes to match the research highlighted in the grant.

For example…

"The research grant R01-23456789 included in this submission aligns with this IRB-approved protocol. Research described in specific aim 1 describes the use of de-identified specimens collected as part of this study (IRB 1234).

This amendment highlights relevant sections from specific aim 1 in the attached grant and protocol. In addition, the consent has been updated to reflect the new funding and CoC language has been added"

When to submit a new study

- The aims and objectives of the grant do not align with the currently approved protocol
- The grant covers the analysis of data/specimens and from a repository/registry IRB protocol
  - Repository studies are generally only for collection and storage, not use in specific research studies
- Study team does not overlap with study team on existing IRB
- New grant introduces regulatory issues not already present in existing IRB (exceptions possible)

For additional information, go to our guidance:

Guidance to Connect Grants and IRB Approved Protocols

Remember: Talk to IRB when in doubt!

Why does the IRB care whether amendment or new study?

- Keeping IRB submissions streamlined reduces potential for regulatory headaches, IRB confusion, and review delays.
- IRB experience with allowing multiple new investigators and their grants to be added to existing IRBs: Saves time for investigators but hard for IRB to track status of various substudies, consent considerations, enrollment numbers, progress…
- Different IRB and ancillary review requirements for different substudies tied to various grants causes confusion.

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