

Medical Institutional Review Board (MIRB) Mentor System Procedures

Mentor Account Creation Process

- 1. After contacting the EBCI MIRB to submit a protocol, you will be given a form code
 - a. Save the form code for account creation
- 2. Visit https://www.axiommentor.com/ebci/newAccount
- 3. Input form code and complete required fields
- 4. After form submission, you will receive an email with a link to set your password
 - a. Set password with email link
- 5. Once password creation is completed, the EBCI MIRB Administrator will be automatically notified of your account request
- 6. Once your account is approved, you will receive an email notification to login to the Mentorsystem
- 7. Visit https://www.axiommentor.com/login/axlogin.cfm?i=ebci to begin the process of submittingyour new protocol

Protocol Submission Process Overview

- 1. Log on to the Mentor system
 - a. https://www.axiommentor.com/login/axlogin.cfm?i=ebci
- 2. From the "Home" page click on "MIRB"
- 3. Click on "My Submissions"
- 4. Click "Create New Submission"
- 5. A field will pop up "Create MIRB Submission"
- 6. Save the submission
- 7. Click "Application Sections" to complete the remaining required fields
- 8. PI and Co-PIs add an electronic signature
- 9. Hit submit

Additional assistance with Mentor protocol submission can be found within your Mentor account. Navigate to the "MIRB" tab and select "Resources" on the left-hand side of the page. Click "Mentor User Guides" then select the "IRB" folder. In the IRB folder, select "PI" and download the appropriate guide.

Detailed to "Create MIRB Submission"

- 1. The person entering will automatically be the PI
- 2. To add CO-PI's or research staff type in the first three letters of the person's **last name**. If their name does not show up, they do not have a Mentor account.
 - a. If someone does not have a Mentor account, they cannot be added to the application.
 - b. To add someone to the system, click "add user" in the right hand corner and completerequired fields. They can now be added to the application.
- 3. Enter the protocol title
- 4. Enter proposed estimated start date
- 5. Enter estimated end date
- 6. Select sites
 - a. Single site OR

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- b. Multiple sites
- 7. Select review type
- 8. Select Waiver of Informed Consent
 - a. Request Full Waiver OR
 - b. Request for Waiver of Alteration of Consent
- 9. Select Waiver of Documentation of Informed Consent
 - a. Not Requested OR
 - b. Requested
- 10. Select HIPAA
 - a. Will Seek Authorization for the Use and Disclosure of PHI OR
 - b. Requesting Waiver of Authorization OR
 - c. HIPAA (PHI) Does Not Apply to this Study
- 11. Total Number of Subjects
 - a. **Note:** Input the maximum number, there cannot be a range
- 12. Please provide a brief summary/abstract (250 words or less)
- 13. Upload all required documents using the "upload" button
 - a. You may rename documents to fit the appropriate title
- 14. Click "save"
 - a. You may now visit "My Submissions" to add additional information to the application. Your submission will not be completed yet.
- 15. Click "Application Sections"
 - a. Protocol Outline
 - i. Risk/Benefit Assessment
 - ii. This protocol has scientific value
 - iii. Risks to subjects are minimized
 - iv. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to be gained
 - v. Subject selection is equitable
 - vi. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence
 - vii. Informed consent is obtained from research subjects or their legally authorized representative
 - viii. There are adequate provisions for monitoring the data to ensure subject safety
 - ix. The provisions to protect the privacy of subjects and maintain dataconfidentiality are adequate
 - b. Informed Consent
 - i. Upload informed consent form
 - c. Subject Populations(s) & Methods
 - i. Name of sponsor
 - ii. Describe where the proposed research study will be conducted
 - iii. Subject Populations
 - iv. Methods
 - v. Interventional Studies
 - d. Personnel
 - i. PI
 - ii. Co-PI's
 - e. **Note:** These are smart forms, they will automatically take you to the next field once you complete one of the entries.
- 16. Once all fields have been completed, you may click "Request Signatures" at the top of the submission page.

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- a. This will send a request to the PI and all Co-PI's. Each person must sign electronically.b. Tracking status at the top of the submission should read "Submitted to MIRB"

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