



Business Process –Biohazard & Recombinant DNA Approvals

Purpose: A business process for Biohazard & Recombinant DNA Approval ensures that the Harvard Environmental Health & Safety (EH&S) Biosafety Office is aware of projects involving biohazards/rDNA and that appropriate reviews are completed and that approvals are in place prior to work commencing on the project. The risk of not adhering to this process is that biological aspects of the research may not be conducted in a safe manner using established biosafety standards, principles and practices.

Considerations:

- 1) The Committee on Microbiological Safety (COMS) is a standing faculty committee that reviews all research involving biohazards/rDNA at the University. The Harvard EH&S Biosafety Office assists Investigators with registering their research protocols with COMS.
- 2) Biohazards/rDNA approvals must be in place prior to commencing work on the project.

Standards of Service: SPA Operations will schedule a non-financial report in GMAS at the R&A stage to notify the SPH Biosafety Officer in sufficient time that biohazards/rDNA approvals are applicable.

Process Steps for Biohazard & Recombinant DNA Approvals

Step	Role	Task/Activity
1	GM	At the time of proposal, as part of the request guided steps, checks off that recombinant DNA and/or biohazards will be involved in the research.
2	OPS	Reviews sponsored notices dashboard in GMAS for awards with biohazards.
3	OPS	Adds Sean Fitzgerald from the Harvard EH&S Biosafety Office in the role of “Lab Administrator” to the project’s Administrative Team in GMAS.
4	OPS	Schedules a non-financial report in GMAS for the project in order to notify Sean Fitzgerald that biohazards/rDNA are involved. When entering report: <ul style="list-style-type: none"> • Chooses “Other non financial” as form type and titles it: Biohazards/rDNA • Selects “Lab Administrator” as preparer • “From” is the start date of the project, “To” is the end date of the project • “Due to sponsor” is either the end date of the first year or the end date of the project if the project is only one year. • Edit frequency to annually if it’s a multi-year project to ensure the report is scheduled every year of the project (approvals must be renewed annually). • Do not send reminders to preparer. • In comments box write: Reminder for OBS to review biohazards approvals.
5	S. Fitzgerald	Reviews “To Dos” in GMAS and follows up on projects which require biohazards/rDNA approvals (this includes communicating with PI as necessary, ensuring training is current, determining if full review is needed and if so, preparing documents, etc.).
6	S. Fitzgerald	When complete, changes biohazards/rDNA approval in GMAS to “Done”, indicates effective and expiry date and includes comments as necessary.
7	SRA	Prior to sending the data sheet to the OPS team to set up the award, checks to ensure that the biohazards/rDNA approval is in the correct status and ensures that the non-financial biohazards/rDNA report for project out years is scheduled.
8	GM	<i>In the event that rDNA/biohazards was not checked off at the proposal stage, contacts SRA to make the change in GMAS and SRA informs the OPS team so they can proceed to step 3.</i>



Keywords for identifying Biohazards/rDNA

This list serves as a guide for quick identification of biohazards/rDNA when reviewing the project summary.

Keywords:

- Cells
- Words that end in “cytes”
- Blood
- Tissues/Tumor
- Viruses/Viral
- Bacteria
- Infection/Infectious
- *In vitro/In vivo*
- Genes/Genetic/Genome
- Recombinant
- DNA/RNA
- Biology/Biological
- Molecular/Cellular
- Therapeutic
- Mention of animals (e.g. mice or rats)

This is a guide, and the list is not exhaustive. When in doubt, contact Sean Fitzgerald, Biosafety Officer (2-0022 or sean_fitzgerald@harvard.edu), with any questions.