

Joint Clinical Trials Office (JCTO)

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.