



## I. Research Study Idea

Have a research idea, protocol in development, or an approved protocol? If you would like to set up an initial planning meeting to speak to clinicians at the CRC about your study, please contact [crcschedule@mit.edu](mailto:crcschedule@mit.edu). Please provide the following information in your email:

- Your name
- The name of the PI on the study (If the PI is someone other than yourself)
- Your department
- The name of your study
- A short description of your study
- The cost object / PO for your study (only for scheduling, you will not be billed!)
- Your COUHES approval number (if you have one)

Following reception of your email, the CRC will create an account in our iLab scheduling system and will notify you of this event. You will then be able to log in to iLab using your MIT credentials and schedule a meeting at your convenience. You can also use iLab to schedule any follow up meetings, schedule use of our resources, and book time to have subjects seen upon the start of your study.

## II. Planning Meetings

During your initial meeting and follow up planning meetings, CRC clinical and project management staff will determine how best to help you achieve your study aims. This will include discussions of:

- Your study aims, requirements, and scope
- Your regulatory status
- Whether you will need regulatory approval at other institutions or will be working with external collaborators
- Your perspective study timeline
- Your study budget
- The services we can provide and the rates for such services

If following these meetings you determine that the CRC is a good fit for your project, we will “instantiate” your study and begin creating the infrastructure necessary for it to begin.

## III. Study Instantiation

This is the final phase before the beginning of your study. During this phase, the CRC will create the infrastructure and processes for your study:

- Your study requirements, aims, and timeline will be formally defined.
- You will be sent a quote covering the expected costs of your study in iLab.
- You will be emailed a regulatory checklist to help insure that you are fully in compliance with MIT, state, and federal regulations. Please complete this checklist and return it to us.
- You will be emailed a usage agreement for the CRC outlining our policies. Please complete this document and return it to us.
- We will establish any physical infrastructure necessary to conduct your study
- We will create accounts for your research team in RedCap, our clinical database. Data gathered during subject visits will be stored securely in RedCap for future access by your investigative team.
- We will create accounts for your research team in our project management tool. This will allow your team to track the progress of your study at multiple levels of detail from start to finish, and will serve as the primary mechanism by which we communicate with you.
- We will create a secure electronic storage space for your team for storage of research data in compliance with MIT data storage standards.

#### **IV. Final Checkpoint**

- We will verify that your regulatory checklist has been completed
- We will verify that you agree to the CRC usage terms
- We will verify the study requirements and budget
- We will verify that all of the necessary services have been prepared

#### **V. Study Begins**

At this stage, you will be free to schedule your subjects and/or the use of CRC research spaces. We will send you periodic updates about your study and inquiries to determine if we are adequately meeting your study needs. You will be able to track the global progression of your study via our project management tool. Billing for services used and agreed upon will occur on a monthly basis via iLab invoices.

#### **VI. Study Follow up**

Following completion of your study the following will occur:

- A follow up questionnaire will be sent out to investigators seeking feedback about our performance
- Data analysis may be available if requested
- We will establish a mechanism to securely transfer any data to you which was not entered into REDCap. You will also be offered the option of secure long term data storage using our storage medium.