Research Congruency Review

What is Grant Congruency Review?

Grant congruency review is an evaluation of a grant award/proposal compared to the associated research protocol(s) to ensure consistency in the research activities that will be conducted.

It is a one-way review grant/proposal-to-protocol(s) – i.e., everything described in the proposal must appear in the protocol(s), but the protocols can have additional experiments/procedures/etc.

How is congruency between a grant proposal and research protocol assessed?

Congruency is evaluated for several parts of the grant application and the protocol. Information to be reviewed includes, but is not limited to:

- Key personnel (as listed on the proposal)
- General scope of work:
  - Specific aims/protocol objectives
- **Human Subjects:**
  - Participant population (number of subjects, age, gender, inclusion/exclusion criteria)
  - Intervention (surveys, interviews, focus groups, etc.)
  - Recruitment and informed consent process
  - Subject compensation (feasibility of financial commitments made to subjects)
  - Protection of human subjects - Potential risks and benefits
  - Privacy and confidentiality - Protection of personally identifiable and/or protected health information
  - Source of materials (e.g., Database or collaborator – is a DUA or MTA needed?)
  - Data and Safety Monitoring Plan
  - Data Management and Sharing Plan
  - Collaborators and performance sites
    - Reliance agreements (external IRBs), multiple IRBs, sIRB
    - Letters of cooperation
- **Animal Research:**
  - Species and strains
  - Animal numbers and age/sex proposed
  - Procedures (e.g., surgeries, tumors, agents administered (route, dosage), etc.)
  - Additional sites for animal experiments – is a Memorandum of Understanding (MOU) needed?
- **Biosafety/Radiation Safety/Chemicals** (this will be reviewed by EHS directly):
  - Are you using rDNA, synthetic nucleic acids or biological materials (e.g., cancer cells, biological toxins, microorganisms)? – Make sure to submit or update your MUA.
  - Do you have up-to-date sublicenses, registrations for radioisotopes, x-rays, lasers?
  - Are you working with controlled substances, hazardous chemicals, select agents, etc?

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What can a PI do to ensure as little delay as possible?

Because the majority of research proposals are not funded, it is unnecessary to submit all proposals for a congruency review at the time of proposal submission. However, when the PI receives a JIT notice, a score that places the proposal in the fundable range, or if there is reason to believe that the work will be funded, s/he should begin the process by contacting RIO. This is the best way to ensure sufficient time for the congruency review and an amendment, if necessary, before the award arrives at UH.

- If a protocol exists, make sure that it fully covers the proposed experiments – submit an amendment/modification to add the funding and modify the protocol as needed.
- If a protocol does not exist, create a new protocol and make sure that it covers all experiments described in the proposal.

What happens if the proposal is deemed to be not congruent with the protocol(s)?

You will receive a communication via e-mail or ICON describing/listing the discrepancies found (e.g., data collection procedures not described in the protocol, insufficient number of participants, different strains, collaborators and/or performance sites not listed in protocol, etc.).

Once you receive this communication you should respond as soon as you can:

- Submit an amendment/modification to your protocol to "fix" the discrepancies

OR

- Provide a justification for the discrepancies. If the justification seems to alter the SOW of the grant, you will be asked to obtain permission from the sponsor.

Are there other types of Research Congruency Reviews?

Both Material Transfer Agreements (MTA) and Data Use Agreements (DUA) undergo a review and approval prior to the contract being signed and executed.

For questions regarding "incoming" and "outgoing" MTAs and DUAs please send an email to dorcontracts@listserv.uh.edu. The Research Contracts office will initiate the process and negotiate the agreement. Other offices will review the contracts (coordinated simultaneously and directly by DOR) as follows:

	MTA	**DUA**
Research Integrity and Oversight (RIO)	Human Subjects samples and/or Animals	Human Subjects data
Environmental Health & Safety (EHS)	Biohazards (rDNA, microorganisms, toxins, select agents, etc.) Chemicals Radiation, x-rays, lasers	X
Office of General Counsel	X	HIPAA, FERPA, Privacy laws
UH Information Security	X	Data transfer and storage

Who do I contact if I have any questions?

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