

The Negotiating Offices, Office of the Vice Provost for Research (OVPR) and Harvard University Information Technology (HUIT) gathered feedback on the following research -related processes:

- Documenting Institutional Review Board (IRB) review;
- Negotiating and executing Data Use Agreements (DUAs); and
- Completing Data Security Review for use and management of research data.

A suite of online applications (Agreements/DUA, Data Safety, ESTR/IRB) was implemented to support management of these processes. The following briefly describes options for where to start when seeking these reviews, when required. Please see [Related Policies and Process Information](#) for all related requirements.

Application Use Overview

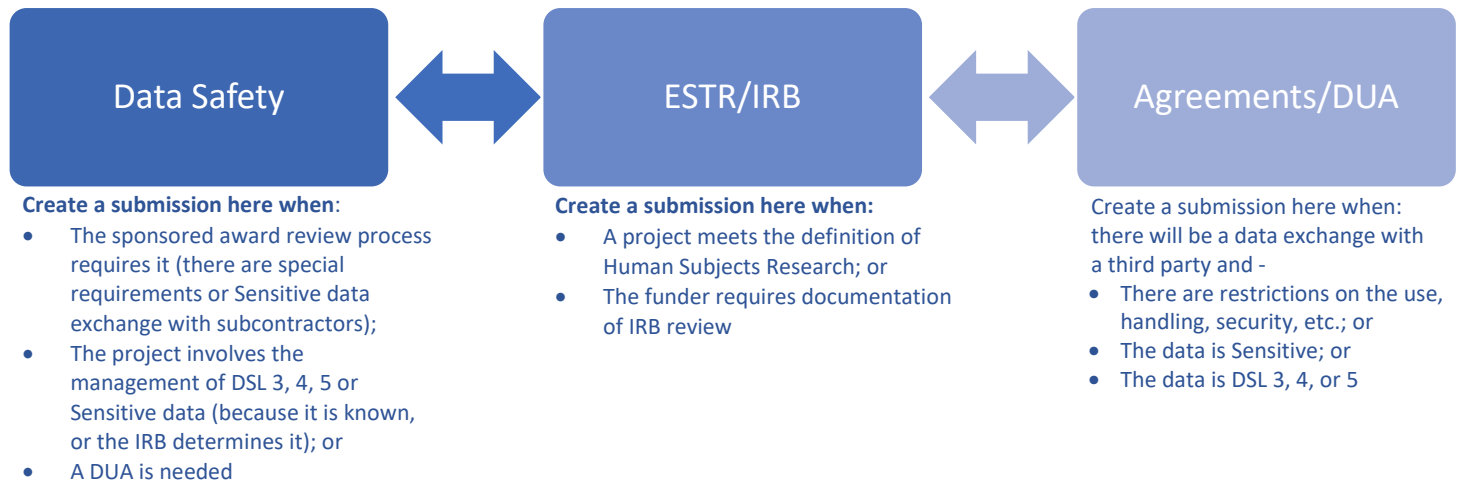
Reviews may be initiated in various applications that can be visited directly or via tab-navigation once you are in the suite. These reviews can be connected via a [Manage Related Projects](#) activity, in the suite.

If the project involves...	... it needs review by a	Manage review in the...
Human Subjects Research where the IRB has determined that the research involves use of only non-Sensitive data	Harvard IRB	ESTR/IRB Application
Use of research data qualifying as Data Security Level 3, 4 or 5 that is not managed via a DUA and is Not Human Subjects Research.	Information Security Reviewer	Data Safety Application
Human Subjects Research where the IRB has determined that the research involves use of Sensitive data	<ol style="list-style-type: none"> 1. Harvard IRB AND 2. Information Security Reviewer <i>IRB review will not be completed (by the IRB) until ISR review is completed.</i>	ESTR/IRB Application Data Safety Application
Data exchange where a contract (or DUA) is needed and the exchange is part of a project that meets the definition of Human Subjects Research	<ol style="list-style-type: none"> 1. Negotiating Office AND 2. Information Security Reviewer AND 3. Harvard IRB <i>DUA will not be signed by the Negotiating Office until ISR & IRB reviews are completed.</i>	Agreements/DUA Application Data Safety Application ESTR/IRB Application
Transfer of non-public data from a third party to Harvard, or from Harvard to a third party, with restrictions on handling, use, retention, security, etc., where a contract (or DUA) is needed.	<ol style="list-style-type: none"> 1. Negotiating Office AND 2. Information Security Reviewer <i>DUA will not be signed by the Negotiating Office until ISR review is completed.</i>	Agreements/DUA Application Data Safety Application
A sponsored award (managed in GMAS) <ul style="list-style-type: none"> • where the funder has added special data management requirements; OR • where Harvard is the prime awardee and there will be Sensitive data exchanged with subaward recipients 	<ol style="list-style-type: none"> 1. Information Security Reviewer <i>Award setup will not be completed by Negotiating Office until ISR review is completed.</i>	Data Safety Application
Human Subjects Research and a sponsored award <ul style="list-style-type: none"> • where the funder has added special data management requirements; OR • where Harvard is the prime awardee and there will be Sensitive data exchanged with subaward recipients 	<ol style="list-style-type: none"> 1. Harvard IRB AND 2. Information Security Reviewer <i>Award setup will not be completed by Negotiating Office until ISR review is completed.</i>	ESTR/IRB Application Data Safety Application

Where to Start Required Reviews

There is no wrong place to start! The suite of online applications allows the initiation and connection of reviews at any time that makes sense for the project and research team. Always start where the most information is known for proposal and review and proceed from there. If more than one or all requirements are known at the same time, initiate reviews in tandem.

Selecting the starting system
(also see [Application Use Overview](#))



When the review of a submission is relevant to another submission (for example, the Security Review of a DUA), link the reviews via the [Manage Related Projects](#) activity in the project workspace. This will allow users of the other applications to see the relationship and the status of that other (possibly required) review.

Application	General information included in this review
Data Safety Application	<ul style="list-style-type: none"> • What kind of data will be managed at Harvard? • Where will data be managed, analyzed, or stored? • Who is accessing the data? • Is there funding for any additional required controls to manage the data?
ESTR/IRB Application	<ul style="list-style-type: none"> • What is the aim/hypothesis of the research? • Who will be the subject of / participant in the research via intervention, interaction, or data/specimen use? • How will consent be obtained and the data/specimens collected? • What is involved in participating in the project (including where the research will take place)? • Who is working on the project (including study team members and collaborating teams or institutions)? • Does the research have funding (sponsored or non-sponsored)?
Agreements/DUA Application	<ul style="list-style-type: none"> • Who will exchange and utilize data? • What kind of data will be exchanged? • Under what terms must the data be exchanged, managed, returned or destroyed?

Related Policies and Process Information

This section is a quick reference centered on research data management and use of a system to support required reviews. Please review related policies and office websites for information on the scope of each review and all relevant requirements.

Policy area	Reviewed by a	Policy and process reference
Information Security Review of Research Data Management	School Security Officer or HUIT InfoSec	<ul style="list-style-type: none"> HUIT Policy: Harvard Enterprise Information Security Policy (HEISP) OVPR Policy: Harvard Research Data Security Policy (HRDSP)
Human Subjects Research	Harvard IRB	University Reference to Area Policies <ul style="list-style-type: none"> Harvard Longwood Campus IRB HMS, HSDM, and HSPH Harvard University Area IRB FAS, HGSE, HKS, HBS, HLS, SEAS, GSD, HDS, WYSS, and the Radcliffe Institute
DUA negotiation and execution	Designated Institutional Official	University Policy on Data Use Agreements Negotiating and Signing Authority for Agreements Related to Research <ul style="list-style-type: none"> Office of Research Administration HSPH Office of Research Administration HMS and HSDM Office of Sponsored Programs FAS, HGSE, HKS, HBS, HLS, SEAS, GSD, HDS, WYSS, and the Radcliffe Institute

Other Reference

- Data Safety Application: researchsafety.harvard.edu
 - Data Safety Help Desk: rshelp@harvard.edu
 - Data Safety Support Site: <https://ras.fss.harvard.edu/data-safety>
- Electronic Submission tracking and Reporting (ESTR) – IRB Application: irb.harvard.edu
 - ESTR Help Desk: estrhelphelp@harvard.edu
 - ESTR Support Site: <https://estrsupport.fss.harvard.edu/>
- Agreements-DUA Application: dua.harvard.edu
 - Agreements-DUA Help Desk: duahelp@harvard.edu
 - Agreements-DUA Support Site: <https://ras.fss.harvard.edu/agreements>