

Properly identifying proposals containing Biosafety/recombinant DNA research in Coeus

Office of Sponsored Programs

Biosafety/DNA notification

- In an effort to proactively identify proposals containing possible biohazard and/or recombinant DNA research, two (2) additional yes/no questions have been added to the Coeus proposal development module. Depending on how these questions are answered, internal Coeus validations are triggered to ensure proper VEHS Biosafety notification.

* IBC=*Institutional Biosafety Committee*

Question 1

Does this research involve the use of recombinant DNA molecules?

- All recombinant DNA research at Vanderbilt, regardless of funding source, must be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules: http://oba.od.nih.gov/rdna/nih_guidelines_oba.html
- The research must also be registered with the Vanderbilt IBC. Please refer to the following guidance for more information to determine if your proposal qualifies for this designation: http://www.safety.vanderbilt.edu/resources/biosafety_rdna.htm

Question 2

Does this research involve the use of biological agents infectious to humans?

- Research at Vanderbilt conducted with microorganisms pathogenic to humans, plants, or animals must be reviewed by the IBC. This review is conducted pursuant to the Centers for Disease Control and Prevention (CDC)/NIH publication, Biosafety in Microbiological and Biomedical Laboratories (currently in 5th edition, December 2009; <http://www.cdc.gov/biosafety/publications/bmbl5/>)
- The below link provides information to help an investigator determine and plan for research involving infectious agents. http://www.safety.vanderbilt.edu/resources/biosafety_references.htm

VEHS Notification

If the PI indicates “yes” to either of these (2) questions, a Coeus validation will require a “Bio-Safety Hazard” and/or “Recombinant DNA” entry in the special review tab; this sends an automatic notification to VEHS.

The Proposal 00018417 validated with the following Warnings

Department : Vanderbilt University !

Your research involves Recombinant DNA. Please include a Special Review for Recombinant DNA. Remember to include the IBC approval number in the Protocol Number field if your lab has a current IBC approval.

Department : Vanderbilt University !

Your research includes biological agents. Please Include a Special Review for Bio-Safety Hazards. Remember to include the IBC Approval Number in the Protocol Number Field if your lab has current IBC approval.

VEHS Notification

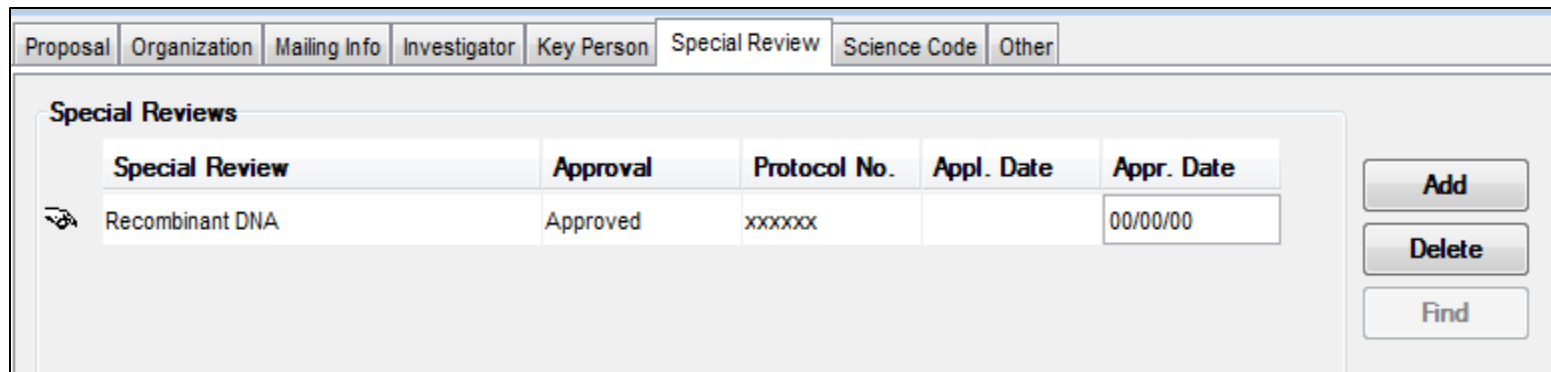
- If PI answers “yes” to question 1 , Coeus will require “Recombinant DNA” be selected under the Special Review. If PI does not have an approved IBC protocol, please mark as “Pending”.

The screenshot shows a web application interface with a tabbed menu at the top. The 'Special Review' tab is selected. Below the tabs is a table titled 'Special Reviews'. The table has five columns: 'Special Review', 'Approval', 'Protocol No.', 'Appl. Date', and 'Appr. Date'. There is one row in the table with 'Recombinant DNA' in the 'Special Review' column and 'Pending' in the 'Approval' column. To the right of the table are three buttons: 'Add', 'Delete', and 'Find'.

Special Review	Approval	Protocol No.	Appl. Date	Appr. Date
Recombinant DNA	Pending			

VEHS Notification

- If PI answers “yes” to questions 1 and your program has an approved IBC, the IBC Approval date and Protocol No. field of the “Recombinant DNA” special review should be complete.



The screenshot shows a software interface with a tabbed menu at the top. The 'Special Review' tab is selected. Below the menu is a table titled 'Special Reviews'. The table has five columns: 'Special Review', 'Approval', 'Protocol No.', 'Appl. Date', and 'Apr. Date'. There is one row of data with the following values: 'Recombinant DNA', 'Approved', 'xxxxxx', an empty field, and '00/00/00'. To the right of the table are three buttons: 'Add', 'Delete', and 'Find'.

Special Review	Approval	Protocol No.	Appl. Date	Apr. Date
Recombinant DNA	Approved	xxxxxx		00/00/00

VEHS Notification


- If PI answers “yes” to question 2, Coeus will require the selection of “Bio-Safety Hazard” under the Special Review tab. If PI does not have an approved IBC protocol, please mark as “Pending”.

The screenshot shows the 'Special Review' tab in the Coeus system. The interface includes a navigation bar with tabs for Proposal, Organization, Mailing Info, Investigator, Key Person, Special Review (selected), Science Code, and Other. Below the navigation bar is a table titled 'Special Reviews' with the following columns: Special Review, Approval, Protocol No., Appl. Date, and Appr. Date. A single row is displayed with 'Bio-Safety Hazard' in the Special Review column and 'Pending' in the Approval column. To the right of the table are three buttons: Add, Delete, and Find.

Special Review	Approval	Protocol No.	Appl. Date	Appr. Date
Bio-Safety Hazard	Pending			

VEHS Notification

- If PI answers “yes” to question 2 and your program has an approved IBC, the IBC Approval date and Protocol No. field of the “Bio-Safety Hazard” special review should be complete.

Special Review	Approval	Protocol No.	Appl. Date	Appr. Date
 Bio-Safety Hazard	Approved	xxxxxx		00/00/00

Buttons: Add, Delete, Find

Information on how to receive IBC approval

If you have answered "yes" to either question and your program has not received IBC approval, please note the following information and guidance:

- Each Principal Investigator (PI) is required to register his/her biological research program involving:
 - Infectious agents
 - Human-derived materials (in basic research)
 - Non-human primate-derived materials
 - Toxins of biological origin
 - Recombinant DNA molecules
- Registration requires submission of a BioWISE application (on-line).
- The BioWISE registry should also include all funding sources, personnel and research locations, including CORE facilities that are used.
- For more information regarding tips and how to register a biological research program, please visit:
http://www.safety.vanderbilt.edu/resources/biosafety_register.htm

Questions?

For questions regarding how to use the “yes/no” questions and/or the special review tab, please contact your Sponsored Programs Specialist.

For information on planning and administering studies involving recombinant DNA molecules or biological agents please visit:

<http://www.safety.vanderbilt.edu/index.htm>

Thank you!