

**Human Research Protections Program (HRPP)**

**IRB Authorization Agreement (IAA) Investigator Checklist**

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| 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. |

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| **Determine eligibility for establishing an IAA** | | |
| Yes  No | Does your research require [Expedited](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#expedited) or [Full Board](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#full) review? | |
| Yes  No | Does the [collaborating organization](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#Collaborating)’s research activities require [Expedited](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#expedited) or [Full Board](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#full) review? | |
| Yes  No | Is the collaborating organization [engaged](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) in the research? | |
|  | **If you answered “no” to any of the above questions, your study is not eligible for an IAA.** | |
| Yes  No | Is the collaborating organization subject to the [single IRB mandate](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/single-irb-sirb-mandate)? | |
|  | Yes  No | Is the collaborating organization within the US? |
|  | Yes  No | Is your study federally funded? |
| Yes  No | Does the collaborating organization have a [Federalwide Assurance Number (FWA)](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#fwa)? \* If you are unsure, you can search the [OHRP Database](https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc) 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.** | |

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| **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*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#ior)*. 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.* | |
|  | [Prime Awardee](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#prime) |
|  | Home Institution of the overall [Principal Investigator](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#pi) (PI) |
|  | Location of research activities |
|  | Location of data storage and analysis |
|  | Organizational ability to provide administrative support |
|  | Sponsor request |
|  | Budgetary Considerations |

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| **Brown processing** | | | |
|  | Ensure Brown [CITI training](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/hrpp-training/citi-instructions) is up-to date for PI and internal Co-Investigators (Co-I) | | |
|  | Determine reliance platform | | |
|  |  | | [SMART IRB](#smart) (Review [SMART IRB Master Reliance Agreement](#smart) section) |
|  |  | | [Advarra](https://www.advarra.com/) (Review [Advarra Master Reliance Agreement](#advarra) section) |
|  |  | | Brown Letter of Agreement |
|  |  | | Collaborator’s Letter of Agreement |
|  |  | | Other: Click or tap here to enter text. |
| **If Brown is IRB of Record**  *Brown will always process an IAA in which we are the IRB of Record as an* [*amendment*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#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.* | | | |
|  | | Submit completed [IAA Application](https://www.brown.edu/research/sites/research/files/IAA%20Application_v4.27.20.docx) for each relying site | |
|  | |  | Ensure all fields have been completed |
|  | |  | Ensure application has been signed |
|  | | Submit any revised materials necessary to approve | |
|  | |  | [Protocol](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#Protocol) |
|  | |  | [Data Security Assessment](https://www.brown.edu/research/sites/research/files/Data%20Security%20Assessment%204.28.20.docx) |
|  | |  | [Consent(s)](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates#Consents) |
|  | |  | Recruitment Materials |
|  | |  | Local context form for each relying institution, if required |
| **If Brown is Relying on another institution** | | | |
|  | | Submit completed IAA Application | |
|  | |  | Ensure all fields have been completed |
|  | |  | Ensure application has been signed |
|  | | Submit Approval Memo from reviewing IRB | |
|  | | Submit approved protocol including Brown research activities and materials | |
|  | |  | Consent form should include Brown researcher and activities, as applicable |
|  | |  | Recruitment and materials citing a Brown research study must adhere to [Recruitment Policy](https://www.brown.edu/research/sites/research/files/Recruitment%20Policy%2C%2010-04-19.pdf) |

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| **Collaborating organization processing** | |
| Communicate with Co-Investigator to ensure the collaborating organization’s external processes are met | |
|  | Submit applications and documents |
|  | Review COI policy |
|  | If using [PHI](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#phi), ensure HIPAA policies are communicated and executed |
|  | Local Context review |

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| **Working with Master Reliance Agreement partners** | | | |
| [**IRB Reliance Exchange (IREx):**](https://www.irbexchange.org/p/)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.* | | | |
|  | Submit completed [IAA Application](https://www.brown.edu/research/sites/research/files/IAA%20Application_v4.27.20.docx) 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. | | |
|  |  | If using SMART IRB, initiate reliance request. (See next section) | |
|  |  | If using Letter of Agreement, HRPP will initiate request with Relying Institution | |
| **[SMART IRB:](https://smartirb.org/)** 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.* | | | |
|  | [Request Investigator Access](https://reliance.smartirb.org/invitations/new) for Principal Investigator | | |
|  |  | | [Request Investigator Access](https://reliance.smartirb.org/invitations/new) for Project Admin to delegate SMART IRB responsibilities |
|  | Complete all required fields | | |
|  | Upload study documents (protocol, consents, recruitment, approval memo) | | |
| **[Advarra:](https://www.advarra.com/)** Brown has negotiated a Master Reliance Agreement with Advarra, which requires a signed cover page with all submissions | | | |
|  | Submit completed [IAA Application](https://www.brown.edu/research/sites/research/files/IAA%20Application_v4.27.20.docx) indicating your request to rely on Advarra. Upon review and acceptance, a cover page will be issued to you for inclusion with your submission. | | |
|  | Submit full application to Advarra (Signed cover page, full protocol, relevant documents) | | |
|  | Submit approval memo from Advarra to Brown | | |