

CLINICAL TRIALS – SUBMITTING A CHANGE IN PRINCIPAL INVESTIGATOR (PI)

Revised October 2, 2025

OVERVIEW – PI Change

- **Description:** To provide study maintenance guidance regarding how to initiate and submit a change in private investigator (PI) for a clinical trial.
- **When to initiate:**
 - When PI or study team confirms a PI change is necessary.
- **Timeline**
 - Submit PI change in BruinIRB after notifying & receiving approval from sponsor via email

ACTION ITEM – HOW TO INITIATE PI CHANGE PROCESS

1. Request/obtain sponsor approval (via email) for PI change.
2. Access [BruinIRB](#).
3. What materials are required for amendment submission?
 - a. PI to PI transfer document
 - i. Signed by both outgoing **and** incoming PIs
 - b. PI assurances for change in PI
 - i. Signed by incoming PI *only*
 - c. Updated ICF with incoming PI name
4. Creating an amendment submission in BruinIRB
 - a. Select “Create Site Modification”

Next Steps



- b. Within page 1, “Modification summary” – outline the change in PI.
 - c. Within the “Documents” page, upload an updated ICF to section #1 and the PI change documents (PI to PI transfer document & PI assurances for change in PI) to section #3.
5. Update study regulatory documents (to be obtained from sponsor) accordingly to reflect new PI’s information.
 - a. 1572
 - b. Financial Disclosure Form (FDF)
 - c. Protocol Signature Page (PSP)
 - d. IB Signature Page

CONTACT/RESOURCES

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