Overview

This job aid will explain the connection between the IRB system (also referred to as "ESTR") and GMAS. The integration between the two systems is intended to provide up to date information about IRB approvals directly from the IRB system, the system of record for Human Subjects Research related determinations and approvals, and eliminate the need to upload IRB documentation or set IRB approval statuses directly in GMAS. This job aid will explain how the IRB systems shares information with GMAS

Prerequisite

This job aid assumes that the reader has a basic understanding of GMAS requests and approvals.

Roles & Responsibilities in GMAS

Central administrators are responsible for checking IRB approval statuses in GMAS prior to major project events to ensure compliance, and for updating IRB approvals to "Harvard IRB review not required" when appropriate to do so. If there are questions about the state of an IRB approval, the Central administrator should work with the Department administrator and/or the PI.

How information from ESTR-IRB is shared with GMAS

GMAS receives information from the IRB system every morning at 5AM Monday through Friday. Connections between the IRB system and GMAS projects are made based on the connection of a GMAS project id in the IRB system as part of the review of the contents of the SmartForm and can be referenced under the "Funding" tab in the IRB workspace.

- If there is no GMAS project associated on the submission in the IRB system, there will be no Harvard IRB information reflected in GMAS.
- GMAS will display IRB information for all projects that are associated to an IRB approval regardless of whether the IRB flag is set in GMAS, or not.

This image shows where the connection between IRB study and GMAS project id can be validated in the IRB system. See the [IRB system guidance on editing a SmartForm](#) on how to add funding to an IRB submission.

The Human participation IRB approval in GMAS

There are four different states of IRB approvals in GMAS:

1. [When GMAS has an IRB approval but there is no project id connection in the IRB system](#)
2. [When GMAS has an IRB approval and there is a project id connection in the IRB system](#)
3. [When GMAS does not have an IRB approval and there is a project id connection in the IRB system](#)
4. [When GMAS has an IRB approval but IRB study review is not required at Harvard](#)

GMAS has an IRB approval (the human subjects question was answered yes at some point) but there is no project id connection in the IRB system:

From the GMAS approval list screen, the approval status will be listed as "No study associated".

From the GMAS IRB approval screen, in the absence of IRB data, it will instead indicate "No study associated".

To ensure any required Harvard IRB review is associated with this project:
- For a new projects, where initial IRB review has not been completed: appropriate members of the study team (such as the PI or primary contact) can follow the steps for creating an initial submission in the IRB system, and include the appropriate GMAS record on the Funding Sources page of the SmartForm. GMAS will update the status as the submission is reviewed and with the determination.
- For an existing project, where the IRB has already made an initial determination: appropriate members of the study team (such as the PI or primary contact) can follow the steps for creating a modification to an existing project in the IRB system, and include the appropriate GMAS record on the Funding Sources page of the SmartForm. GMAS will update only after the modification is approved.

GMAS has an IRB approval (the human subjects question was answered yes at some point) and there is a project id connection in the IRB system:

From the GMAS IRB approval screen, the following information will be provided
- The last time the IRB system sent data to GMAS related to the approval
- A link to the study in the IRB system
- High-level information about the study

Human subjects - IRB approval

💬 Comments (0) | 🔗 Related links

ESTR last queried on Oct 29, 2021 5:00 AM

Generated by Initial proposal: 5601711
Generated date Aug 20, 2013

IRB14-1352 ⬏		Lapsed	Expired May 3, 2021	⊖
Study title	Birth Outcomes Surveillance			
Assurance number	FWA00002642			
Effective date	Sep 29, 2020			
Expiration date	Expired May 3, 2021			

Documents	2 documents	Upload	Download all	⊕

- While there is still a document repository for the IRB approval, this repository should not be used to house IRB letters since they are already associated to the IRB study linked to the approval. If access to the IRB study is needed to view the letters, please work with the PI or PI support staff for access to that study, or follow these steps for access to all ESTR records at a particular department or school.
- Multiple IRB studies can be associated to one GMAS project id. All associated studies will be displayed in GMAS.

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GMAS does not have an IRB approval (the human subjects question has not been answered yes) and there is a project id connection in the IRB system:

From the GMAS approval list screen, a warning at the top of the approval list will display information about the IRB study associated to the project. This may be an indicator* that either the GMAS project has not correctly identified that there is human subjects work associated to the project, or the incorrect project id has been associated in the IRB system. If the issue is related to the latter, appropriate members of the study team (such as the PI or primary contact) can follow the steps for creating a modification to an existing project in the IRB system, and include the appropriate GMAS record on the Funding Sources page of the SmartForm. GMAS will update only after the modification is approved.

Note that sometimes documentation of IRB determination is simply validation that the project is not research, does not involve human subjects, or that IRB review is not required because Harvard is not 'engaged' (as defined under regulation). The approval status helps to indicate if any one of these determinations were made. If so, it is possible that no further action is required.

HarvardGMAS

Harvard GMAS	Search	🔍 ▾	Advanced	**People**	**Organizations**	🔗 Links ▾	👤 Jessica Perreault ▾

LINCS Phase II : Pharmaco Response Signatures and Disease Mechanism

PI Peter Sorger
Fund 152296

Sponsor NIH/NHLBI
Anticipated $13,064,531
Obligated $13,064,531

Segment 1 of 1 | Active
Sep 10, 2014 - Jun 30, 2021

01-Pharmaco Response Signatures and D... > Approvals

Approvals   🔗 Related links | ℹ Info

Approval attributes		3 apply	5 do not apply	⊕

⚠ IRB studies   1 associated study   ⊖

Study number	IRB15-1871
Title	Using patient derived xenografts to develop new treatments for TNBC
Status	Not Human Research
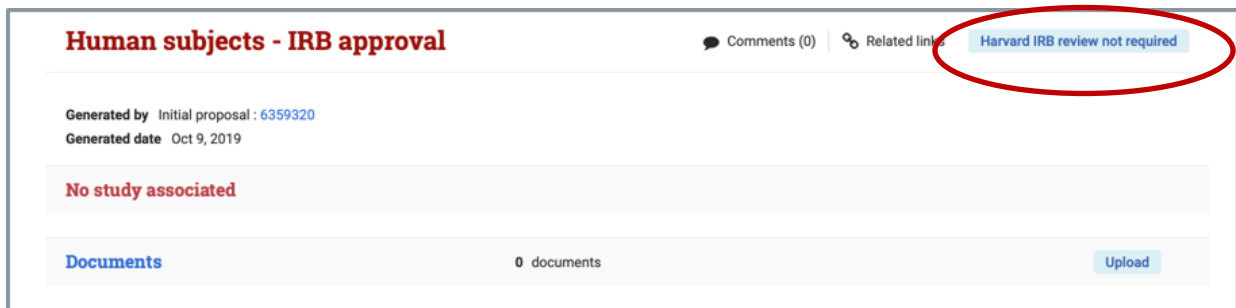
Open all | Close all

Approval type	Status	Responsible party	Due	Effective	Expires	Comments
Needed approvals						
Administrative salaries	Needed	PI / Department	Submission			💬 (0)
Biohazards/rDNA	Needed	PI / Department	Submission			💬 (0)
Biohazards/rDNA	Needed	PI / Department	Submission			💬 (0)
Done approvals						

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GMAS has an IRB approval (the human subjects question has not been answered yes) but IRB study review is not required at Harvard (there is no connection of project id in the IRB system):

When needed, Central Administrators are able to mark IRB approvals as "Not Harvard IRB" by selecting the "Harvard IRB review not required" button from the IRB approval screen. This can only be done when there are no IRB studies associated to the GMAS project id.

Once the IRB approval has been bypassed, the comments entered by the Central Administrator explaining the reason for the bypass will be displayed. If at any time after the approval has been bypassed the GMAS project id is associated to an IRB study, the bypass information will be overwritten with the IRB study information.

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Questions

For additional questions or assistance, please reach out to either the GMAS help (contactgmas@harvard.edu) desk or the ESTR help desk (estrhelp@harvard.edu).