Human Research Participant

COMS Requirements & Registration

Even if your project does not meet the regulatory definition of human subjects research, COMS registration may still be required when research involves human participants and the collection or administration of COMS-regulated materials (CRM).

Research proposals that administer or collect CRM from participants require COMS approval unless:

- The administered/collection materials are not CRM.¹
- A product/material that would otherwise be COMS-regulated (e.g., human cells, probiotic bacteria) is FDA-approved and used in strict accordance with the FDA-approved use during research.
- Only standard clinical procedures (usually designated by specific insurance codes) are used for administering CRM or collecting patient material as part of a medical procedure.

Only CRM-involving experimental procedures require registration.

Registration

Administration

1. Navigate to Hazard Identification within the COMS protocol.

2. Select “Yes” for involvement of “Human Research Participants”.

¹ COMS may require registration of research in which animal materials (non-CRM) are administered to human research participants.
3. Navigate to and complete Human Research Participants.

4. List all CRM on respective pages (e.g., Use of Recombinant & Synthetic Nucleic Acids).

5. Follow the COMS policy on clinical trial studies for submission (if applicable), including attaching any required documents.

**Collection**

1. Navigate to the COMS protocol.

2. Add the materials collected from participants to “Use of Tissues, Blood, or Body Fluids” (including the applicable IRB number).

3. Determine who performs collection.

   If **non-Harvard personnel** perform collection (e.g., collaborator, commercial source):

   1. Update “Research Description” if making experimental changes.

   If collection is performed at **Harvard University and/or Harvard personnel** perform collection:

   1. Navigate to “Hazard Identification”.

   2. Select “Yes” for involvement of “Human Research Participants”.

   3. Complete “Human Research Participants”.

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Human Research Participant COMS Requirements

Will COMS-regulated materials (CRM) be administered to subjects?

Are all administered materials FDA approved and used in accordance with FDA approval?

Yes

Are all administered materials used in a manner that aligns with clinical standard of care?

Yes

The research proposal does not require COMS approval.
- FDA approval for the product is adhered to in the research (deviation requires COMS registration).
- Standard clinical procedures (usually designated by specific insurance codes) do not require COMS registration. Only experimental procedures require registration when involving CRM.

No

COMS registration is required. Within the COMS protocol:
- Select "Yes" for involvement of "Human Research Participants" on the Hazard Identification page and complete the Human Research Participants page.
- List all CRM on respective pages (e.g., Recombinant & Synthetic Nucleic Acids page).
- Follow COMS Clinical Policy for submission, including attaching required documents.

Or

Will COMS-regulated samples be collected from subjects?

Yes

COMS registration is required. Within the COMS protocol:
- Include information on the COMS Tissues, Blood, and Body Fluids page, including applicable IRB number. If collection is not performed at Harvard by Harvard personnel, only additions to this page and the Research Description must be completed.
- If collection is performed at Harvard by Harvard personnel, also select "Yes" for involvement of "Human Research Participants" on the Hazard Identification page and complete the Human Research Participants page.

No

If no CRM are administered or collected from participants, the research proposal does not require COMS approval.