

Research Study Feasibility Tool

How to assess whether a new study is a good fit for you and your team

Science	Population	Resources
<p>Is the question important?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Does this study really matter to you? <input type="checkbox"/> Do you believe it will make a significant contribution to the existing body of knowledge? <input type="checkbox"/> Who are your internal stakeholders? Think about your department, the clinical population, access to colleagues and research staff, as well as research facilities and services. <input type="checkbox"/> Who is it that will directly support this effort? Do you have an established research team? If not, how will you find people to help? <p>Do you have personal passion for this project?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Conducting clinical research is challenging. Are you willing to accept that there will be continuous problems? <input type="checkbox"/> In the face of potential chaos and challenge, are you willing to be your #1 stakeholder? <input type="checkbox"/> Is your research team willing to commit and persevere to get the study done? <p>Strength of the study's design:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Does the design employ a practical, realistic method to answer the study question? <input type="checkbox"/> Is the study adequately powered? <input type="checkbox"/> Do you realistically have sufficient patient population to recruit from? (Link to Cohort ID) <input type="checkbox"/> Will there likely be a high screen failure rate? <input type="checkbox"/> If you're administering a clinical intervention, are there potential benefits to the participants? <input type="checkbox"/> How much risk will participants have to endure? <input type="checkbox"/> Is the time required for participation reasonable? Will participants have to miss work or school in order to participate? <input type="checkbox"/> Does the benefit to society outweigh the burden to your participants? <input type="checkbox"/> Are the study procedures realistic? <input type="checkbox"/> Can you easily capture the data at your site? 	<p>Review eligibility criteria:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Are the inclusion/exclusion criteria too specific, too broad, or just right to get the data you need? <input type="checkbox"/> If they seem reasonable, do you have easy access to your target population? <input type="checkbox"/> How will you identify potentially eligible participants? <input checked="" type="checkbox"/> Electronic medical records <input checked="" type="checkbox"/> Clinic setting <input checked="" type="checkbox"/> Local advertisements <input checked="" type="checkbox"/> Referrals from colleagues <p>Is it easy for volunteers to participate?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Are research activities matched to study population preferences? <input type="checkbox"/> Are there significant obstacles for your study population that you could remove or mitigate? <input type="checkbox"/> Can you provide sufficient participant incentive? <input type="checkbox"/> Are there anticipated language issues? <input type="checkbox"/> How will you approach people? <input checked="" type="checkbox"/> While the PI might have the most information about the study, someone else may have more time to conduct in-depth informed consent discussions, or conduct certain study activities. <input checked="" type="checkbox"/> It's possible that the role of being both a clinician and PI may inadvertently influence a participant's decision to take part, since the person may interpret the opportunity to participate in research as a clinical recommendation. 	<p>Find other PIs or trusted research staff in your department who do similar work. Your goal is to find out how much time it typically takes for a study like yours to complete the following activities:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Initial and ongoing budgeting and billing <input type="checkbox"/> Initial and ongoing contracting <input type="checkbox"/> Initial and ongoing IRB review <input type="checkbox"/> Designing recruitment materials <input type="checkbox"/> Translating participant materials into other languages <input type="checkbox"/> Designing and/or training on implementation materials and systems, like the study database <input type="checkbox"/> Identifying and ordering study supplies <input type="checkbox"/> Creating operating procedures and recordkeeping systems <input type="checkbox"/> Outreach and interaction with participants for recruitment, consent, enrollment, and scheduling study visits <input type="checkbox"/> Capturing study data, chart abstraction, and data entry <input type="checkbox"/> Processing, analyzing, storing, and shipping specimens <input type="checkbox"/> Regulatory maintenance, record-keeping, and study monitoring <input type="checkbox"/> Managing adverse events and protocol deviations, and meeting your research compliance responsibilities <input type="checkbox"/> Coordinating communication (formal/informal meeting time) within the research team, and departments/facilities who are supporting the study, to catch up and troubleshoot problems. <p>Estimate salary support percentage for the different types of research team members who will carry out the activities above.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Research teams typically consist of PI, co-investigators and research staff (project managers, research coordinators, research nurses, research assistants, medical assistants, and data managers). Your Human Resources department may be able to give you salary estimates for these positions. If you already have an established research team, your Human Resources department can likely give you actual salary rates to calculate an accurate cost. <input type="checkbox"/> Check with departments who will support the study through their facilities and services to confirm they have the resources you need to seamlessly carry out all aspects of the study plan. Common departments to check with include: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Pharmacy <input checked="" type="checkbox"/> Laboratory Services <input checked="" type="checkbox"/> Pathology <input checked="" type="checkbox"/> Radiology <input checked="" type="checkbox"/> Central Research Office <input type="checkbox"/> Calculate the true cost for your volume of study activities and procedures versus the amount allowed by the study budget to determine if you have the funding you need. If not, work with your fiscal team to renegotiate the budget to ensure you can cover all your costs.