

Submitting a Protocol to The IRB at  
Partners:

Partners Human Research Committee

# Definitions

## Research

- *Research is a systematic investigation*, that includes research development, testing and evaluation, that is designed to develop or contribute to **generalizable** knowledge.
- A *systematic investigation* is an activity that involves a prospective research plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question.

## Quality Improvement

- Formal and systematic exercise in monitoring and reviewing care delivery and outcomes.
- QI designs activities to improve health care and overcome identified deficiencies in providers, facilities or systems.
- QI uses follow-up steps to ensure that actions have been effective and that improvements in quality as a result of process improvement is maintained.

# Actions

## Research

- When individuals request a determination from the PHRC, they are asked to submit the appropriate PHRC forms describing the activity in sufficient detail to make the required determinations.
- When an Insight/eIRB application form is submitted to the PHRC, the PHRC staff will provide the individual making the request with written documentation of the determination and the basis for the determination usually within two weeks.

## Quality Improvement

- The Partners IRB requires submission of any quality measurement initiative or database if the primary intent is to conduct or support research (i.e., internal or external analyses of identifiable clinical information for a generalizable purpose, such as a scientific publication).
- Alternatively, if the only purpose of a quality measurement initiative or database is quality measurement (including publication of benchmarking analyses or reports), then no submission to the Partners IRB is required

# INSIGHT

- Partners Human Research Committee requires submission through an electronic portal, INSIGHT:
  - To Request Access or Training: 617.424.4175
  - Email to [insighthelpdesk@partners.org](mailto:insighthelpdesk@partners.org)



# Prepare Study Documents

Apply through Insight

<https://insight.partners.org/public/>

Intake person determines appropriate review:

**Expedited or Full Board**



Welcome to Insight.

Please Login below.

Partners UserName:

Login

✦ Forgot UserName or Password?

✦ Request Insight Access – Central

✦ Request Insight Access – Departments

✦ Request Insight Help

✦ Request Insight Training

✦ PHS Research Applications Group

Insight 3.6.4 released 06/03/2016.

## Insight - Partners Electronic Research Administration Portal

[Click here to view key updates](#)

### Important Updates

Beginning with the Insight 3.5 release, the process for requesting Central and Departmental access to Insight has been updated. There are two new links accessible from the In Access - Departments. Clicking the Central access link will present an access request form to be completed and submitted to the Insight Help Desk. Clicking the Department access link will present an access request form to be completed and submitted to the Insight Help Desk. Clicking the Department access link will present an access request form to be completed and submitted to the Insight Help Desk. Clicking the Department access link will present an access request form to be completed and submitted to the Insight Help Desk. Clicking the Department access link will present an access request form to be completed and submitted to the Insight Help Desk.

### System Information

Insight is supported on machines with the following configurations:

# New Protocol

Active Protocols > New Protocol Application

## New Protocol Application

Please answer the following questions in order to customize your human-subject research submission. The answers to these questions will determine what information is required for review by the Partners Human Research Committee.

Once you have completed the application you will be able to add or delete a form on the application, if you feel you answered any questions incorrectly. This can be done by clicking on the "Add / Delete Forms" button.

**Please enter the full title of the study.**

**If applicable, enter the sponsor protocol designation/number, e.g., acronym or cooperative-group protocol name/number.**

### Intervention and/or Interaction

Does your research involve **intervention** and/or **interaction** with human subjects?

Yes  No

# Intake

- **Full Board Review:**

Research does not meet criteria for expedited review  
Intake confirms that required documents are submitted

**Tip:** Use the intervention/interaction submission checklist

- **Expedited review:**

Research is no more than minimal risk (PHRC decides) AND entire proposal falls into expedited review categories of the Federal Register.

<http://www.hhs.gov/ohrp/policy/expedited98.html>

Application forwarded to expedited review team



# PHRC Intervention/Interaction Protocol Checklist

- New protocol submissions for studies involving an intervention and/or interaction with subjects must include the following documents, when applicable:
  1. Protocol Summary (see Partners [Protocol Summary](#) template)
  2. ~~[Schema](#), required for studies with multiple groups, treatment arms, or randomization~~
  3. ~~Detailed Protocol (always submit the sponsor's/cooperative group's protocol if there is one)~~

~~When the research is investigator-initiated, the investigator should submit a protocol prepared according to [PHRC Detailed Protocol Instructions](#).~~ **NIH OR OTHER GRANT APPLICATIONS CANNOT BE SUBSTITUTED FOR THE PHRC DETAILED PROTOCOL**



# PHRC Intervention/Interaction Protocol Checklist

- ~~4. DSMB/DMC Charter and Membership, if applicable~~
5. Questionnaires, Psychological Instruments, or Patient Diaries, if applicable
6. Recruitment Materials (letters, postcards, postings, advertisements, telephone scripts, etc.), if applicable Whenever possible, submit copies of print and audio/video ads in the form in which they will be used, e.g., print ads for newspapers and audio/video ads for radio/television broadcast.
7. Consent Form(s), if applicable (see [Partners Research Consent Form Templates](#))
8. Clinical Trials Registration Responsible Party [Designation Letter](#) (FDAAA applicable trials)

# Internet Surveys

Internet-based research must meet the same criteria for IRB approval and offer the same level of protections to human research subjects as research conducted through more traditional methods.

When the IRB reviews the use of web-based survey tools, the IRB must specifically consider whether the web-based survey tool affords adequate privacy and confidentiality protections and ensures that additional risks related to Internet research are minimized.

# General Guidelines for Preparation of IRB Submissions Involving Web-Based Survey Tools & Internet Research

- Consider keeping identifying information (names, addresses, emails) in one file, and data in a second. Use an arbitrary code number to link the two files.

Consider validity of data and the possibility of people completing surveys multiple times. Utilize methods to authenticate, track or restrict access to the Web survey.

# General Guidelines for Preparation of IRB Submissions Involving Web-Based Survey Tools & Internet Research

- Consider offering alternative methods of participating in the study if subjects prefer not to submit their information online.
- When applicable, follow legal requirements for obtaining permission to use copyrighted instruments in your online research.

# Digital Health Methods Research

- This is the collection, transmission, and/or dissemination of private or non-private actively or passively collected data using software, technology or communication devices or sensors to collection information at a point or over a period of times.
  - Homegrown smartphone apps or wearables
  - Use of marketed and readily available apps
  - Pervasive data collection using multiple sensors



# Digital Health Methods Research

- **Pre-approvals**
  - Use for Clinical Care
  - Research Information Security (RISO)
  - Clinical Trails Office (CTO)
- **Potential Ancillary Review**
  - Partners eCare
  - Biomedical Engineering
  - Innovative Research Management
  - FDA - diagnostic
  - Partnerships with outside entities
  - Office of Interaction with Industry (OII)





Go to the Insight Research Portal:  
<https://insight.partners.org>

Enter your Partners user name and password to login to Humans/eIRB

Click on  the button

Click  the button



Protocol #

Title

Limit Search By:



PI



ORG

**search**

[Clear Selection](#)

[▶ Show Advanced Search Options](#)

To create a new protocol application, please select a type from the dropdown and click the Create New Protocol button.

Standard Protocol



**Create New Protocol**

## New Protocol Application

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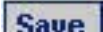
### Intervention and/or Interaction

Does your research involve **intervention** and/or **interaction** with human subjects?

Yes  No

Intervention/Interaction with human subjects requires an estimated 11 forms to be completed



Answer the New Protocol Application configuration questions, then click the button 

Click each form name to complete the questions, then click the button 

Form	Last Modified
<b>Sponsor / Funding</b>	
<a href="#">Sponsor/Funding</a>	
<b>Intervention</b>	
<a href="#">Study Details</a>	
<a href="#">Study Population</a>	
<a href="#">Performance Statistics</a>	



Click the 'Staff & Access' tab


Click the  button to build the study staff list (CITI education within 3 years)

If the submitter also has a study-related role on the protocol, click the  button to move the submitter name from the Non-Study Staff Access to the Study Staff grid.



# Non-Partners Employees

Do not add Non-Partners collaborators unless they are engaged in the conduct of the research at a Partners institution or they plan to rely on the Partners IRB, and not their own IRB. If you are unsure, contact the IRB office before proceeding.

If you know you need to add these people, answer 'yes,' click the button, and enter the person information. If no, click the  button to proceed to the Staff & Access page.





# Attachments

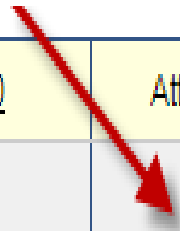
Home    Agreements    Humans

Forms    Staff & Access    Attachments    Sub

Version Name:    Sponsor:    Overall Status

\* Required Attachment

Attachment Type	Title	Attachment Mode	File Name	Forms ID	Attach / Edit	Delete Row	Version
Protocol Summary *	Protocol Summary			IR		X	Add Version
Detailed Protocol *	Detailed Protocol_01			IR		X	Add Version



add row

# Submission



#	Form / Type	Description
1	Staff	<u>Protocol must have a staffed Principal Investigator</u>
2	Attachments	<u>Protocol Summary must be attached.</u>
3	Attachments	<u>Detailed Protocol must be attached.</u>
4	Attachments	<u>attach the i</u>



# Approvals

- The first step in the workflow of a protocol application is the certification and sign-off by the Principal Investigator and any Site Responsible Investigators staffed to the study.
- The protocol will not progress to the next steps until all critical study staff has completed the sign-off process.
- The next step in the workflow of a submitted application is the approval of the Department Chair(s).

# Ancillary Approvals

- Biomedical Engineering
  - If Medical Device or Non-hospital device form is completed and the device is electrically powered

Nursing

Use of Nurses time

# Committee's Overall Determination

## **Approval**

You are good to go - very unlikely

## **Requires modifications**

Revisions are needed to secure final approval

Response can be reviewed by the Chair in the office

## **Deferral**

Not all criteria for approval were met

Response needs to be reviewed by the same panel

## **Disapproval**

The protocol as proposed cannot be approved

Serious revisions or study design changes are required to be reconsidered by the same panel - very rare

# Response to Review

Provide point by point complete response to each question

Do NOT just refer to the study documents in which a revision was made. Specify to which document(s) and to what page #s revisions were made

For example: Changes were made in the Protocol Summary p.2 [not preferred] Individuals with a CrCL > 60ml/min will be excluded.

Revision was made in the Protocol Summary p.2 [preferred]

Submit a clean and marked copies for each document that was revised

# PHRC Site in Research Navigator

[https://partnershealthcare.sharepoint.com/sites  
/phrmdepartments/poc/irb](https://partnershealthcare.sharepoint.com/sites/phrmdepartments/poc/irb)