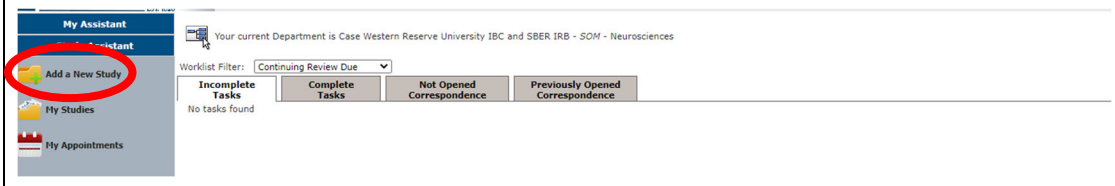
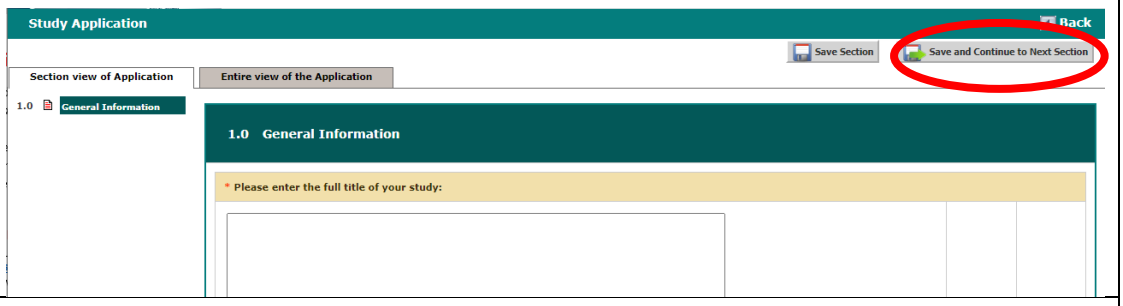
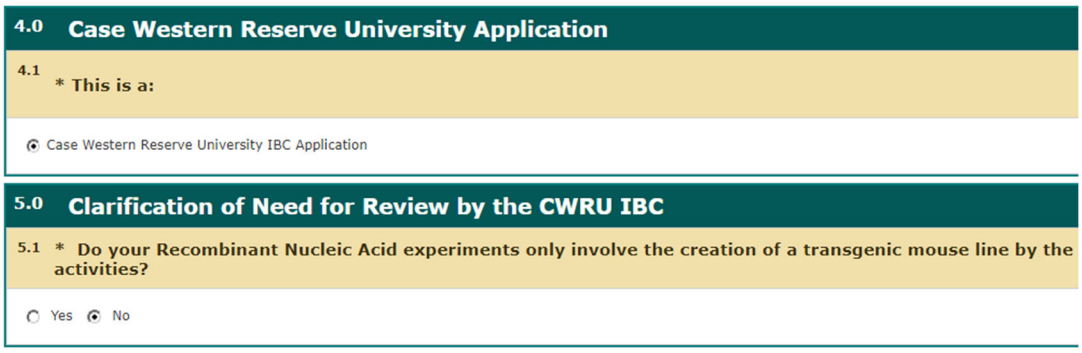
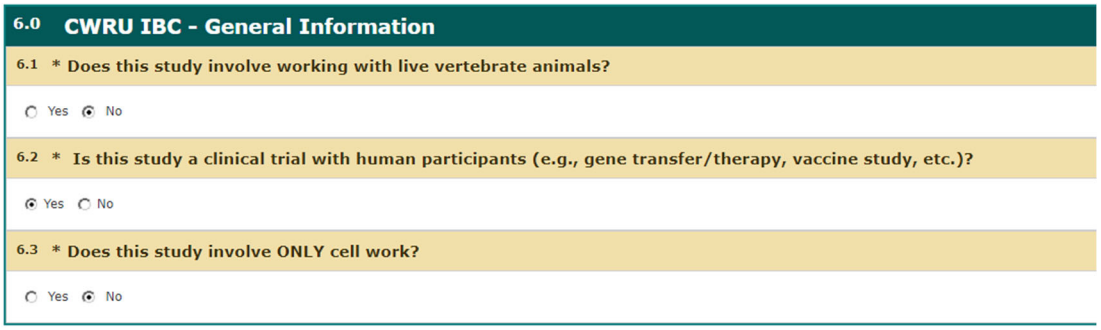
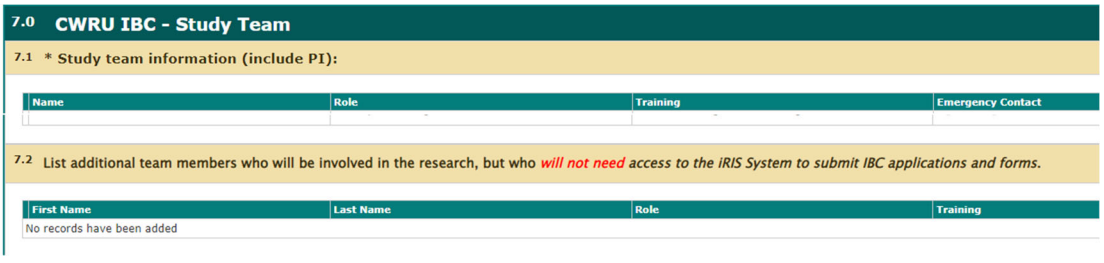
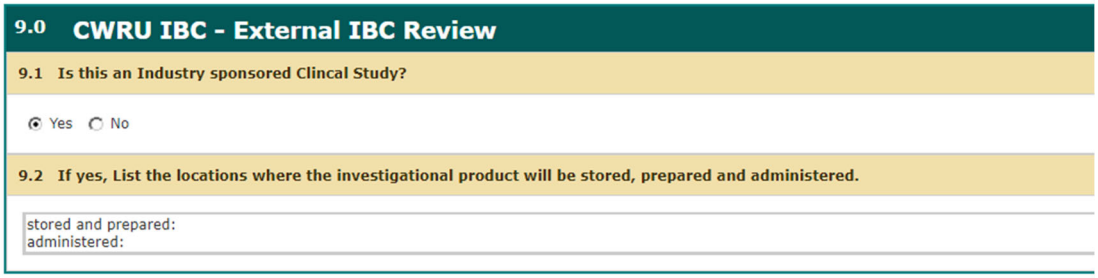
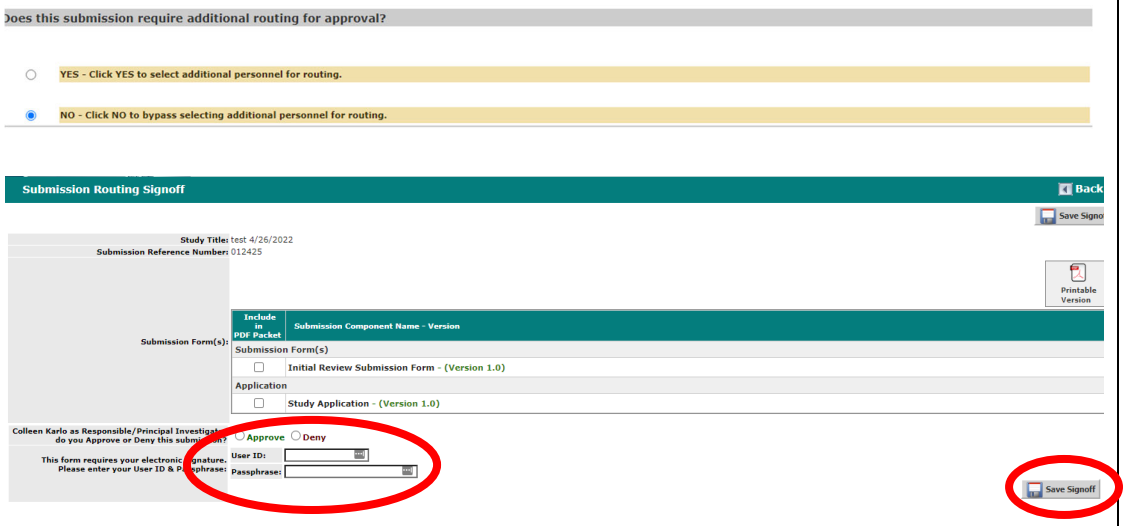
Institutional Biosafety Committee (IBC) Submission for Industry- Sponsored Clinical Studies (at UH or Metro)

- This is applicable to studies that fall under Section III-C of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, research involving the transfer of recombinant or synthetic nucleic acids into human research participants.
- These submissions will be reviewed by an external IBC registered with the NIH Office of Science Policy.
- Any clinical study at the VA should follow the Initial Submission Guide.

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	Section 1 – List the title of the study. Section 2 – Department will be populated automatically.
Step 4	Section 3 - Key Personnel 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 (Section 7) to enter individuals who do not need access.

Step 5	Sections 4 and 5 – Confirm this is an IBC application and that it is not for the generation of a transgenic mouse line.  **4.0 Case Western Reserve University Application** 4.1 * This is a: ◉ Case Western Reserve University IBC Application **5.0 Clarification of Need for Review by the CWRU IBC** 5.1 * Do your Recombinant Nucleic Acid experiments only involve the creation of a transgenic mouse line by the activities? ○ Yes ◉ No
Step 6	Section 6 – Indicate that is a clinical study and it does not involve animals or only laboratory cell work.  **6.0 CWRU IBC - General Information** 6.1 * Does this study involve working with live vertebrate animals? ○ Yes ◉ No 6.2 * Is this study a clinical trial with human participants (e.g., gene transfer/therapy, vaccine study, etc.)? ◉ Yes ○ No 6.3 * Does this study involve ONLY cell work? ○ Yes ◉ No
Step 7	Section 7 – Study team 7.1: List those key personnel that were entered into Section 3. The PI should be the emergency contact. 7.2: List individuals who do not need access in iRIS. *for training, select In-lab training and EHS training, which refers to study specific training, UH Bloodborne Pathogen training, and CITI training  **7.0 CWRU IBC - Study Team** 7.1 * Study team information (include PI): Name | Role | Training | Emergency Contact 7.2 List additional team members who will be involved in the research, but who *will not need* access to the iRIS System to submit IBC applications and forms. First Name | Last Name | Role | Training No records have been added Indicate UHCMC as the hospital affiliate. Confirm the training attestation.
Step 8	Section 8 – Funding should indicate Industry funding, and the Sponsor name entered into 8.2.

Step 9	Section 9 – confirm this study is an industry sponsored clinical study at UH or Metro by answering "yes". Provide the locations for handling of the investigational product in Section 9.2 
Step 10	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. Please upload the Clinical Protocol, the Investigator Brochure, the Pharmacy manual, and any other handling manuals (as applicable). The external IBC will also request the CV of the PI, so it can be provided here.
Step 11	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. 

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