|  |  |
| --- | --- |
| **Instructions** | |
| * Complete this template at the time of the first modification or continuing review in Click™ IRB if the study was transferred from the MSU IRB Online System to Click IRB. * You may want to “View Study” or select “Printer Version” to review the study information before selecting the modification scope (to determine if you need to update study team members). * CLICK IRB   + Include this template with the first Modification or Modification and Continuing Review Submission in Click (see instructions in Question 4).   + Upload the completed template to the Basic Information SmartForm page, Question 10. * NOTE: if you are CLOSING the study, you *do not need* to complete this template and you *do not need* to complete all the steps to finish the transfer of the study to Click IRB. Instead, you will follow the process to close the study. | |
| **Complete Questions 1 – 5.** | |
| 1 | Study title. |
| 2 | Describe the current status of the study. |
| 3 | Estimated remaining duration of the study, including analysis of identifiable private information. |
| 4 | Upload the following documents in the SmartForm:   * If submitting a renewal (continuing review) or a renewal revision in Click IRB:   + Locate the study in the “Active” submissions tab and open the study workspace.   + Select “Create Modification/CR.”   + For the purpose of the submission, select “Modification and Continuing Review” (*even if you are not proposing modifications, you need to select “Modification and Continuing Review” to upload document(s) and to update any data in the SmartForm, if needed*).   + For the Modification Scope, there are two options: “Other Parts of the Study” and “Study Team Members.” Select:     - For all renewals, you must select “Other Parts of the Study.”     - If you intend to modify the study team, also select “Study Team Members.”   + Upload the completed HRP-510 – Template – Legacy Protocol (this document) on the Basic Information SmartForm page, Question 10.   + Upload any current IRB approved consent documents (including parental permission forms, assent forms, translated consent forms) in the Consent Forms and Recruitment Materials SmartForm page, Question 1.   + For FDA regulated studies:     - Upload the currently approved protocol in the Basic Information SmartForm page, Question 10.     - Upload the currently approved Investigator Brochure in the Supporting Documents SmartForm page. * If submitting a revision (modification) in Click IRB:   + Locate the study in the “Active” submissions tab and open the study workspace.   + Select “Create Modification/CR.”   + For the purpose of the submission, select “Modification.”   + For the Modification Scope, there are two options: “Other Parts of the Study” and “Study Team Members.” Select:     - For all renewals, you must select “Other Parts of the Study.”     - If you intend to modify the study team, also select “Study Team Members”   + Upload the completed HRP-510 – Template – Legacy Protocol (this document) on the Basic Information SmartForm page, Question 10.   + Upload the revised document(s) (if any) in the relevant SmartForm pages. |
| 5 | Before submitting: confirm, update, and/or add information in the SmartForm pages.   * Update funding information (if any) on the Funding Sources SmartForm page. * Add Study Team Members if needed (only the secondary investigator and study coordinator were transferred over as part of the partial data conversion). * If the project involves external sites: on the External Sites SmartForm page, review the data included as part of the data conversion.   + If updates are needed:     - Click the name of the external site.     - This will open a window that will allow you to edit the External Site information.   + Delete the external site by clicking the “x” at the right side of the row. * If the project involves investigational drugs: on the Drugs SmartForm page, if the project involves use of an investigational drug, the drug was entered with “Investigational Drug.”   + To update with the study drug name:     - Click “Add.”     - Enter the study drug name within the “Generic name” field.     - Enter “Investigational Drug” within the “Brand name” field.     - Delete the original “Investigational Drug” entry by clicking the “x” at the right side of the row. * If the project involves investigational devices: on the Devices SmartForm page, if the project involves use of an investigational device, the device was entered with “Investigational Device.”   + To update with the study device name:     - Click “Add.”     - Enter the study device name within the “Device Name” field.     - Delete the original “Investigational Device” entry by clicking the “x” at the right side of the row. * Complete the MSU Additional Study Information SmartForm page.   + If you select “Protected Health Information as defined by HIPAA,” the SmartForm will require you to upload a document. You can upload a blank use of PHI form (you do not need to re-complete). * Confirm data on all other SmartForm pages and update as needed. |