Harvard Medical School   **Effective:** 08/19/15
Sponsored Programs Administration   **Revised:** 12/14/15
Business Process – IRB & Human Subjects Training Approvals in GMAS

Purpose: GMAS generates automatic project Approvals based on data entered in the Initial Request. One of these Approvals is for human subjects research, often referred to as IRB (Institutional Review Board) approval. Additionally, any individual working directly with human subjects or accessing identifiable data/specimens must document that they have completed a human participant training program (CITI) within the past 3 years. (For more information on human subjects training requirements, visit http://www.hsph.harvard.edu/ohra/human-subjects-training-requirements/) As it is HMS practice to refrain from setting up accounts when there are any outstanding Approvals, SPA must ensure that the IRB, human participant training, and all other segment-level Approvals have been cleared at the time of award and prior to any subsequent revisions.

Harvard LMA IRB Policy: http://www.hsph.harvard.edu/ohra/investigator-manual/

Considerations:

1) IRB and human participant training approvals are maintained in a separate system, ESTR. Since currently there is no system feed from ESTR into GMAS, SPA has the responsibility of transferring this information manually.

2) IRB approvals are typically not finalized until the JIT or award stage. If the PI identifies which IRB protocol corresponds to the project at proposal stage, the protocol number should be recorded in GMAS. Then at JIT or award time, SPA will check that a congruency review has been done before marking an approval as complete.

3) HMS researchers can "self-determine" whether activity on a specific sponsored project qualifies as "human subjects research" as defined by DHHS and FDA regulations. The Harvard LMA IRB can also provide consultation and/or formal determination for investigators or SPA as necessary. If the determination has been made that no human subjects research is being conducted, the GMAS question for human subjects research should be marked as No and no IRB approvals should appear. (When this approval attribute is corrected from Yes to No, the initial IRB approval should be marked as N/A.)

4) HMS researchers **cannot** self-determine whether their human subjects research qualifies as **exempt**. Only a designated reviewer from the IRB office can make the exemption determination. If exempt, SPA must receive an exemption letter from our IRB, noting which exemption (1-6) applies to the research in question, before marking the GMAS approval as Exempt.

5) No accounts (including at-risk) should be established until:
   a. The human participant training approvals for each research team member who has been designated as "involved with human subjects" have been received and uploaded in the GMAS approval; and
   b. IRB approval noting the specific award name/number has been received. EXCEPTION: if the PI verifies that human subjects research will not take place until later in the project. When this is the case, it should be documented in GMAS by the GM/SPA Portfolio Owner (PO) uploading the email into the Approval Documents and adding a Comment about when the human subjects research is expected to take place.

6) **VA awards** with human subjects (HS) research always require <u>both</u> VA IRB approval <u>and</u> Harvard LMA IRB approval. If HS work is being conducted at an affiliate hospital, the hospital's IRB approval is also required before the GMAS Approval can be cleared and the account established (unless the hospital has agreed to formally rely on the Harvard LMA IRB).

Standards of Service: SPA POs (portfolio owners) will enter the IRB and human participant training approval information into GMAS at the JIT stage (when available), or upon receipt and review of award notice. The GM (grants manager) should provide to their SPA rep the IRB protocol number that corresponds to the GMAS project/segment as soon as it is received.

Process Steps for IRB (Human Subjects) Approvals

Step	Role	Task/Activity
		At Proposal Stage:
1	GM	At the time of initial **proposal**, in consultation with the PI or other technical staff, department* administrator/grants manager (GM) checks Yes to the human subjects question in the GMAS request, indicating that HS activity will be performed within the scope of the project.
2	SPA PO	Reviews the proposal; ensures that the human subjects question has been answered accurately. • If any human subjects research is being performed off-site (e.g., on a subaward) human subjects should be marked as Yes. • If the project involves **stem cells**, human subjects should be marked as Yes. • For NIH awards, if the project involves large scale human or non-human **genomic data**, human subjects should be marked as Yes. (NIH GDS policy: https://gds.nih.gov/03policy2.html)
		At JIT or Award Stage:
3	SPA PO	At JIT stage, for NIH awards with **genomic data**, asks GM for **GDS (Genomic Data Sharing) Institutional Certification letter** from the Harvard LMA IRB office. (The HMS researcher will be prompted to submit an application to the IRB in ESTR at this time. If timely IRB approval cannot be obtained, the IRB may provide a Provisional Institutional Certification.) Once received, PO submits certification to NIH with other JIT documents.
4	SPA PO	Checks for Human part. IRB Approval in the segment at **JIT or award** stage. If the Approval appears, PO checks for the IRB protocol number as entered by the GM in any of the following areas: Request/Segment Approval for Human part. IRB – in Comments or Documents Request-level Comments Request-level Documents If approval/protocol number is not in GMAS, asks the GM for it.
5	SPA PO	Upon receipt of the IRB protocol number, PO logs into ESTR (see note on 1st page for VA IRB approvals) and: Selects the "IRB" tab at the top of the page Selects the "Active" tab in the middle of the page (only if protocol is Approved; otherwise, check "in-review" tab) Under Filter by "ID" enters the IRB protocol number and hits Go button Clicks on protocol title to view approval information
6	SPA PO	Checks that the IRB protocol record in ESTR references the award number or the award title and sponsor. If it doesn't, email the IRB contact to ask whether the grant in question has been checked for congruency against the protocol. Ask for an updated approval letter once the congruency check has been performed.
7	SPA PO	Navigates to the Human part. IRB Approval in GMAS and enters the following: Due Date: select "Upon Award" Status: select "Done" *(or "Exempt" if we have an exemption letter)* Approval/Assurance number: enter IRB protocol # *If exempt, check box for Exemption Number (from IRB exemption letter)* Received: enter Initial Approval Date from ESTR Effective: enter Initial Approval Date from ESTR Expires: enter Expiration date from ESTR *(not applicable for exempt studies)*

		Clicks OK.
8	SPA PO	Navigates to the Approvals section from the segment homepage and makes a note of the name associated with each required human participant training Approval.
9	SPA PO	Returns to ESTR, to the specific IRB protocol record. Selects the "Project Contacts" tab in the middle of the page

10	SPA PO	Navigates to <u>each</u> Human part. training Approval in GMAS and enters the following:
		Due Date: select "Upon Award"
		    Status: select "Done"
		    Approval/Assurance number: enter info. from Training Type column in ESTR
		    Received: enter Training Complete Date from ESTR
		    Effective: enter Training Complete Date from ESTR
		    Expires: enter Training Expiration Date from ESTR
		Clicks OK.

*The term "department" is used here to refer to any school unit and includes divisions, centers, institutes, programs, and the like.