



BROWN

Human Research Protections Program (HRPP) IRB Authorization Agreement (IAA) Investigator Checklist

Checklist for researchers in preparing for an IRB Authorization Agreement (IAA) request with a collaborating organization. This process is available for non-Exempt research only.

*Please do not submit this checklist with your Application for IRB Authorization Agreement.

Determine eligibility for establishing an IAA

<input type="checkbox"/> Yes <input type="checkbox"/> No	Does your research require Expedited or Full Board review?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the collaborating organization 's research activities require Expedited or Full Board review?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the collaborating organization engaged in the research?	
	If you answered "no" to any of the above questions, your study is not eligible for an IAA.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the collaborating organization subject to the single IRB mandate?	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the collaborating organization within the US?
	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is your study federally funded?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the collaborating organization have a Federalwide Assurance Number (FWA)? * If you are unsure, you can search the OHRP Database for registered FWAs	
	If you answered "no" to any of the above questions, your study may need further review to determine IAA eligibility. Consult with HRPP for next steps.	

Determine the institution / organization that will serve as the IRB of Record

The following factors are all possible determinants in deciding which organization will serve as the [IRB of Record](#). Researchers should consult with their collaborators to select the appropriate site for providing ethical oversight.

Brown can only serve as the IRB of Record for up to 3 sites including Brown.

<input type="checkbox"/>	Prime Awardee
<input type="checkbox"/>	Home Institution of the overall Principal Investigator (PI)
<input type="checkbox"/>	Location of research activities
<input type="checkbox"/>	Location of data storage and analysis

<input type="checkbox"/>	Organizational ability to provide administrative support
<input type="checkbox"/>	Sponsor request
<input type="checkbox"/>	Budgetary Considerations

Brown processing	
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<input type="checkbox"/>	Ensure Brown CITI training is up-to date for PI and internal Co-Investigators (Co-I)
<input type="checkbox"/>	Determine reliance platform (Select One)
<input type="checkbox"/>	SMART IRB (Review SMART IRB Master Reliance Agreement section)
<input type="checkbox"/>	Advarra (Review Advarra Master Reliance Agreement section)
<input type="checkbox"/>	Brown Letter of Agreement
<input type="checkbox"/>	Collaborator's Letter of Agreement
<input type="checkbox"/>	Other: Click or tap here to enter text.

If Brown is IRB of Record	
<i>Brown will always process an IAA in which we are the IRB of Record as an amendment. If the IAA Application is for a new study, once we approve the Application for Expedited / Full Board Review, we will immediately create an amendment to start the IAA review process, ensuring the relying site has accurate and approved materials to review.</i>	

<input type="checkbox"/>	Submit completed IAA Application for each relying site
<input type="checkbox"/>	Ensure all fields have been completed
<input type="checkbox"/>	Ensure application has been signed
<input type="checkbox"/>	Submit any revised materials necessary to approve
<input type="checkbox"/>	Protocol
<input type="checkbox"/>	Data Security Assessment
<input type="checkbox"/>	Consent(s)
<input type="checkbox"/>	Recruitment Materials
<input type="checkbox"/>	Local context form for each relying institution, if required

If Brown is Relying on another institution	
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<input type="checkbox"/>	Submit completed IAA Application
<input type="checkbox"/>	Ensure all fields have been completed
<input type="checkbox"/>	Ensure application has been signed
<input type="checkbox"/>	Submit Approval Memo from reviewing IRB
<input type="checkbox"/>	Submit approved protocol including Brown research activities and materials

<input type="checkbox"/>	Consent form should include Brown researcher and activities, as applicable
<input type="checkbox"/>	Recruitment and materials citing a Brown research study must adhere to Recruitment Policy

Collaborating organization processing

Communicate with Co-Investigator to ensure the collaborating organization's external processes are met

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| <input type="checkbox"/> | Submit applications and documents |
| <input type="checkbox"/> | Review COI policy |
| <input type="checkbox"/> | If using PHI, ensure HIPAA policies are communicated and executed |
| <input type="checkbox"/> | Local Context review |

Working with Master Reliance Agreement partners

IRB Reliance Exchange (IREx): Brown has signed on with IREx to document reliance agreements. This platform serves as a central location to upload materials and complete local context review. An IAA Application and reliance through SMART IRB or a Letter of Agreement are required when using IREx. *The initiation of the reliance should be done by the overall PI.*

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| <input type="checkbox"/> | Submit completed IAA Application indicating your request to use IREx. Upon review, HRPP will initiate the study in the IREx portal. You will receive notification from IREx to log-in and complete required elements. |
| <input type="checkbox"/> | If using SMART IRB, initiate reliance request. (See next section) |
| <input type="checkbox"/> | If using Letter of Agreement, HRPP will initiate request with Relying Institution |

SMART IRB: The SMART IRB request is in conjunction with the IRB Authorization Agreement Application to be reviewed and approved by Brown's HRPP. *The initiation of the reliance should be done by the overall PI.*

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| <input type="checkbox"/> | Request Investigator Access for Principal Investigator |
| <input type="checkbox"/> | Request Investigator Access for Project Admin to delegate SMART IRB responsibilities |
| <input type="checkbox"/> | Complete all required fields |
| <input type="checkbox"/> | Upload study documents (protocol, consents, recruitment, approval memo) |

Advarra: Brown has negotiated a Master Reliance Agreement with Advarra, which requires a signed cover page with all submissions

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| <input type="checkbox"/> | Submit completed IAA Application indicating your request to rely on Advarra. Upon review and acceptance, a cover page will be issued to you for inclusion with your submission. |
| <input type="checkbox"/> | Submit full application to Advarra (Signed cover page, full protocol, relevant documents) |
| <input type="checkbox"/> | Submit approval memo from Advarra to Brown |