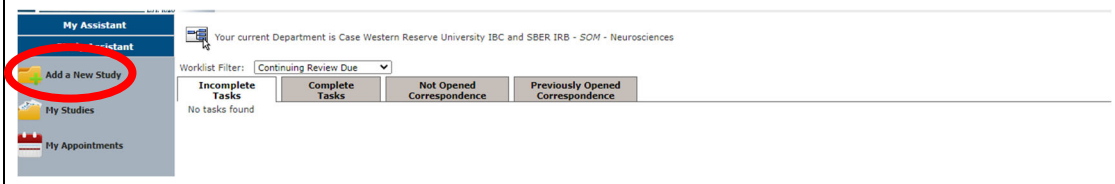
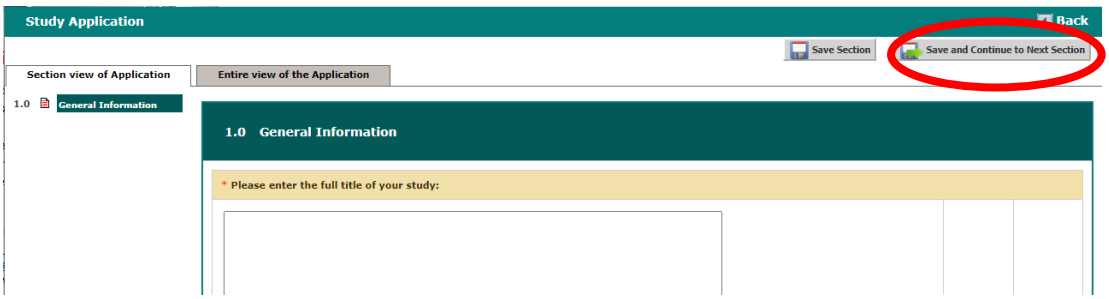
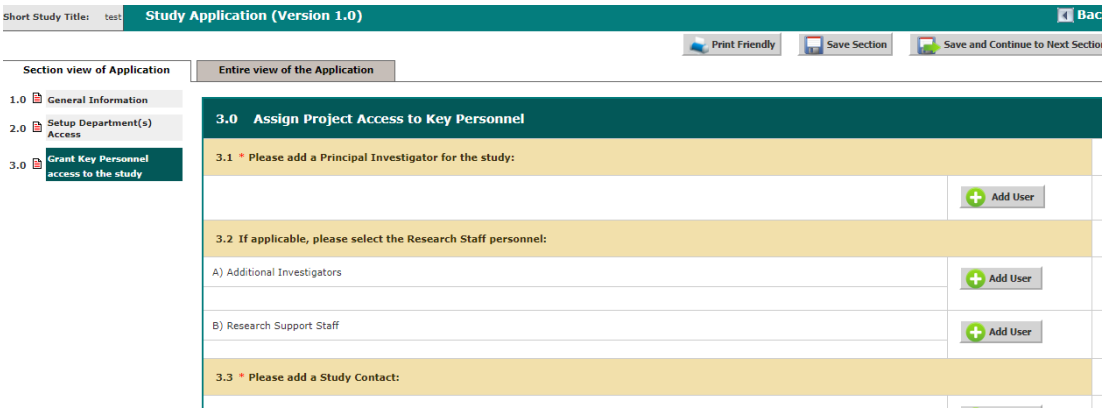
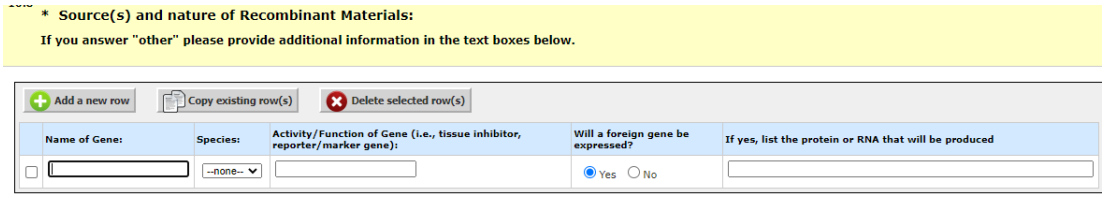
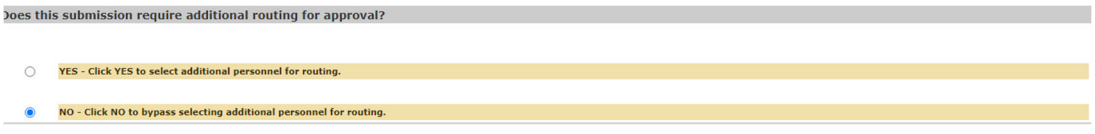
Institutional Biosafety Committee (IBC) Initial Submission

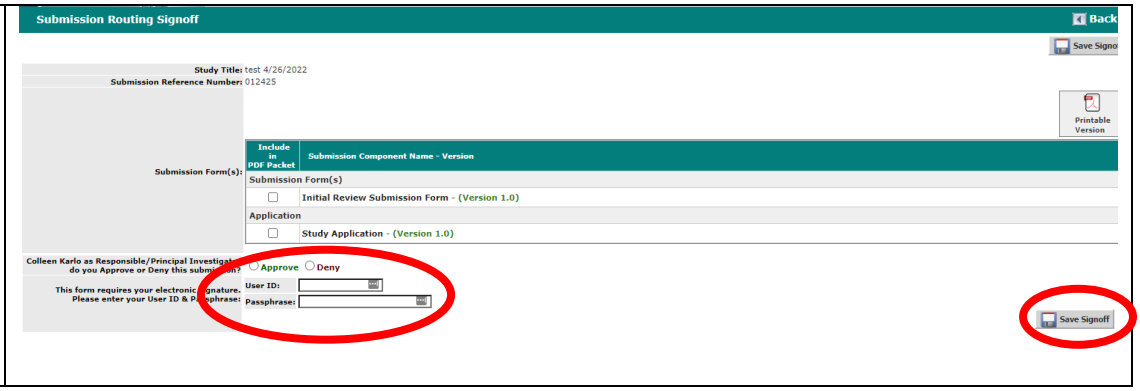
- All work that falls under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* needs to be submitted to the CWRU IBC for review and approval. PIs should be familiar with the *NIH Guidelines* and be able to identify what category(ies) of the *NIH Guidelines* the experiments fall under.
- Most submissions are reviewed by the convened committee which meets monthly on the second Thursday of the month. Submissions should be received by the IBC office one month prior to a meeting. (See exception for industry-sponsored clinical studies in Step 4).

How do I submit a new protocol?

Step 1	Log into iRIS: **https://spartaIBC.case.edu**. On the Home screen, click My Studies on the left, then "Add a New Study." 
Step 2	You will walk through the completion of a new study application. Use the "Save and Continue" button on the right as you complete each page. 
Step 3	The Key Personnel section is for individuals who should have access to the study in iRIS. Study contacts will receive all notifications from iRIS. These individuals will need an account created in iRIS – if you are unable to find them, please email case-ibc@case.edu and provide the individual's name, CWRUnet ID and department. Also provide an email address if it is something other than their CWRU email (such as a UH email).

	There is another section for Study Team later in the study application, and this section can list individuals who do not need access in iRIS. 
Step 4	Section 9 will specify the review process for clinical studies. For industry sponsored studies at UH or Metro, answer “yes” and only the information needed for the external IBC review will be collected with this submission form (jump to Step 9 in this guide). Clinical studies at the VA, and studies that are federally funded or PI initiated at UH or Metro should be marked “no” and the rest of the study application completed.
Step 5	Section 10 should contain general information regarding the nature of the research as well as all the details of the experiments involving recombinant or synthetic nucleic acid molecules that are covered under the *NIH Guidelines*. Section 10.4 needs to contain both a description of the experiments to be conducted, as well as a section describing the biosafety measures to be followed when conducting the research with recombinant or synthetic nucleic acid molecules.
Step 6	If the work involves vertebrate animals, please complete the section on Animal Details and provide the corresponding IACUC protocol number(s). The work described in this study application will need to be consistent with the IACUC protocol, including personnel listed as working with the recombinant DNA.
Step 7	If the work involves human subjects research, please complete the section on Human Participants.
Step 8	In the Recombinant Materials Section, please complete all sections. In the table for the Source and Nature of Recombinant Materials, please list each gene separately.

	This includes any genes overexpressed, as well as a gene that will be targeted for knockdown by si/shRNA or editing by CRISPR or other nuclease.  The question regarding expression of a foreign gene would only be "no" if you are overexpressing a gene of the same species within a cell line or animal model. For example, expressing the mouse ERK2 gene in a murine cell line would not be expressing a foreign gene. However, if you are expressing GFP, you would answer "yes"; similarly, expressing a human ERK2 gene in a murine cell line would also be expression of a foreign gene. For si/shRNA and editing using a gRNA, you would answer "yes" to this question. The last column should provide the type of manipulation of the gene: • Overexpression of [gene name] • si/shRNA to knockdown [gene name] • [gene name] knockout/edit by CRISPR
Step 9	Once the study application has been completed, you will move to the Initial Review Submission form. Section 2 should show the study application attached, and in Section 3 you can upload any supporting documents. If you are working with viral vectors, you will need to upload the vector maps. If you are conducting a clinical study, please upload the Clinical Protocol, the Investigator Brochure, and the Pharmacy manual (as applicable).
Step 10	Once the submission packet is complete, you will need to "Save and Continue" again to route the submission for signoff (if you are not the PI on the study) or to submit to the IBC. At Signoff, no additional routing is needed. 



More questions? Contact the Institutional Biosafety Committee:
case-ibc@case.edu