ESTR-IRB, Agreements (DUA), and Data Safety Records in GMAS

User Role(s): All roles
Last Updated: 5/15/2024

Overview

GMAS connects with the ESTR-IRB (IRB), Agreements (DUA), and Data Safety systems every morning to identify records associated with GMAS projects. This job aid has information about the following:

How information from IRB, DUA, and Data Safety is shared with GMAS
How to see in GMAS if there are any IRB, DUA, or Data Safety records associated with a project
The Human participation IRB approval in GMAS
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How information from IRB, DUA, and Data Safety is shared with GMAS

GMAS receives information from the three systems every morning Monday through Friday. Connections between the systems and GMAS projects are made based on the association of a GMAS project ID in the IRB, DUA, or Data Safety systems as part of the review of the contents of the SmartForm.

- If a GMAS project is not associated in the SmartForm for any of the systems, there will be no IRB, DUA, or Data Safety information reflected in GMAS.
- For more information about how to associate GMAS project IDs in the systems, reference the relevant sections from the submission guides,
    - Agreement DUA submission guide
        - "Amendment-Making Changes after Activation"
          "SmartForm Section: DSP Agreement Information"
    - Data Safety submission guide
        - "Requesting Changes or Extension after Initial Approval"
          "SmartForm Section: Funding Sources"
    - IRB study submission guide
        - "Creating a Follow-On Submission after Study Approval"
        - "SmartForm Section: Study Funding Sources".

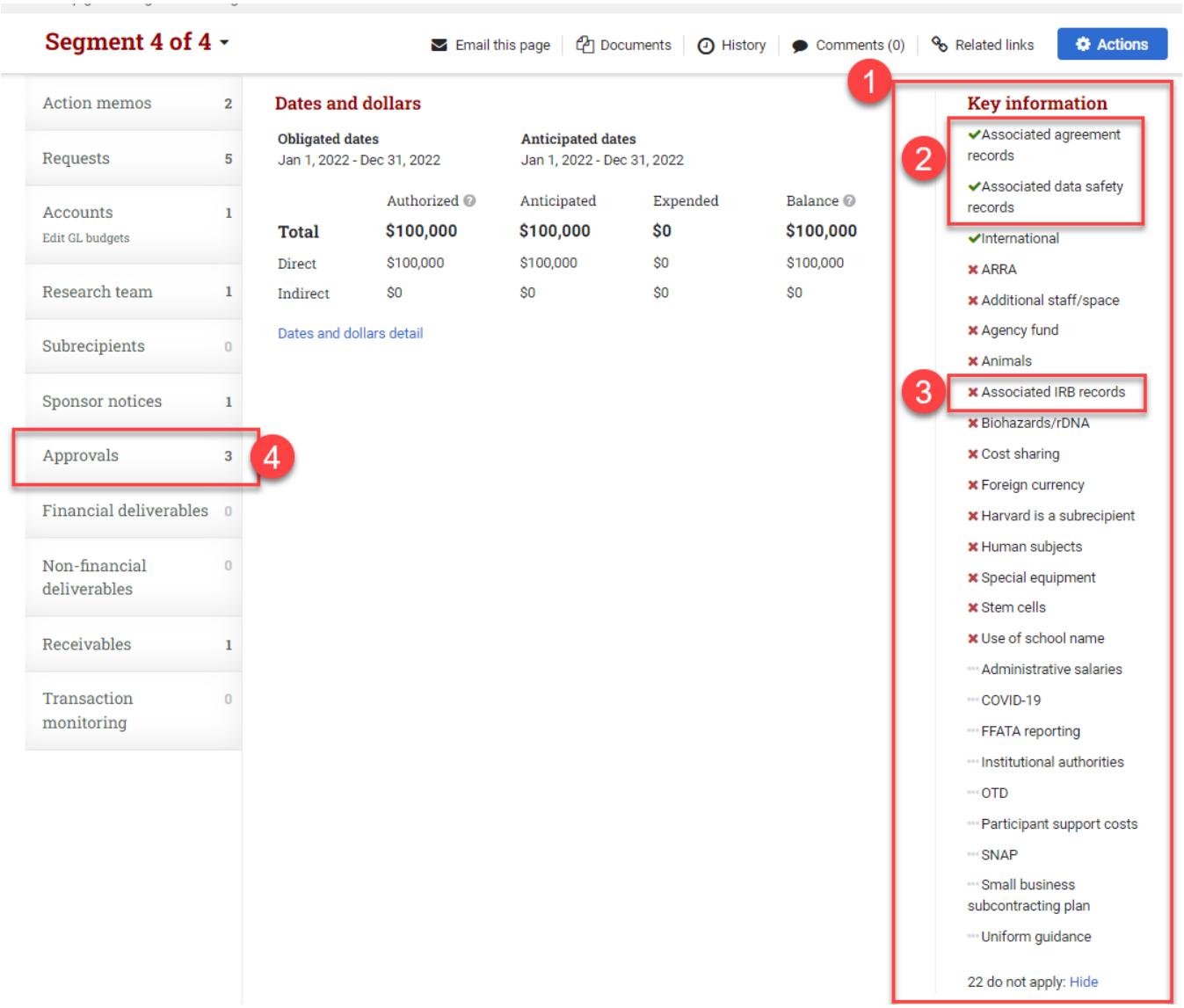
***Note**: Outside Activity and Interest Reporting (OAIR) information is also shared with GMAS, but the integration is unique for those approvals and not documented in this job aid. For more information about OAIR, see the Outside Activity and Interest Reporting (OAIR) and GMAS Integration Job Aid.*

How to see in GMAS if there are any IRB, DUA, or Data Safety records associated with a project

From the GMAS segment homepage, you will be able to see if there are any records from the IRB, DUA, or Data Safety systems associated from the "Key Info" section (1). If there are any associated records, you will see a green checkmark with the system association (2). If there are no records associated, you will see a red X with the system association (3) hidden in the "More" view that expands to show items that do not apply. The key info items have the following names:

- Associated agreement records
- Associated data safety records
- Associated IRB records
    - If the "Human subjects" item does not have a green checkmark in the Key info section, but the "Associated IRB records" does, it means that the GMAS project wasn't identified as having human subjects, but the GMAS project was associated with a record in the IRB system.

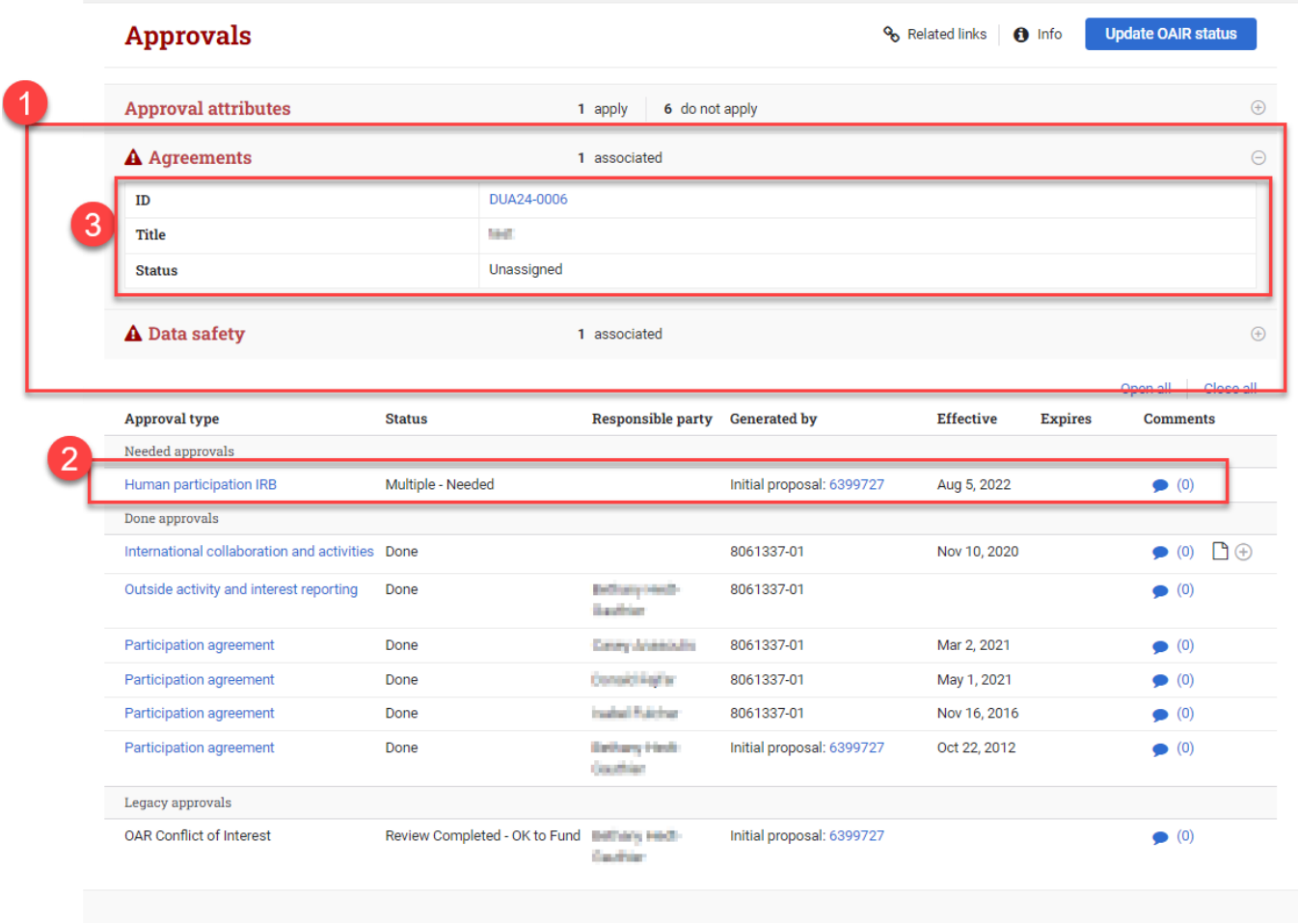
If there are records associated with the GMAS project, more information about those records can be found from the segment approvals list (4).



From the approval list screen, you can see more information about the associated IRB, DUA, and Data Safety records.

- DUA and Data Safety records will be displayed in their own panels at the top of the approvals list screen.
- IRB records will also be displayed in their own panel at the top of the approval list screen unless there was an IRB approval generated on the segment (the human subjects approval question was flagged as Yes on the segment). In that case, the IRB records will appear in the IRB approval instead of in a panel at the top of the approval list screen.

Expanding the panels will display the record ID which links to the corresponding record in the associated system, the title, and the status.



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 project, where initial IRB review has not been completed: appropriate members of the study team (such as the PI or primary contact) can include the appropriate GMAS record on the Funding Sources page of the SmartForm in the IRB system. 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.

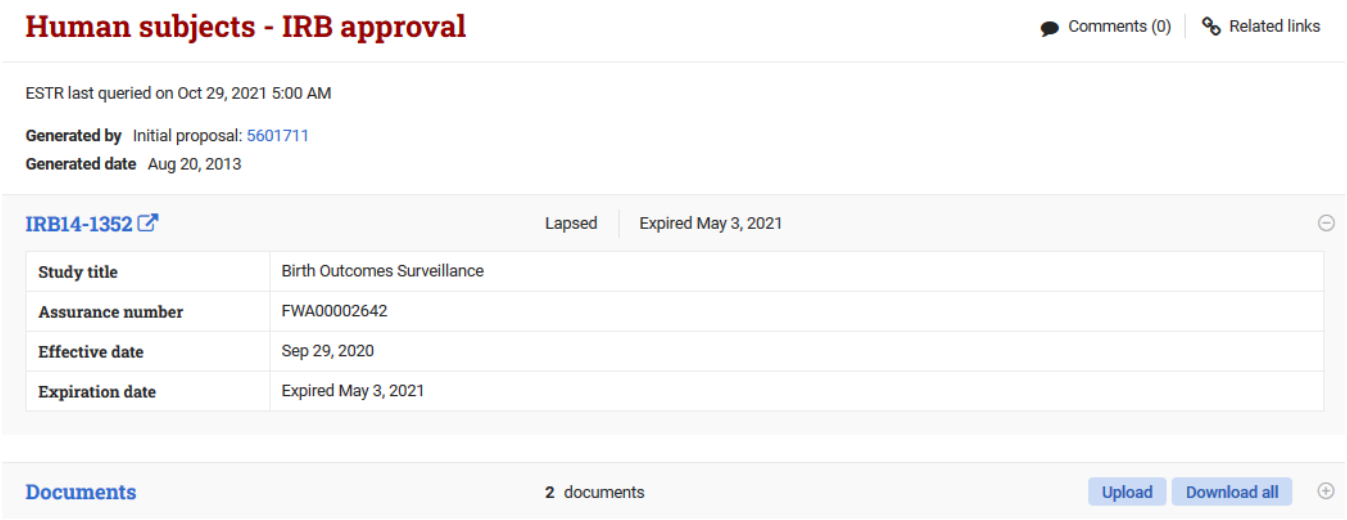
For more information about how to associate GMAS project IDs in the ESTR-IRB system, reference the relevant sections from the IRB study submission guide, "Creating a Follow-On Submission after Study Approval" and "SmartForm Section: Study Funding Sources".

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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



- 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.

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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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Helpful links

- Agreements DUA support site
  - Agreement DUA submission guide
- Data Safety support site
  - Data Safety submission guide
- ESTR – IRB support site
  - IRB study submission guide
- GMAS support site

System Links

- Agreements DUA application
- Data Safety application
- ESTR-IRB application
- Grants Management Application Suite (GMAS)

Where to go for systems help

- For additional questions or assistance with GMAS, please reach out to the GMAS help desk (contactgmas@harvard.edu)
- For additional questions or assistance with Agreements, please reach out to the Agreements help desk (duahelp@harvard.edu
- For additional questions or assistance with Data Safety please reach out to the Data Safety help desk (rshelp@harvard.edu
- For additional questions or assistance with ESTR-IRB, please reach out to the ESTR help desk (estrhelp@harvard.edu).