Overview of Reliance Request System Content

Contents

Overview

This document outlines all possible questions in the electronic Reliance Request System in Qualtrics.

Basic Questions

RELIANCE REQUEST SYSTEM The first step in research involving reliance or a Single IRB (sIRB) mechanism for multi-site research is to complete a Reliance Request. Please answer the following questions, so that we may better serve you. We will review the information provided in this request and will contact you with next steps. Pitt Reliance Team
Pitt/UPMC Principal Investigator: Name Education credentials Title (to appear on all correspondence) Department Email address
Pitt/UPMC Study Coordinator: Name Email address **Other Pitt/UPMC individual that should be included in Pitt Reliance communication:** *(e.g., Regulatory Affairs Coordinator, Secondary Research Coordinator, etc.)* Name Title/Role Email Address

Select the reason for reliance request:
Pitt to Serve as IRB of Record [Note, do not submit this request until the notice of award (NOA) is received.]
Pitt to Cede IRB Review
Letter of Support for Grant Submission
Individual Investigator Agreement (IIA)

Request for Pitt to Serve as IRB of Record

REQUEST FOR PITT TO SERVE AS IRB OF RECORD

Instructions for Use: To be completed when a Pitt/UPMC investigator is submitting an initial request for the Pitt IRB to serve as the IRB of record for a multi-centered research study.

Note, if any of this request is incomplete at the time of submission, you will be prompted to submit another request until a complete submission is received by our office.

Attestation
I attest to *both* of the following:

I have reviewed the "Pitt IRB of Record" guidance document found at www.irb.pitt.edu, under "Guidance & Forms", "R" for "Reliance Guidance".

The information provided in this request is complete and accurate.

Study Title:
(Note, this is the verbatim title that will appear on the agreement for this project; ensure all sites involved are using the same title.)

Is this study transitioning to a single IRB (i.e., Is this study already approved in PittPRO)?
Yes, specify study ID:
No

Study ID:
(Note, if you have not yet created a submission, please do so now in PittPro. The IRB application does not need to be completed at this time; this step is to generate a STUDY# for tracking purposes.)

Funding source (Select all that apply):
Federal, specify agency:
Foundation, specify agency:
Industry, specify agency:
Internal (Department funds)
Other, specify:
No support

For federally funded projects:

Name of Institution that is the Primary Awardee of the grant:

Duration of the grant in years:

Total number of relying sites for the project (not including Pitt/UPMC site):

Which research office is processing your funding (the grant or subcontract)?
Pitt Office of Research
Magee Women's Research Institute

Why is the reliance request being made?
Condition of funding
Pitt PI relocating
External site(s) not engaged in human subjects research
Other, specify:

What is the risk level of the study?
Greater than Minimal Risk
Minimal Risk
Not sure

At which local sites will research procedures be performed? (Select all that apply)
University of Pittsburgh
UPMC
Other, specify:

Select all vulnerable populations that apply to this research study.
Pregnant Women
Fetuses
Neonates
Children
Decisionally Impaired
Prisoners
Non-English Speakers
Not applicable

Does this research study involve the use of a device?
Yes
No

Is there an Investigational Device Exemption (IDE)?
Yes
No

Institution that holds the IDE:

Does the research study involve the use of a drug?
Yes
No

Is there an Investigational New Drug (IND) application?
Yes

No

Institution that holds the IND:

Does the research study involve an FDA exception from informed consent?
Yes
No

Upload the protocol summary or human subjects section of the grant application for review.

Appendix A Loop

Appendix A - Relying Site(s)

Instructions for use: Complete a separate Appendix A for each institution requesting to rely on the University of Pittsburgh IRB.

Relying Site:
Legal Name
Address
City
State
Postal code

Does the Relying Site have their *own* IRB (e.g., does not contract to a commercial IRB)?
Yes
No

Does the Relying Site have a Federal Wide Assurance (FWA)?
Yes, indicate FWA number:
No

Relying Site IRB Representative:
Name
Email address
Phone number

Lead Investigator at Relying Site:
Name
Education credentials
Email address

Study Coordinator at Relying Site:
Name
Email address

Role(s) of Lead Investigator at Relying Site (Select all that apply):
Recruitment
Obtaining consent
Data collection

Implementing/administering research intervention
Identifiable data/sample analysis
De-identified data/sample analysis
Other, specify:

Does the Relying Site have a post-IRB approval auditing/monitoring program?
Yes
No

Request for Pitt to Cede IRB Review

REQUEST FOR PITT TO CEDE IRB REVIEW

Instructions for use: To be completed when a Pitt/UPMC investigator is submitting an initial request for the Pitt IRB to rely on an external IRB for a multi-site research study.

Note, if any of this request is incomplete at the time of submission, you will be prompted to submit another request until a complete submission is received by our office.

Attestation
I attest to *both* of the following:

I have reviewed the "Pitt Cede IRB Review" guidance document found at www.irb.pitt.edu, under "Guidance & Forms" "R" for "Reliance Guidance".

The information provided in this request is complete and accurate.

Study Title:
(Note, this is the verbatim title that will appear on the agreement for this project; ensure all sites involved are using the same title.)

Is this study transitioning to a single IRB (i.e., Is this study already approved in PittPRO)?
Yes, specify study ID:
No

PittPro Study ID:
(Note, if you have not yet created a protocol for this project in PittPro, please do so now. The IRB application should not be completed/submitted at this time; this step is to generate a STUDY# for tracking purposes.)

Funding source (Select all that apply):
Federal, specify agency:
Foundation, specify agency:
Industry, specify agency:
Internal (Department funds)
Other, specify:
No support

For federally funded projects:

Name of Institution that is the Primary Awardee of the grant:

Which research office is processing your funding (the grant or subcontract)?
Pitt Office of Research
Magee Women's Research Institute

Why is the reliance request being made?
Condition of funding
Required by National Research Consortium/Network
Pitt/UPMC PI relocating
Other, specify:

Is this project part of a consortium or network for which a Master Service Agreement is already in place (e.g., StrokeNet, TrialNet, PaTH, NMDP, etc.)?
Yes
No

Role(s) of Pitt/UPMC PI and staff in this research study (Select all that apply):
Recruitment
Obtaining consent
Data collection
Implementing/administering research intervention
Identifiable data/sample analysis
De-identified data/sample analysis
Other, specify:

If available, upload the consent template(s) and local context form from the external site.

If available, upload the local context form from the external site.

Do the research procedures pose a risk of physical injury to participants?
Yes
No

Will any radioactive materials or external ionizing radiation be used specifically for research purposes at the Pitt/UPMC site(s)?
(For more information, go to http://www.radsafe.pitt.edu/human-use-research/guidance.php)
Yes
No

Will there be any administration of recombinant or synthetic nucleic acid molecules or DNA or RNA-derived from this technology at the Pitt/UPMC site(s)?
Yes
No

At which local sites will research procedures be performed? (Select all that apply)
University of Pittsburgh
UPMC
Other, specify:

Will protected health information (PHI) from a UPMC/Pitt HIPAA covered entity be collected for research purposes or will research data be placed in the non-UPMC/Pitt medical record?
Yes
No

Select all vulnerable populations that apply to this research study.
Pregnant Women
Fetuses
Neonates
Children
Decisionally Impaired
Prisoners
Non-English Speakers
Not applicable

Does this research study involve the use of a device?
Yes
No

Is there an Investigational Device Exemption (IDE)?
Yes
No

Institution that holds the IDE:

Does the research study involve the use of a drug?
Yes
No

Is there an Investigational New Drug (IND) application?
Yes
No

Institution that holds the IND:

Institution you are requesting to act as IRB of Record:
Name
Address
City
State
Postal code
Federal Wide Assurance (FWA) number

Does the institution that will serve as IRB of Record have AAHRPP accreditation?
Yes
No

Has the institution that will serve as IRB of Record undergone OHRP self-assessment or another process of assessing standards?
Yes

No, explain:

Is this institution a commercial IRB (e.g., WCG IRB, Advarra, etc.)?
Yes, explain why a commercial IRB will be used for this study:
No

Upload the IRB authorization agreement from the external site, if available.

External Lead Investigator, typically at the institution that will serve as the IRB of Record:
Name
Education credentials
Email address

External Lead Study Coordinator at the institution that will serve as IRB of Record:
Name
Email address

IRB Representative at institution that will serve as IRB of Record:
Name
Email address
Phone number

Is there an external individual that should be included in Pitt Reliance communication?
(e.g., national-level Regulatory Affairs Coordinator, Coordinating Center representative, etc.)
Yes
No

If yes, **Other Individual:**
Name
Title/Role
Email address

Is this study funded in part or whole by a PHS Agency?

[e.g., Agency for Healthcare Research & Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control & Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Substance Abuse & Mental Health Sevices Administration (SAMHSA)]
Yes
No

Does any Pitt/UPMC Investigator* involved in this study (Select all that apply):

*Investigator means the PI, co-investigators, and any other member of the study team, regardless of title, who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. The PI is responsible for ensuring that s/he and all other relevant members of the study team review the above questions describing Significant Financial Interests.

**such as salary, consulting fees, honoraria, or paid authorship

***through the provision of funds, drugs, devices, or other support for this research

****Such as serving on the Board of Directors or Board of Managers or a position that carries a fiduciary responsibility to the company (e.g., CEO, CFO, CTO, or CMO).

A. Have equity in a publicly-traded entity that either sponsors** this research or owns the technology being evaluated or developed that exceeds a 5% ownership interest or a current value of $10,000?
B. Have equity in a non-publicly-traded entity that either sponsors this research or owns the technology being evaluated or developed?
C. Receive salary, consulting fees, honoraria, royalties or other remuneration from an entity that either sponsors this research or owns the technology being evaluated or developed that is expected to exceed $10,000 during the past or next 12 months?
D. Have rights as either the author or inventor of intellectual property being evaluated or developed in this research that is the subject of an issued patent or has been optioned or licensed to an entity?
E. Have an officer or management position**** with a Licensed Start-up Company overseen by the COI Committee that either sponsors this research or owns the technology being evaluated or developed?
F. Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed?
None of the above options apply and there are no other financial conflicts of interest in the conduct of this research.

Does any Pitt/UPMC Investigator* involved in this study (Select all that apply):

**Investigator means the PI, co-investigators, and any other member of the study team, regardless of title, who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. The PI is responsible for ensuring that s/he and all other relevant members of the study team review the above questions describing Significant Financial Interests.*

***such as salary, consulting fees, honoraria, or paid authorship*

****through the provision of funds, drugs, devices, or other support for this research*

*****Such as serving on the Board of Directors or Board of Managers or a position that carries a fiduciary responsibility to the company (e.g., CEO, CFO, CTO, or CMO).*

A. Have a financial interest (aggregated value of equity and remuneration** during the past or next twelve months) in a publicly-traded entity that either sponsors*** this research or owns the technology being evaluated or developed that exceeds $5,000 but not $10,000?
B. Have a financial interest (aggregated value of equity and remuneration during the past or next twelve months) in a publicly-traded entity that either sponsors this research or owns the technology being evaluated or developed that exceeds $10,000?
C. Receive remuneration (during the past or next twelve months) from a non-publicly traded entity that either sponsors this research or owns the technology being evaluated or developed that exceeds $5,000 but not $10,000?
D. Receive remuneration (during the past or next twelve months) from a non-publicly traded entity that either sponsors this research or owns the technology being evaluated or developed that exceeds $10,000?
E. Have equity in a non-publicly traded entity that either sponsors this research or owns the technology being evaluated or developed?
F. Receive reimbursement or sponsorship of travel expenses (for one trip or a series of trips during the past or next twelve months) by an outside entity that either sponsors this research or owns the technology being evaluated or developed that exceeds $5,000?

G. Have rights as either the author or inventor of intellectual property being evaluated or developed in this research that is the subject of an issued patent or has been optioned or licensed to an entity?
H. Have an officer or management position**** with a Licensed Start-up Company overseen by the COI Committee that either sponsors this research or owns the technology being evaluated or developed?
I. Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed?
None of the above options apply and there are no other financial conflicts of interest in the conduct of this research.

Provide the name of the Pitt/UPMC Investigator(s) and describe the nature of the Significant Financial Interest(s):

Upload the protocol summary or human subjects section of the grant application for review.

All local research staff have completed the education and training modules required for this research study.
A summary of required training can be found at: http://rcco.pitt.edu/training-courses/training-table-list
Yes
No

Request for sIRB Fee Budget and/or Letter of Support for Grant Submission

REQUEST FOR SIRB BUDGET AND/OR LETTER OF SUPPORT (LOS) FOR GRANT SUBMISSION

Instructions for Use: To be completed when a Pitt/UPMC investigator is requesting a LOS for grant submission.

Note, if any of this request is incomplete at the time of submission, you will be prompted to submit another request until a complete submission is received by our office.

Study Title:
(Note, this is the verbatim title from the grant application.)

Are you requesting a letter of support (LOS)?
Yes
No

Recipient of LOS Information:
Name of individual(s) to whom the letter should be addressed
Education credentials
Title (to appear in letter)
Name of Institution
Address
City
State
Postal code
Grant title
RFA/RFP number

For which direction are you requesting a LOS?
Pitt to serve as IRB of Record
Pitt ceding IRB review to external institution

Not sure

Select the funding agency that is requesting the LOS.
Federal, specify:
Foundation, specify:
Industry, specify:
Other, specify:

Is this project supported by a U01 grant application?
Yes, specify the number of anticipated projects under this grant
No

What is the anticipated risk level of this research study?
Greater Than Minimal Risk
Minimal Risk
Not sure

If requesting *Pitt to serve as IRB of Record*, what is the maximum number of relying sites that will be budgeted for this project (not including the Pitt/UPMC site)?
(If requesting Pitt to cede IRB review to external institution, indicate '999' in this section.)

When is the grant deadline? [mm/dd/yyyy]

How many years is the grant?

Upload the research plan or the human subjects section of the grant application for review

Attestation
I attest to *both* of the following:

I have reviewed the "Pitt IRB of Record" or "Pitt Cede IRB Review" guidance document found at www.irb.pitt.edu, under "Guidance & Forms," "R" for "Reliance Guidance", depending on the direction requested.

The information provided in this request is complete and accurate.

Note, once funding has been confirmed for this project, a formal reliance request will need to be submitted through this system.

Request for Individual Investigator Agreement (IIA)

REQUEST FOR INDIVIDUAL INVESTIGATOR AGREEMENT (IIA)

Instructions for Use: To be completed when a Pitt/UPMC investigator is requesting an IIA for an external individual who does not have access to an IRB to provide approval and/or oversight for research activities being performed.

Note, if any of this request is incomplete at the time of submission, you will be prompted to submit another request until a complete submission is received by our office.

Attestation
I attest to *both* of the following:

I have reviewed the "Individual Investigator Agreement" guidance document found at www.irb.pitt.edu, under "Guidance & Forms", "R" for "Reliance Guidance".

The information provided in this request is complete and accurate.

Study Title:
(Note, this is the verbatim title that will appear on the agreement for this project; ensure all sites involved are using the same title.)

PittPRO Study ID:

External individual for whom you are requesting an IIA:
Name
Education credentials
Address
City
State
Postal code
Phone number
Email address

Select the education and training program that this external individual has completed:
(Note, the external individual must complete one of these training programs prior to executing an IIA.)
Collaborative Institutional Training Initiative (CITI)
Community Partner Research Ethics Training (CPRET)

Upload the CPRET certificate of completion.

Select the role(s) of the external individual in this research study:
Recruitment
Obtaining consent
Data collection
Implementing/administering research intervention
Identifiable data/sample analysis
De-identified data/sample analysis
Other, specify:

Indicate the mechanism for which this external investigator will be compensated for their role in this research study.
Note, University agreements must be channeled through and administered by either the Pitt Office of Sponsored Programs or the Pitt Purchasing Services Department (https://cfo.pitt.edu/pexpress/purchases/serviceagreements.php).
Subcontract though the Pitt Office of Sponsored Programs
Service contract through the Pitt Purchasing Services Department

Upload the *Scope of Work* or *Scope of Services* document.

Is this study funded in part or whole by a PHS Agency?

[e.g., Agency for Healthcare Research & Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control & Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Substance Abuse & Mental Health Services Administration (SAMHSA)]
Yes
No

Does the external investigator* involved in this study (Select all that apply):

**External investigator means the external individual who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. The PI is responsible for ensuring that s/he and all other relevant members of the study team review the above questions describing Significant Financial Interests.*

***such as salary, consulting fees, honoraria, or paid authorship*

****through the provision of funds, drugs, devices, or other support for this research*

*****Such as serving on the Board of Directors or Board of Managers or a position that carries a fiduciary responsibility to the company (e.g., CEO, CFO, CTO, or CMO).*

A. Have equity in a publicly-traded entity that either sponsors** this research or owns the technology being evaluated or developed that exceeds a 5% ownership interest or a current value of $10,000?
B. Have equity in a non-publicly-traded entity that either sponsors this research or owns the technology being evaluated or developed?
C. Receive salary, consulting fees, honoraria, royalties or other remuneration from an entity that either sponsors this research or owns the technology being evaluated or developed that is expected to exceed $10,000 during the past or next 12 months?
D. Have rights as either the author or inventor of intellectual property being evaluated or developed in this research that is the subject of an issued patent or has been optioned or licensed to an entity?
E. Have an officer or management position**** with a Licensed Start-up Company overseen by the COI Committee that either sponsors this research or owns the technology being evaluated or developed?
F. Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed?
None of the above options apply and there are no other financial conflicts of interest in the conduct of this research.

Does the external investigator* involved in this study (Select all that apply):

**External investigator means the external individual who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. The PI is responsible for ensuring that s/he and all other relevant members of the study team review the above questions describing Significant Financial Interests.*

***such as salary, consulting fees, honoraria, or paid authorship*

****through the provision of funds, drugs, devices, or other support for this research*

*****Such as serving on the Board of Directors or Board of Managers or a position that carries a fiduciary responsibility to the company (e.g., CEO, CFO, CTO, or CMO).*

A. Have a financial interest (aggregated value of equity and remuneration** during the past or next twelve months) in a publicly-traded entity that either sponsors*** this research or owns the technology being evaluated or developed that exceeds $5,000 but not $10,000?
B. Have a financial interest (aggregated value of equity and remuneration during the past or next twelve months) in a publicly-traded entity that either sponsors this research or owns the technology being evaluated or developed that exceeds $10,000?
C. Receive remuneration (during the past or next twelve months) from a non-publicly traded entity that either sponsors this research or owns the technology being evaluated or developed that exceeds $5,000 but not $10,000?
D. Receive remuneration (during the past or next twelve months) from a non-publicly traded entity that either sponsors this research or owns the technology being evaluated or developed that exceeds $10,000?
E. Have equity in a non-publicly traded entity that either sponsors this research or owns the technology being evaluated or developed?
F. Receive reimbursement or sponsorship of travel expenses (for one trip or a series of trips during the past or next twelve months) by an outside entity that either sponsors this research or owns the technology being evaluated or developed that exceeds $5,000?
G. Have rights as either the author or inventor of intellectual property being evaluated or developed in this research that is the subject of an issued patent or has been optioned or licensed to an entity?
H. Have an officer or management position**** with a Licensed Start-up Company overseen by the COI Committee that either sponsors this research or owns the technology being evaluated or developed?
I. Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed?
None of the above options apply and there are no other financial conflicts of interest in the conduct of this research.

Describe the nature of the Significant Financial Interest(s):