The following information is meant to serve as a guide as you determine study subject recruitment and retention needs for enrollment efforts. Developing a proactive recruitment and retention strategy in advance of study start will help the study to be a success, as well as potentially off-setting the costs of implementing a rescue plan down the road.

We highly encourage you to include a full range of subject recruitment tactics during the initial IRB submission process.

- What is the target enrollment?
  - Is enrollment competitive?
  - Will the study be terminated once enrollment is met?

- What are the recruitment milestones / timelines?

- Target population: inclusion / exclusion criteria?

- What does the recruitment funnel look like?
  - Enrollment vs screen failure rates (do screen fails count towards enrollment?)

- What is the study design (e.g. open label vs. placebo-controlled) risks, potential benefits?

- What strategies have you previously employed?
  - What worked?
  - What didn’t work?

- What resources do you need?
  - Do you have a research nurse
  - Residents / Fellows
  - Do you need additional recruitment support?

- How will you recruit?
  - EHR databases (ARCH reports, i2b2 cohort discovery)
    - Good for feasibility during CSEC process
    - IRB approval not required for de-identified search
    - Once cohort discovery is complete, IRB approval required for de-identified records and treating physician approval to reach out to patients
  - Existing patient base
  - Advertising – flyers, table tents, websites, newspapers, radio, television
  - Community outreach / events
  - External clinics / schools / facilities
  - Physician referrals (department, private practice)
  - Websites (PHI must be protected; HIPAA)
    - Include online recruitment in eIRB as standard for interventional & observational studies
    - Submit clinical trial summary template for posting to JCTO website
  - Social media – requires regular ongoing content updates (permission required from External Affairs)

- Does the study offer compensation / reimbursement?
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- How much?
- What form of compensation are you using?
  - ClinCard, check, gift card

- Is the sponsor offering a recruitment budget?
  - If yes, how much?
  - If no, is it possible to ask for funding?

- Is the sponsor providing recruitment materials?
- Can you support other languages for recruitment efforts?
- Do you have a screening log for documentation? Including:
  - Number of participants screened
  - Dates
  - Reason for exclusion
  - Gender
  - Age
  - Referral source

- What is your process for retaining subjects throughout the course of the study?
- Is there a study algorithm for enrolling in multiple trials?
- Do you have an enrollment waiting list or database for reaching out to subjects for new studies?
- Other?

Sample tactical materials
Subject Recruitment Copywrite
Subject Recruitment Flyer 1
Subject Recruitment Flyer 2
Subject Recruitment Patient Study Notice
Subject Recruitment Physician Referral Request
Subject Recruitment Study Q&A
Subject Recruitment Tracker

For additional information about or support with subject recruitment efforts and the various opportunities, please e-mail JCTOSRC@med.cornell.edu.