

Guidelines for incorporation of Ancillary Study Research at FHS in-person Offspring/Omni-1 examination 11/6

There has been tremendous interest by the FHS Ancillary Study community in participating in Offspring exam 11/Omni exam 6. We have received 20 exciting and creative exam-related proposals across a range of scientific disciplines. Typically, we can accommodate a 4-to-4.5-hour examination, which means that not all proposals can be included in the Research Center exam time frame. The FHS Exam Committee assumes the responsibility for time burden proposed for participants and assembles an exam around participant safety and science.

The Committee is guided by the existing FHS Executive Committee Ancillary Study Research Applications Policy to ensure equity with a goal to include a diversity of investigators, institutions, and science in the exam and to support and promote Early Career Investigators. For a study with participant burden to be included in the exam, funding is needed at least 3 months prior to the start of the exam to ensure adequate planning and testing readiness (e.g., IRB approved informed consent, staff hiring/training, equipment purchase, pilot testing, quality control protocols). Below are some guidelines for new exam components.

- Secure funding early. Applications funded after the exam planning period (minimum of 3 months prior to exam start) will not be considered for the in-person exam 11/6. This includes participant testing that can be done outside the research center entirely remotely as many applications are proposing in-person and remote testing as part of their protocol.
- If more applications are funded than can be accommodated in the single core visit, a second Exam 11/6 visit (Exam 11/6 Part 2) will be considered but will need Executive Committee and OSMB approval. At present there is not infrastructure from the FHS contract for this activity so studies participating in a potential Exam 11/6 Part 2 will likely be assessed additional costs.
- Priority will be given to applications funded from non-commercial entities that are subject to a rigorous competitive review process.
- Communications with Ancillary Study PIs will continue as we gain more information throughout the grant application submission process to determine if the content for the exam becomes full or is exceeded.
- Proposals with overlapping content: If two or more proposals with overlapping content are submitted and funded simultaneously, study teams will be required to jointly develop a single methodology. A written agreement must be signed by both investigators. There will be no exclusivity period between study teams for data derived as part of these studies.
 - IF one FHS study proposal is funded before another FHS study proposal with overlapping content is submitted, or resubmitted for funding, FHS will notify the subsequent study that the specific overlapping content will need to be excluded from any future request for funding support. At that time, approval for the relevant FHS proposal will be withdrawn, and investigators may proceed with the following options:
 - A.) Contact the funded PI and request permission to collaborate. A funding proposal may then be submitted excluding the overlapping content. *A written agreement must be signed by both investigators.*

- B.) Submit an amendment to their prior FHS proposal to the APRC, excluding the overlapping component. A funding proposal may then be submitted excluding the overlapping content.

We appreciate your interest in the FHS and look forward to working with you.