**Human Subjects Questionnaire**

**For studies recruiting human subjects, provide responses to all of the questions below.** Save as a PDF and compile into the appropriate section within the Body of the Application.

1. Provide justification for the proposed clinical population based on the mechanism for the therapeutic agent or biomarker.
2. Discuss the inclusion of control groups and/or placebo arms.
3. Clearly define the clinical population and include detailed inclusion/exclusion criteria.
4. Provide a statistical analysis plan. Include a power analysis to justify the number of subjects per group. Has your power analysis accounted for previously observed variability in your outcome measures?
5. How will dropouts be reported and managed in the statistical analysis?
6. 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?
7. Have you or your collaborators previously recruited the proposed patient population?
8. What strategies will be used to promote recruitment and complete enrollment in a timely manner? List the channels (i.e. media, public events, community physicians’ offices, etc.) that will be used to reach the targeted patient population. Describe the types of materials that will be developed as part of the recruitment toolkit.
9. How many other academic or industry-sponsored trials in the same patient population as the proposed study are ongoing at your trial site(s) or within the same geographical area?

**For clinical trials only, provide responses to all of the questions below if your proposal includes clinical testing of a therapeutic agent in humans.**

1. What are your primary and secondary outcome measures? Have the biomarkers been validated to detect changes in defined patient population within the specified treatment time of the proposed trial.
2. What is the pharmacodynamic readout of target engagement?