

GUIDE Special Review



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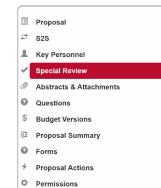
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Special Review Overview

The **Special Review** section of Streamlyne identifies any components of the research that require special regulatory compliance.

In Grants.gov S2S proposals, Special Review selections may also be used to populate forms required by the Sponsor.

Addition of one or more Special Review components will not delay the submission of a proposal.



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Special Review Types

HUMAN SUBJECTS

Project involves human subjects and will require Institutional Review Board approval prior to the start of research.

- According to <u>45 CFR 46</u>, a human subject is "a living individual about whom an investigator (whether professional or student) conducting research:
 - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."
- Cognizant Office: UNM Office of Research Integrity and Compliance, Institutional Review Board, <u>irb.unm.edu</u>
- UNM Faculty Handbook Policy E90: Human Beings as Subjects in Research: handbook.unm.edu/e90/

ANIMAL SUBJECTS

Project involves animal usage and will require Institutional Animal Care and Use Committee approval (IACUC) prior to the start of research.

The IACUC requires that an Animal Protocol be submitted for all educational, research, teaching and testing projects that will utilize live animals or (non-living) tissues from species regulated by the USDA Animal Welfare Act.

Cognizant Office: UNM IACUC Committee, hsc.unm.edu/research/compliance/oacc.html

UNM Faculty Handbook Policy E100: Policy Concerning Use of Animals, handbook.unm.edu/e100/

IT CYBERSECURITY

Project solicitation or proposal requires safeguards or special handling of Controlled Unclassified Information (CUI) or other sensitive data. This includes projects with a requirement to comply with NIST-Special Publication 800-171 and Cybersecurity Maturity Model Certification.

- Cognizant Office: UNM Information Technologies/Information Security & Privacy Office, <u>ispo.unm.edu</u>
- UNM Information Portal: Research Data Security, research.unm.edu/research-data-security
- UNM Administrative Policy 2550: Information Security, <u>policy.unm.edu/university-policies/2000/2550.html</u>



Adding a Special Review Component

Compliance approvals are generally required before the research can begin, but investigators should indicate the status of all special review components at the time of proposal submission.

Special review components can be added using the drop-down menu next to the text Add:

HUMAN SUBJECTS RESEARCH

- 1. If the proposal involves human subjects research, select "Human Subjects" in the dropdown menu for **Type**.
- 2. This special review component is linked to the Streamlyne IRB Module. The field labeled **Protocol Number** will change to a search field with a magnifying glass icon.
 - a. If an IRB protocol has been initiated in Streamlyne, click the magnifying glass icon to search for the relevant protocol number. The **Approval Status** and other information will be automatically populated if a protocol record exists.
 - b. If an IRB protocol has not yet been initiated, you may select "Not Yet Applied" as the **Approval Status**. No other information is required.
 - c. Alternatively, click **Start Protocol** to automatically create a new blank IRB protocol record and add it to this proposal. This protocol will be available for completion at a later time, and once submitted, its status will automatically update in the proposal and award records.
- 3. Click Add to confirm the selection of a Human Subjects Special Review Component.

~ :	Special Review								
	Identify any elements of the proposal that involve special regulatory compliance (e.g., Human Subjects, Animal Subjects, hazardous materials). Please select an applicable item, identify protocol number (if applicable) and select "Add".								
	Special Review 🧑								
	* Туре	* Approval Status	Protocol Number	Application Date	Approval Date	Expiration Date	Exemption #	Actions	
Add:	Human Subje 🗸	select v	E Q				E1 Add E2 E3 V	tart Protocol	

OTHER SPECIAL REVIEW COMPONENTS

For all special review types except Human Subjects,

1. Select the special review component **Type** from the drop-down menu.



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	* Type	* Approval Status	Protocol Number	Application Date	Approval Date	Expiration Date	Exemption #	Actions
Add:	select select Human Subjects Animal Subjects	select v	E			() #	E1 E2 E3 ▼	dd Rese
Comments :	IT Cybersecurity					66		

- 2. Select the applicable Approval Status from the drop-down menu:
 - a. Approved
 - b. Exempt
 - c. Not yet applied
 - d. Pending
- 3. (optional) Provide a **Protocol Number**, **Application Date**, and/or **Approval Date** by typing it into the relevant fields. This is recommended for Animal Subjects research in the case that an IACUC application has been submitted.
- 4. Click Add to confirm the Special Review component.
- 5. Once all Special Review components are added, click **Save** at the bottom of the screen.

Conflict of Interest

Submission of project-specific conflict of interest (COI) disclosures for all investigators is required <u>prior</u> to proposal submission for certain sponsors, including Department of Energy (DOE) and Public Health Service (PHS) agencies, such as the National Institutes of Health (NIH).

An "investigator" is someone:

- Defined as the PD/PI and any other person, *regardless of title or position*
- Who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding
- Which may include, for example, collaborators or consultants

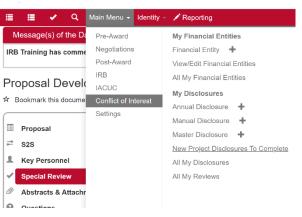


Once Key Personnel are added to the proposal, the status of Conflict of Interest disclosures will be shown in a panel below the Special Review panel. This panel is for information purposes and cannot be edited.

✓ COI Review
All UNM investigators must have completed a conflict of interest disclosure in the last 12 months. Navigate to Main Menu > Conflict of Interest to check the status of your disclosures and/or submit a new Annual Disclosure. Proposals to PHS agencies (e.g., NIH) and DOE must also submit a project-specific disclosure. Navigate to Main Menu > Conflict of Interest > New Project Disclosures to Complete.
Conflict of Interest Review ⊘

To submit a conflict of interest disclosure for the project, navigate to Main Menu -> Conflict of Interest -> New Project Disclosures to Complete

- You may wish to open a new Streamlyne window in order to avoid losing your place in the proposal
- A list of available projects will be shown. Click the Proposal Number or Report COI to complete the disclosure



• Guidance for using the Streamlyne COI Module can be found here: researchcompliance.unm.edu/training-and-resources/index.html

New Projects For Disclosure

✓ New Proposals for Disclosure										
Proposal List 🧿										
Proposal Number	Proposal Title	Sponsor	Start Date	End Date	Reporter	Action				
224	testing session 6/27	National Science Foundation	2022-09-01	2025-08-31		Report COI				
226	TESTING \$2\$	National Institutes of Health	2022-09-01	2027-08-31		Report COI				