Research being conducted at IFH site(s) ONLY?

YES → **IFH IRB of record**

NO → **Are you using the IFH IRB as IRB of record?**

Are you using the IFH IRB as IRB of record?
- **YES** → IFH IRB of record
- **NO** → **External IRB of record**

IFH IRB of record

Here's the steps you need to follow!

- Research Committee
- IRB *Reliance agreement
- Study

External IRB of record → What type of project? (pick 1)

In-development application or proposal

PROCEED TO… (please allow 6-8 weeks)

Research Comm. Review

Submit required documents:
- RC external IRB of record questionnaire

IF RC approves project, the **RC will provide** (as needed/appropriate):
- LOI/LOS
- MOU

If funded, any major changes, adverse events, etc. go to IRB admin comm for review and comments

Funded multi-site research project / Unfunded multi-site research project

PROCEED TO… (please allow 6-8 weeks)

Research Comm. Review

Submit required documents:
- RC external IRB of record questionnaire
- Approved IRB application from IRB of record

IF RC approves project, the **RC will provide** approval letter (etc.)

Any major changes, adverse events, etc. go to IRB admin comm for review and comments

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*MUST have reliance agreement in place when outside org. has access to own IRB & opting to use ours. OR, in instances of federal funding and single external PI. Need the PI with federal funding to sign agreement to extend FWA to cover investigator on project.

THE INSTITUTE FOR FAMILY HEALTH
PRELIMINARY QUESTIONNAIRE FOR PROPOSED RESEARCH*
*THIS FORM IS ONLY FOR RESEARCH PROPOSALS USING THE INSTITUTE'S INSTITIONAL REVIEW BOARD (IRB) AS THE IRB OF RECORD

Please complete this document to inform the Institute of your proposed research. Answers may be brief. Forms must be submitted at least two weeks prior to the Research Committee meeting. All proposed studies must have a Research Committee approval letter before being submitted to the IRB.

Date: _____

Contact Name: _____   Title: _____

Contact Phone Number: _____

Contact E-Mail: _____

Title of Project: _____

Expected duration of project: from: _____ to: _____

Principal Investigator (if different from contact): _____

Institute Co-PI (if PI is not employed by the Institute): _____

Does this study include an external PI/organization?   ☐ Yes   ☐ No
If yes, complete Appendix A: External Research Partnership Information.

Are you a faculty member?   ☐ Yes   ☐ No

If yes, how many residents are or will be on this research project? _____

Proposed Practice Site(s): _____

Summary of Project:

Select your research category:

- ☐ Racial and ethnic health disparities
- ☐ Patient-centered care
- ☐ Health information technology
- ☐ Integration of mental health care and primary care
- ☐ Women's health
- ☐ Other

INTRODUCTION

- Briefly summarize the literature review you conducted for the proposed study. In the summary, include any gaps in the literature and how your proposed study addresses them. Based on the literature, why is this study important?

- Please state your research questions or hypotheses:

- Describe how this project supports the Institute's mission:

METHODS

- Provide a brief description of the study design.

- Provide a brief timeline of research activities and person/position responsible.

- Present a detailed workflow of the intervention(s). Also, include any changes to the current clinical workflow that will be required in order to implement this intervention(s).

- Participant Recruitment (if applicable): what is the eligibility criteria, how will you develop a recruitment list, who will recruit, and when and how will recruitment take place.

- Consent: what type of consent is necessary, what does the consent process involve, who will review the consent, when and how consent will be obtained from participants.

- Data collection/analysis: what is the sample size and how was it determined, how will data be collected, what data instruments will be used, what is the analysis plan, who will conduct the data analysis

- Provide a brief summary of your dissemination plan

RESOURCE UTILIZATION & REMUNERATION

Describe any anticipated staff/site support and requests for new Epic features/build or patient/staff data reports. Note: If you are requesting any Epic-related support, you will need to include the elements listed below. *You **must** also contact Amandari Kanagaratnam at akanagaratnam@institute.org to discuss your Epic-related needs prior to your submission of this questionnaire.*

- Timeframe for when you need the Epic request completed
- If applicable, what new Epic features (BPAs, smartsets, etc.) do you need?
- If applicable, list specific data elements (i.e. all patients with asthma ages 18 and older)
- Use of Epic Research Functionalities (i.e. assigning patients to your study, etc.)

Is this project funded? ☐ Yes   ☐ No

        If yes, funding information:

                Funder Name:

                Total Award Amount:

                Total Institute Award/Sub-award:

                Full Grant Period (Dates):

                Link to RFP (if applicable):

Please list all Institute senior/site staff or management from whom you have received the approval.

Principal Investigator Signature: _____

If you are a resident/student, please include the following:

Supervisor Name (if applicable): _____

Supervisor Signature: _____

APPENDIX A: EXTERNAL RESEARCH PARTNERSHIP INFORMATION

Directions:
If you are collaborating with an external research partner, you **<u>must</u>** complete this document as thoroughly as possible and submit it with your research questionnaire.

Title of Project:

_____

Name of External Partner (please include their institutional affiliation):

_____

1. **Have you previously collaborated with this external partner?**

   ☐Yes ☐No ☐N/A

   If "Yes," briefly describe your/Institute's collaborative history.

   If "No," briefly describe how this partnership was formed.

2. **Is this project funded?**

   ☐Yes ☐No ☐N/A

   If "Yes," will the Institute receive funding as a project partner?

   ☐Yes ☐No ☐N/A

3. **Briefly describe the Institute's role in this project.** *(Note: This could include recruiting participants – providers or patients, training staff, completing surveys, implementing new workflows, etc.).*

4. **Briefly describe how the Institute benefits from this partnership/project.** *(Note: This could include building research capacity (publications, fulfills Institute's research agenda, staff training, etc.)).*