Recruitment Materials

1. The Reviewing IRB is solely responsible for reviewing and approving the recruitment plan and materials for the study. Recruitment plans and materials cannot be modified for each site with the exception of local contact information.

2. The Reviewing IRB evaluates recruitment plan based on its effect on equitable subject selection and study inclusion/exclusion criteria, and should not include payment arrangements that target economically disadvantaged participants or can lead to unfair selection of participants.

3. The Reviewing IRB reviews proposed recruitment plan and advertising materials to judge whether they fulfill the requirements for consent.

4. Suggested Key Elements:
   a. Purpose of the study
   b. Risks of the study
   c. Benefits of the study
   d. Description of study procedures
   e. Basic eligibility criteria

5. Target return time for review of IRB documents:
   - 5-7 days

6. Significant Modifications:
   a. Pre-approval: N/A
   b. Post-approval:
      Any changes to the recruitment materials first vetted through Relying Institutions for any local institutional policies related to recruitment including local contact assessments. Once its verified, the recruitment is sent to the Reviewing IRB