

## **Ancillary Studies with Exam content for Exam11/6: Information to include with the FHS Research Application**

### **Testing components:**

#### **Questionnaires**

- Please include the questionnaire(s) with the proposal documents
- Please indicate whether the questionnaire has been validated
- Has the questionnaire been used in a sample of a similar age range to the FHS Offspring/Omni (mean age 80 years)?
- How much time does the questionnaire take to administer in adults in this age range?
- Has the questionnaire been used in a population setting? If not, what is the rationale for use in the FHS?
- If ascertaining sensitive information e.g., finances, does the PI have any feedback from participants who have responded to the questionnaire? Are there any data security concerns?

#### **Testing proposed**

- If the PI has used the same/similar testing at a previous FHS exam cycle, what proportion of participants were tested (what proportion of eligible participants agreed to take part in the study)? Were data returned to FHS? Have any publications resulted from the data?
- If similar testing is in progress, please provide some metrics of data collection quality; participant acceptance
- If proposed testing is new to FHS, does the PI have experience with the testing elsewhere?
- Are there complications/adverse side effects associated with testing? If yes, what are the expected complications/side effects? How often? What response is needed in the research center?

#### **Lab testing**

- Specimen type? Volume? Assay?
- Proposed Lab for analyses?
- Preliminary data?

#### **Statistical power to support study aims**

#### **Medically actionable results from data collected**

If there is a medically actionable result that might come from the data collected, what is the process for participant and healthcare provider notification (action plan)?

#### **Commercial Partners?**

Will commercial partners seek access to data or have any input on study design?

**Funding sources** Please list all funding sources that PI plans to submit the application for potential funding support.