study Population worksheet

**SECTION I**

Provide answers to each of the questions listed below:

1. Provide justification for the proposed study population based on the biomarker category and context of use.

2. Clearly define the baseline characteristics of the study population, including control groups (e.g. age, MMSE score, ApoE status, amyloid status, co-morbidities, medications, etc.).

3. Describe your plans to include individuals from minority and disparity populations?

4. **For validation studies**, describe which relevant clinical neuroimaging and CSF endpoints will be used to correlate with the candidate biomarker(s).

**SECTION II**For projects that plan to recruit human subjects or use specimen from active clinical trials, please provide answers to each of the questions listed below.

1. Briefly describe the design of the clinical study.
2. Is this a single or multi-site study? If the study includes more than one site, what strategies will be used to reduce variability across different trial sites?
3. Have you or your collaborators previously recruited the proposed patient population?
4. What strategies will be used to promote recruitment and complete enrollment in a timely manner?
5. Has the study been IRB approved? If not, please comment on the expected timeline for approval. Does the protocol and the informed consent provide specific approval for use of patient/subject data and collected/stored specimens as proposed?
6. For longitudinal studies, how will dropouts be reported and managed in the statistical analysis?