Overview of Reliance Request System Content

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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
Department
Email address

Pitt/UPMC Study Coordinator:
Name
Email address

Select the reason for reliance request:
Pitt to Serve as IRB of Record
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.hrpo.pitt.edu](http://www.hrpo.pitt.edu), under A-Z Guidance, “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 OSIRIS or PittPRO)?**

Yes, specify study ID:

No

**Study ID:**

*(Note, if you have not yet created a submission, please do so now in OSIRIS. The IRB application does not need to be completed at this time; this step is to generate a PRO# 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?**
<table>
<thead>
<tr>
<th>Condition of funding</th>
<th>Pitt PI relocating</th>
<th>External site(s) not engaged in human subjects research</th>
<th>Other, specify:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>What is the risk level of the study?</th>
<th>Greater than Minimal Risk</th>
<th>Minimal Risk</th>
<th>Not sure</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>At which local sites will research procedures be performed? (Select all that apply)</th>
<th>University of Pittsburgh</th>
<th>UPMC</th>
<th>Other, specify:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Select all vulnerable populations that apply to this research study.</th>
<th>Pregnant Women</th>
<th>Fetuses</th>
<th>Neonates</th>
<th>Children</th>
<th>Decisionally Impaired</th>
<th>Prisoners</th>
<th>Non-English Speakers</th>
<th>Not applicable</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Does this research study involve the use of a device?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Is there an Investigational Device Exemption (IDE)?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

| Institution that holds the IDE:                                     |                                             |
----------------------------------------|

<table>
<thead>
<tr>
<th>Does the research study involve the use of a drug?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Is there an Investigational New Drug (IND) application?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

| Institution that holds the IND:                                     |                                             |
----------------------------------------|

<table>
<thead>
<tr>
<th>Does the research study involve an FDA exception from informed consent?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

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.

<table>
<thead>
<tr>
<th>Relying Site:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal Name</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>Postal code</td>
<td></td>
</tr>
</tbody>
</table>

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.hrpo.pitt.edu](http://www.hrpo.pitt.edu), under A-Z Guidance, “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 OSIRIS or PittPRO)?**

Yes, specify study ID:

No

**OSIRIS Study ID:**

*(Note, if you have not yet created an External Pathway (EXT) submission in OSIRIS, please do so now. The IRB application should not be completed/submitted at this time; this step is to generate a EXT# 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
<table>
<thead>
<tr>
<th>Other, specify:</th>
</tr>
</thead>
</table>

| 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: |

<table>
<thead>
<tr>
<th>If available, upload the consent template(s) and local context form from the external site.</th>
</tr>
</thead>
</table>

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

| Will any radiation be used specifically for research purposes at the Pitt/UPMC site(s)? |
| 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 |

<p>| Does this research study involve the use of a device? |
| Yes |
| No |</p>
<table>
<thead>
<tr>
<th>Question</th>
<th>Option</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there an Investigational Device Exemption (IDE)?</td>
<td>Yes, No</td>
<td></td>
</tr>
<tr>
<td>Institution that holds the IDE:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the research study involve the use of a drug?</td>
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<td>Is there an Investigational New Drug (IND) application?</td>
<td>Yes, No</td>
<td></td>
</tr>
<tr>
<td>Institution that holds the IND:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institution you are requesting to act as IRB of Record:</td>
<td>Name, Address, City, State, Postal code, Federal Wide Assurance (FWA) number</td>
<td></td>
</tr>
<tr>
<td>Does the institution that will serve as IRB of Record have AAHRPP accreditation?</td>
<td>Yes, No</td>
<td></td>
</tr>
<tr>
<td>Has the institution that will serve as IRB of Record undergone OHRP self-assessment or another process of assessing standards?</td>
<td>Yes, No, explain:</td>
<td></td>
</tr>
<tr>
<td>Is this institution a commercial IRB (e.g., WIRB, Advarra, etc.)?</td>
<td>Yes, No</td>
<td></td>
</tr>
<tr>
<td>Upload the IRB authorization agreement from the external site, if available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lead Investigator, typically at the institution that will serve as the IRB of Record:</td>
<td>Name, Education credentials, Email address</td>
<td></td>
</tr>
<tr>
<td>Lead Study Coordinator at the institution that will serve as IRB of Record:</td>
<td>Name, Email address</td>
<td></td>
</tr>
<tr>
<td>IRB Representative at institution that will serve as IRB of Record:</td>
<td>Name</td>
<td></td>
</tr>
</tbody>
</table>
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 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

University of Pittsburgh • Human Research Protection Office • 3500 Fifth Avenue • Phone 412-383-1480 www.hrpo.pitt.edu

V8. 07.07.2020
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 Letter of Support for Grant Submission

REQUEST FOR 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.

For which of the following are you requesting a LOS?
Pitt to serve as IRB of Record  
Pitt ceding IRB review to external institution  
Not sure

**How many relying sites are anticipated for this project?**  
Number of sites  
Not sure

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

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

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

**How many years is the grant?**

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

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

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

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**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.hrpo.pitt.edu](http://www.hrpo.pitt.edu), under A-Z Guidance, “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.*

**OSIRIS or 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](https://cfo.pitt.edu/pexpress/purchases/serviceagreements.php)).*
- Subcontract through 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.

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****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):**