Hello all,

The Office of Research has performed a major revision of the Proposal Data Sheet. We have added, combined, revised, and moved questions. Below we outline the changes, and provide some reasoning why the changes were made:

**Assurance #1:**

**New language:**

“Will any human subject research be conducted on this proposal? Yes No
Will any of the H.S. research be performed at UCSB or by UCSB personnel? Yes No

Human subjects means a living individual about whom an investigator conducting research: 1) Obtains information or biospecimens through intervention or interaction with an individual, and uses, studies, or analyzes the information or biospecimens; or 2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (Private means information an individual can reasonably expect will remain private, like a school/medical record or identifiable tissue/blood.)”

We split the question of whether human subject research is involved into two questions to clarify when the human subject research (HSR) described in the proposal is being performed at a sub-award site(s) only (not at UCSB). The “old” process was burdensome, requiring us to create place holder HS protocol in ORahs so funds could be released when the proposal has been marked as having human subjects research (HSR), but the HSR is only being performed at a sub-award site. The new questions allow us to remove this step if the HSR is being perform at a sub-award site only and not at UCSB - this stops unnecessary work for the HS staff and gets rid of the delay for our researchers to get their money. The subrecipient performing HSR will not receive any money until they provide us with the proper paperwork.

**Assurance #2:**

**New language:**

“Does this proposal involve non-exempt human subject research to be conducted at multiple U.S. sites involving NIH-funding through a grant, cooperative agreement, or contract (excluding career development, research training or fellowship awards)?
A multi-site study is where the same non-exempt HS research study is being conducted at more than one domestic site.

*If Yes to the above, please contact UCSB’s HS staff at hsc@research.ucsb.edu.*”

This is for NIH-funded (prime or flow through; grant or contract or cooperative agreement) proposals only. This is in response to the new NIH mandate for single IRBs. We want to know this at the proposal stage because setting up a single IRB to serve as the IRB of Record for multiple institutions will likely require additional time and effort. This process should not be put off until “just in time” rolls around.
The process of coordinating could take months depending on the number of institutions involved and the complexity of the research.

**Assurance #5:**

**Language:**

“If the proposal is being submitted to PHS/NIH, will the research generate large scale human and/or non-human genomic data? If Yes, a Genomic Data Sharing plan needs to be included with the proposal.

Large scale genomic data includes phenotypic data, genome wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, genomic sequencing, transcriptomic metagenomic and epigenomic data, gene expression data, and any use of that data for future research.

If the proposal involves sharing human data, then you will need to obtain an Institutional Certification from the Research Integrity Office to assure compliance with NIH regulations. You are encouraged to contact a Research Integrity Specialist (researchintegrity@research.ucsb.edu) at the initial “Just in Time” notification to obtain the Certification.”

This assurance was once grouped with a COI question and has now been separated out and moved near the other Human Subjects questions. No new requirements here.

**Assurance #6:**

**New Language:**

“Will any vertebrate animal research be performed on this proposal? Yes No
If Yes, will any of the vertebrate animal research be performed at UCSB or by UCSB personnel? Yes No

Have you discussed animal housing needs with the ARC Director? Yes No
If No, the PI must seek approval from the ARC Director for animal housing space”

This assurance was split into two questions for the same reason that the human subject research question (Assurance 31) was split. This “new” assurance allows us to identify when Animal Subjects research is being perform at a sub-award site(s) only. This allows us to avoid having to create a placeholder protocol and removes the delay for our researchers getting their money.

**Assurance #8**

**New Language:**

“Will any of the following be used for this project: Chemicals (solids, liquids, or gases); Radioactive materials; X-ray producing machines; Non-ionizing radiation (lasers, UV, microwave); Biosafety Level 2, Level 3, or “Select” Biological agents; Recombinant DNA; Human/primate tissues or fluids; Animals or animal tissue/fluids; Research divers/dive equipment/small boats; Controlled Substances (DEA Schedule I-IV)?
If Yes, complete the EH&S Contract and Grant Questionnaire (http://www.ehs.ucsb.edu/lab safety/ehs-contract-and-grant-approvals).”

This question combines the two “old” EH&S questions into one and now asks if the researchers are using any Controlled Substances (DEA Schedule I-IV).

**Assurance #10**

**New Language:**

“Does the proposed research involve any of the following: foreign sponsor, foreign collaboration, foreign sub-recipient(s), international shipments of any commodities or technology (e.g. materials, software, etc.), travel to foreign countries or research at foreign sites by UCSB personnel? Please contact Research Integrity staff at exportcontrol@research.ucsb.edu for any questions regarding this assurance.

Please provide a brief description of the foreign/international involvement “

This is a new question to help the Export Control staff determine if there are any issues that they need to follow up on. If you answer “Yes”, then you will be expected to provide a very brief description of what is going on. For example, a description stating “Foreign travel” is insufficient. However, “Foreign travel to China and Japan” is great. We simply need to know what foreign country(ies) is involved and how.

In the near future there will be an add-on ORBiT update that will include a new Research Integrity Export Control Queue.

We will be holding a Zoom meeting in the upcoming weeks to go over these changes and to answer any questions.

However, please feel free to reach to us for clarification at any time.

Thanks,

Brandt