HARVARD
Campus Services
ENVIRONMENTAL HEALTH & SAFETY

COMS Registration for Research with Human Participants

Projects that do not meet the regulatory definition of human subjects research may still require COMS registration if their 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:

- Administered or collected materials are not CRM.[1]
- Products or materials that would otherwise be COMS-regulated (for example, human cells, probiotic bacteria) are 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 **experimental procedures** require registration when involving CRM.

Research Registration

- For collection procedures, within the COMS protocol:
  - Add the materials to be collected from participants on the *Use of Tissues, Blood, or Body Fluids* page, including applicable IRB number.

[1] COMS may require registration of research in which animal materials (non-CRM) are administered to human research participants.

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- **If collection is performed at Harvard/by Harvard personnel**: Select "Yes" for involvement of "Human Research Participants" on the *Hazard Identification* page and complete the *Human Research Participants* page.
- **If collection is performed by non-Harvard personnel (e.g., collaborator, commercial source)**: Only the *Use of Tissues, Blood, or Body Fluids* page needs to be updated, as previously indicated. The *Research Description* page must also be updated if experimental changes are being made.

- For administration procedures, 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., *Use of Recombinant & Synthetic Nucleic Acids* page).
  - Follow COMS Policy on Clinical Trial Studies for submission, if applicable, including the attachment of required documents.

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Research Requirements Flowchart