

GUIDELINES FOR NIH STUDY TEAMS COMPLETING THE NIH RELIANCE AGREEMENT REQUEST FORM

These guidelines are for NIH Study Teams submitting a Reliance Agreement Request Form using the internal [NIH reliance system](#). The request form is used when an NIH team requests to rely on an external IRB or when they request for an external site to rely on the NIH IRB.

OVERVIEW

- A Reliance Agreement is a written agreement between institutions that identifies which institution will serve as the Reviewing IRB and which will cede IRB review i.e., the Relying Institution. It outlines the respective roles and responsibilities and is negotiated by the respective Human Research Protection Programs.
- Reliance Agreements can document NIH relying on an external IRB, or an external institution relying on the NIH IRB.
- To initiate a request for a Reliance Agreement the NIH PI/designee submits a reliance request in the [NIH reliance system](#) – the application is found in the *Agreement Request* section of the [Reliance & Single IRB \(sIRB\) Resources](#) page of the [IRBO](#) website.
- The request form includes branching to ensure that appropriate information is captured from study teams. It also allows a single submission to request that up to 10 external sites (Participating Sites) rely on the NIH IRB. However, the request form needs to be completed in one go and cannot be saved to complete later. Once submitted, the forms cannot be edited by the requester.
- Attached are 2 PDFs of the request form to help NIH investigators prepare their requests.
 - [Appendix A](#): Request form questions when requesting to rely on an external IRB
 - [Appendix B](#): Request form questions when requesting that an external site(s) relies on the NIH IRB
- Submitting the request form only initiates the reliance process. For detailed instructions on the steps that need to be completed to rely on an external IRB or to request that the NIH serve as the Reviewing IRB for a multi-site study, please contact the NIH Reliance and Single IRB Team at NIH-Reliance-sIRB@nih.gov.



NIH IRB Reliance Request Form

A Reliance Agreement is a written agreement between institutions that identifies which institution will serve as the Reviewing IRB and which will cede IRB review i.e., the Relying Institution. Complete this request form if you are an NIH PI/designee that needs NIH to rely on an external IRB, or you want to request for an external site(s) to rely on the NIH IRB. If additional guidance is needed, please contact the NIH Reliance and Single IRB Team at:

NIH-Reliance-sIRB@nih.gov (<mailto:NIH-Reliance-sIRB@nih.gov>).

* Required

Complete this Form and click Submit

NOTE: This form cannot be saved to return to later

This form can only be used to add up to 10 Participating Sites (pSITES). However, if you have not confirmed that the NIH IRB can review for a study with more than 5 pSITES, contact the Reliance and sIRB team at NIH-Reliance-sIRB@nih.gov (<mailto:NIH-Reliance-sIRB@nih.gov>) BEFORE starting on this form.

Individual Requesting Agreement

1. Date of this Request: *



Format: M/d/yyyy

2. Role of Requestor

Principal Investigator

Associate Investigator

Protocol Navigator

Other

Your Information

You will enter the PI's information in the NEXT section.

3. Your First and Last Name *

4. Your Email Address *

NIH Principal Investigator Information

5. Is the NIH Principal Investigator an NIH Employee? *

Yes

No

6. What is the First and Last Name of the NIH Principal Investigator? *

7. What are the Credentials of the NIH Principal Investigator? (e.g., MD, PhD, etc.)

8. What is the email of the NIH Principal Investigator?

Protocol Information

9. Title of the Protocol: *

10. NIH Protocol Number (if available):

11. Brief Description of Protocol:

12. Are any of the other involved sites receiving federal funding to conduct this study? If so, provide the site name and funding source. *

13. What is the current protocol status? *

If this protocol has already been reviewed and approved by an external Reviewing IRB in the United States (i.e., this is an open and on-going study), provide their approval date for this study.

14. Is this a request to rely on the NIH IRB or a Non-NIH IRB? *

- NIH IRB
- Non-NIH IRB

Reviewing IRB Information

15. Name of the external IRB providing oversight (aka. Reviewing IRB, IRB of Record): *

WCG IRB

Advarra IRB

Other

16. If NIH is to rely on the WCG or Advarra IRB, will the IRB fees be covered by the NIH IC? *

Yes

No

17. Is the Reviewing IRB a signatory to the SMART Agreement?

*

To find out, look them up here: <https://smartirb.org/participating-institutions/>
(<https://smartirb.org/participating-institutions/>).

Yes

No

18. If it is not a SMART signatory, provide the First and Last Name of the Reliance/Human Research Protections Program (HRPP) contact: *

19. Reliance/HRPP Contact Person's Email: *

20. Provide the IRB institution's FWA or IRB# *

You can look up the IRB institution's FWA here: <https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>
(<https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>).

If it is a standalone IRB, look up the IRB Number here: <https://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc>
(<https://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc>).

NIH Research Activities When Relying On An External IRB

21. Which of the following research activities will be conducted by the NIH

*

Check all that apply:

- Obtain informed consent (including screening)
- Interact with subjects and/or conduct research activities i.e., carry out research interventions
- Analyze identifiable data/ specimens
- Analyze coded data/ specimens and have access to the code key
- Serve as Coordinating Center
-

Other

22. Will any of the above research activities take place away from the NIH site?

- Yes
- No


23. Provide details as to where these activities will take place *

Thank You for Completing the Form

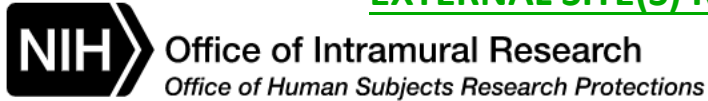
The NIH Reliance and sIRB Team will contact you if any further information is needed during the processing of this request.

If you have any questions, contact NIH-Reliance-sIRB@nih.gov (<mailto:NIH-Reliance-sIRB@nih.gov>)

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APPENDIX B: REQUEST FORM QUESTIONS WHEN REQUESTING THAT AN EXTERNAL SITE(S) RELIES ON THE NIH IRB



NIH IRB Reliance Request Form

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1. Date of this Request: *



Format: M/d/yyyy

2. Role of Requestor

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Other

Your Information

You will enter the PI's information in the NEXT section.

3. Your First and Last Name *

4. Your Email Address *

NIH Principal Investigator Information

5. Is the NIH Principal Investigator an NIH Employee? *

Yes

No

6. What is the First and Last Name of the NIH Principal Investigator? *

7. What are the Credentials of the NIH Principal Investigator? (e.g., MD, PhD, etc.)

8. What is the email of the NIH Principal Investigator?

Protocol Information

9. Title of the Protocol: *

10. NIH Protocol Number (if available):

11. Brief Description of Protocol:

12. Are any of the other involved sites receiving federal funding to conduct this study? If so, provide the site name and funding source. *

13. What is the current protocol status? *

If this protocol has already been reviewed and approved by an external Reviewing IRB in the United States (i.e., this is an open and on-going study), provide their approval date for this study.

14. Is this a request to rely on the NIH IRB or a Non-NIH IRB? *

- NIH IRB
- Non-NIH IRB

Participating Site Involved in the Study (1)

Please enter the information regarding the participating site involved in the study.

24. Name of the Participating Site (pSITE) that would like to rely on the NIH IRB: *

25. pSITE FWA Number: *

You can look up the pSITE's FWA Number here:

<https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc> (<https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>).

26. Name of the pSITE Principal Investigator and their credentials (e.g., MD, PHD etc.): *

27. Email of the pSITE Principal Investigator:

28. Which of the following research activities will be conducted by the pSITE? *

Check all that apply:

- Obtain informed consent (including screening)
 - Interact with subjects and/or conduct research activities i.e., carry out research interventions
 - Analyze identifiable data/ specimens
 - Analyze coded data/ specimens and have access to the code key
 - Serve as Coordinating Center
 -
- Other

29. Is the pSITE a signatory to the SMART Agreement? *

To find out, look them up here: <https://smartirb.org/participating-institutions/>
(<https://smartirb.org/participating-institutions/>).

- Yes
- No

30. If it is not a SMART signatory, provide the First and Last Name of the Reliance/Human Research Protections Program (HRPP) contact: *

31. Reliance/HRPP Contact Person's Email: *

32. Do you need to enter any more participating sites that would like to rely on the NIH IRB?

Yes

If "Yes" is checked, questions 24-32 will repeat to allow the addition of more pSITES, up to a maximum of 10.


No

Thank You for Completing the Form

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