

Collaborating with TraCS resources and services

Mandatory Questions for Full Proposals

Please answer the following questions related to your project and TraCS resources & services:

1. Project Management

- a. Will your team be budgeting for a dedicated Project Manager/Coordinator for all aims of the project? (Yes; No)
- b. Has your team already identified a dedicated Project Manager/Coordinator for all aims of this project? (Yes; Not yet, but will if project is funded; No, not planning to hire one; Other)
 - i. If Yes: The following individual will support the following day-to-day management of project activities: _____
 - ii. Describe Other: _____

2. Research Coordination and Management Unit (RCMU)

- a. Will your team need assistance with study start-up, study execution, and/or study close-out? (Yes/No)
 - i. If No: Identify who on your team will provide this support: _____

3. Recruitment & Retention

- a. Are you recruiting participants for any part of your project? (Yes; No)
 - i. If Yes: Are you planning to engage with TraCS Recruitment & Retention to support this project? (Yes; No)
 1. If No: Do you have to the infrastructure necessary to support recruitment efforts (i.e. staff time, clinic support, specialized skills)? (Yes; No)

4. Regulatory Support & Agreements

- a. Will you need assistance with any of the following for this project?
 - o Protocol development support
 - o Guidance on human subjects and clinical trial information forms
 - o IRB guidance
 - o Clinical monitoring plan development
 - o Quality assurance/study monitoring services
 - o Drug/device development regulatory support
 - o Other regulatory assistance, guidance, or education
 1. Please describe: _____
- b. Briefly describe (2-3 sentences) any IRB or IACUC approvals that will be needed for this project: _____
- c. Does your project require the development of any Data Use Agreements (DUAs) or other approvals/agreements to begin any of its aims? (Yes/No)
 - i. If Yes: Please describe: _____

5. Informatics and Data Science (IDSci)

- a. Will your project require data from CDWH? (Yes/No)
- b. Will your project require additional support from TraCS data scientists? (Yes/No)
 - i. If Yes: Provide a brief 1-2 sentence description: _____