APPLICATION: Research Personnel Amendments

Use this application only to request changes to approved research personnel, including updating roles or contact information, changing the Principal Investigator (PI) to a minimal risk study. ***Important:*** *If a PI change applies to a* ***study that is more than minimal risk, do not use this form****. Submit a full Amendment application for convened IRB review.*

GENERAL STUDY INFORMATION

- *If more than one study applies, enter each IRB-approved study title and corresponding IRB number on a separate line.*
- *All research personnel* ***amendments*** *documented within this application (including additions and removals) apply to* ***all*** *projects listed in the General Study Information section.*
- *Include personnel changes only if they apply to all listed projects. If a change affects only some projects, do not include it in this submission, submit a separate Research Personnel Amendment form for those projects.*

Dropdown Menu Selection Instructions: *Please select the option that best applies in the dropdown menu. If none of the listed options accurately describes your role or department, selecting "Other" will allow free-text to be entered.*

Principal Investigator (PI) Name *(Current)*:

Department: *Select Department

IRB PROJECT #	STUDY TITLE

Version Date: 05/20/2026

TYPE OF CHANGE

Check all that apply.

- ☐ Add research personnel
- ☐ Remove research personnel
- ☐ Update role or contact Information change *(includes updates to Principal Investigator contact information)*
- ☐ Principal Investigator (PI) – **Minimal Risk Studies Only** *(Complete "PI Investigator Change" section)*

RESEARCH PERSONNEL ADDITIONS ☐ N/A

- *An annual (June – May) Financial Conflict of Interest (FCOI) Form must be submitted with this application if no current form is on file with the RCD office or if the information on file requires updating.*
  ***Note:** The FCOI annual disclosure cycle begins in April, with a submission deadline of May 31, 2026. A new Financial Conflict of Interest disclosure form must be submitted during this period, even if there are no changes to report.*
- *CITI certificates for Conflict of Interest (COI), Responsible Conduct of Research (RCR), and Human Subjects Research (HSR) must be submitted with this application.*
- *CITI Good Clinical Practice (GCP) certificate is required only for investigators and key personnel involved in FDA-regulated studies, in accordance with Trinity Health policy.*
- *List research personnel being added to all projects listed under General Study Information. Do not include Principal Investigator (PI) changes in this section.*

FULL NAME	ROLE ON STUDY	DEPARTMENT	EMAIL
	Clinical Research Coordinator	Select the Department	
	*Select Role	Select the Department	
	*Select Role	Select the Department	
	*Select Role	Select the Department	
	*Select Role	Select the Department	
	*Select Role	Select the Department	
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	*Select Role	Select the Department	
	*Select Role	Select the Department	
	*Select Role	Select the Department	
	*Select Role	Select the Department	

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RESEARCH PERSONNEL REMOVALS ☐ N/A

- *List research personnel being removed from all projects listed under General Study Information. Removal indicates that the individual will no longer have access to study data or conduct study activities as of the date listed.*

FULL NAME	ROLE ON STUDY	DATE OF REMOVAL
	*Select Role	
	*Select Role	
	*Select Role	
	*Select Role	
	*Select Role	
	*Select Role	
	*Select Role	
	*Select Role	
	*Select Role	
	*Select Role	
	*Select Role	
	*Select Role	

PRINCIPAL INVESTIGATOR CHANGE ☐ N/A

*Complete this section only if a change in Principal Investigator (PI) for a **minimal risk study** is requested.*

1. Principal Investigator Full Name:

2. Institution / Trinity Health Ministry:	
3. Address / Department:	
4. Email / Phone Number:	

☐ Check if signature of current PI cannot be obtained *(If the current PI's signature cannot be obtained, select one reason below. A valid justification is required. If "Other" is selected, an explanation must be provided.)*

☐ PI left the institution ☐ PI unavailable due to medical issue ☐ PI on leave of absence

☐ Other *(explain)*:

PARTICIPANT NOTIFICATION METHOD

☐ N/A

Select one option below to indicate how participants will be informed of the PI change

- ☐ Reconsent will be obtained
- ☐ Participants will be reconsented using a consent addendum
- ☐ Participants will be notified by certified mail (attach notification letter)
- ☐ Participants will not be informed

Provide details below regarding re-consent or justification if participants will not be informed:

SUPPORTING DOCUMENTS

Check all documents included with this submission. Not all items apply to every request.

- ☐ CITI training certificates
- ☐ Principal Investigator CV
- ☐ FCOI Form (current within last 12 months)
- ☐ Updated Consent Form (if applicable)
- ☐ Updated Protocol (if applicable)
- ☐ Other *(specify)*:

CURRENT PI SIGNATURE

By signing below, the current Principal Investigator attests that:

- All newly added research personnel have completed a FCOI form, the required human subjects protection training and, when applicable, Good Clinical Practice (GCP) training for FDA-regulated studies.
- Study team roles and responsibilities are appropriate for the scope and risk level of the research.
- The IRB will be notified prior to implementing any future research personnel changes.
- If applicable, the change in Principal Investigator is acknowledged and supported.

SIGNATURE OF CURRENT PRINCIPAL INVESTIGATOR:		DATE OF SIGNATURE:	

Note: When adding a new PI, the new PI must sign first. The current PI should review the form to ensure it is accurate and complete before signing. Once signed, the document will lock and no further changes can be made.

Submit completed form and applicable documents to aasjirbsubmissions@trinity-health.org

NEW PI ATTESTATION

By signing below, I affirm that I accept responsibility as the Principal Investigator for this study and attest that:

1. The protocol is scientifically sound and of scientific and social value.
2. Conduct and supervise the study in accordance with the terms of the IRB approval (including the current IRB approved protocol); including maintaining the highest ethical and scientific research practices in the conduct of the study.
3. Sufficient oversight over all study activities and tasks delegated to others to ensure that the research is conducted in compliance with all applicable Federal Regulations and TH institutional policies and procedures.
4. IRB approval will be obtained before engaging in research.
5. Review and comply with the THM IRB policies and procedureshttps://www.trinityhealthmichigan.org/research-compliance/policies.
6. After obtaining IRB approval, all required reports including amendments/revisions, continuing review, unanticipated problems, and protocol deviations, will be submitted to the IRB, the study sponsor and the relevant funding agencies in accordance with THM policies and procedures and sponsor/funding agency requirements.
7. No changes will be made to the research without first obtaining IRB approval for the amendment/revision, except where necessary to eliminate apparent immediate hazards to participants (45 CFR 46.103(b)(4), 21 CFR 56.108(a)(4)). If a change is needed to eliminate immediate hazards to participants without prior IRB approval, the PI must report those changes promptly to the IRB.
8. Maintain required training, licensure, and certification throughout the conduct of the study.
9. Inform research participants that the drugs, devices, biologics, or interventions are being used for investigational purposes, and will ensure that the requirements for obtaining informed consent are conducted in accordance with IRB approval.
10. Ensure that the content of submissions to the IRB are accurate and complete, including providing all documents, subject to IRB review, in accordance with THM policy and regulations.
11. Respond to all IRB requests for information and ensure that a study closure form is submitted to the IRB once the study is completed.
12. Ensure that all members of the study team are trained and qualified to perform their delegated role in meeting the requirements of the written protocol. All study procedures considered to be human subject research activities, including obtaining informed consent, will only be carried out by members of the IRB-approved investigative team.
13. Ensure that data and study records will be stored, retained, and protected in accordance with the approved protocol, HIPAA requirements, THM policies and procedures and other applicable regulations (e.g., FDA).
14. There are adequate resources (i.e., facilities, personnel, time, funding, and equipment) to conduct the study.
15. Ensure the current Annual Significant Financial Disclosure form for all study team members has been completed and is on file with the Research Compliance Department (RCD), in accordance with Leadership Policy – Promoting Objectivity in Research – Financial Interest Disclosure. Notify the RCD immediately of any actual or potential financial or ethical conflict of interest that arises for any study team member during the conduct of the study.
16. Ensure that all study team members complete their study specific conflict of interest disclosure in an accurate and complete manner. Notify the IRB immediately of any actual or potential financial or ethical conflict of interest that arises for any study team member during the conduct of the study.

SIGNATURE OF NEW PRINCIPAL INVESTIGATOR:		DATE OF SIGNATURE:	

If adding a new PI, the new PI must sign here first.