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| **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.
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| **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.
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| 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.
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