IRBMED eResearch Cross-Reference

Related Changes Guide

In eResearch (Regulatory Management), changes in one section may impact other sections. Sometimes these additional sections/changes are NOT automatically triggered by eResearch. The purpose of this document is to provide direction to the study teams on the most common changes to the eResearch (IRB) application or the supporting materials.

NOTE: When making changes to the IRB application, always start at a system-required page (page 01 or, if you use the "Jump To:" menu, select a page shown on the menu in **black type** rather than in *gray italic* type). Use the "Continue" button to let the eResearch 'system logic' lead you through system-required pages. Additional information and Step-by-step guides on using eResearch are available through the ITS eResearch Regulatory Management website https://its.umich.edu/academics-research/research/eresearch/regulatory-management/reference-materials

CHANGE(S) TO IRB APPLICATION	ITEMS THAT MAY BE IMPACTED BY THIS CHANGE AND OTHER CONSIDERATIONS	RESOURCES
Section 1.3 Study Team Members: changes to study team members	When adding a study team member, • Select appropriate role as well as the corresponding appointment dept • Ensure that the PEERRS "Human Subjects Protection" module is current for team members in all applicable roles per the IRBMED Statement of Practice • For PI, Co-I, and Faculty Advisors: ensure that CV is not more than 2 years old • Section 5.1 Protocol, update as appropriate • Section 5 Study team expertise • Section 8-1.8 Recruitment materials –IRBMED encourages listing only the PI and one study coordinator • Section 10-1 Informed consent documents (ICDs) –IRBMED encourages listing only the PI and one study coordinator • Section 15-1 (Research Pharmacy) Authorized Prescriber info • Section 21-1 (RDRC/SHUR) Authorized User When deleting a study team member, • In the Printer Friendly version of the IRB application, Ctrl+Find to find any sections where the study team member is previously listed so they can be updated appropriately. • Check the remaining study team members to ensure that the list is current. Remove the study team members who are no longer associated with the project or clarify why they should be listed. • Section 5.1 Protocol • Section 5 Study team expertise • Section 8-1 Recruitment document(s) • Section 10-1 Informed consent documents (ICDs) • Section 15-1 List of Authorized Prescriber info	ITS Guides for PI & Study Team Adding a Study Team Member Changing the PI… U-M HRPP Operations Manual (OM) Part 6 PEERRS Main Website IRBMED Statement of Practice PEERRS IRBMED Guidance External (non-UM) Study Team Members

	For external (non-UM) study team member(s): • Refer to IRBMED website guidance on the external study team members • Authorization agreement (IIA or IAA) may be necessary	U-M HRPP Authorization Agreement Process

Section 1.3 Study Team Members: PI change	When the current PI is no longer associated with the IRB application:
	• Section 01, List the new PI (The new PI will submit the Amendment)
	• The IRB application (Sections 5, 15) should be updated as appropriate
	• Section 10 Informed Consent should be updated if the subject enrollment is ongoing
	• If the former PI remains involved and they are no longer at this institution:
	  ○ Data Use Agreement (DUA) and/or Materials Transfer Agreement (MTA) may be necessary.
	  ○ Authorization agreement (IIA) may be necessary.
	  ○ List as 'Other' if external and no adjunct position.
	NOTE: If a study is under an IND/IDE, the change in the PI must be communicated with the Sponsor. If U-M PI is the IND/IDE holder, the PI/Co-I changes may trigger additional requirements (for example, reports to FDA). Contact MICHR MIAP for assistance if U-M PI is the IND/IDE holder.
		ITS Guides for PI & Study Team
		Changing the PI…
		
		U-M HRPP
		Authorization Agreement Process
		
		MICHR
		IND/IDE Assistance Program (MIAP)

Section 01-2.8 Clinical Trial question	The help text in eResearch includes the U-M definition of what is a clinical trial.
	
	When question 1-2.8 ("**Is this a clinical trial?**) is answered "Yes", the following additional questions are triggered:
	• Question 1-2.8.1 opens and it captures the trial phase
	• Question 5.2.7 (or 05-2.7 for cancer studies) opens which is regarding the applicability of ICH-GCP E6. If 'yes' to ICH-GCP E6 question
	  ○ the answer should be supported by a specific language in the Protocol
	  ○ ICD(s) should include the ICH-GCP E6 specific items that are identified in the orange text in the IRBMED standard consent template.
	• Question 10-1.1.1 opens regarding the "Applicable Clinical Trial" language.
	  ○ The IRBMED Standard consent template includes guidance on whether to use this language and possible alternate language.
	  ○ FDAAA "Applicable Clinical Trial" is a subset of "clinical trials."
	  ○ Some Funding agencies (e.g. NIH) and journals (e.g. ICJME members) have additional requirements for ClinicalTrials.gov registration.
		IRBMED Guidance
		ICH-GCP
		
		MICHR
		ClinicalTrials.gov Support
		
		MSA Regulatory Affairs
		ClinicalTrials.gov
		
		U-M HRPP
		Clinical Trials Registration & Results Reporting
		
		NIH Definition of clinical trial

Section 2 Sponsor: changes funding source (PAF, AWD, or internal funding)	• Section 02, list the PAF/AWD ID for external funding • Section 02, list the internal funding resources as applicable • Section 5.1 Protocol, update to reflect the Sponsor/Funding agency • Section 10-1 ICD, update the Sponsor in Section 01.2 and any other places as applicable For Federal Funding (NIH, CDC, FDA, certain MICHR grants, etc.)	ITS Guides for PI & Study Team Adding a Sponsor U-M HRPP

	• Assess whether there is a Certificate of Confidentiality. If applicable:
	  ○ Section 11 - Answer Sections 11.4 "Yes" and complete 11-2
	  ○ Section 10-1 Add the IRBMED suggested Certificate of Confidentiality language to the consent document
	  ○ Section 07-1 IF NIH-sponsored research – update 7-1.10 (Data and Safety Monitoring Plan) to Yes, if not already indicated. Complete Section 32.
	
	For other Federal agencies (DOD, DOE, DOJ, EPA, ED, etc.), review the additional requirements as applicable https://research-compliance.umich.edu/hrpp-policies
		Certificates of Confidentiality
		
		IRBMED Guidance
		Genomic Data Sharing (GDS) Policy

Section 2 Support: adding an agreement (UFA) or transfer of data/samples	• Section 1.8 Project Summary, add a statement that data/samples will be transferred • Section 02 list the associated UFA ID • Section 11.5 and 11.5.1 when data is being provided to a repository • If the data is incoming, list the data source in Section 24 (by changing 7.2 to "Yes") • If the samples are incoming, complete Section 18 (by changing 7.1 to "Yes") Additional approvals: • Transfer from U-M to Industry or Non-Academic & Non-Governmental Entities of individual-level patient/participant data or biospecimens is subject to review and approval by the Medical School Human Data & Biospecimen Release Committee and the Dean of the Medical School. • Faculty, chairs, and departmental administrators do not have the authority to sign DUAs and MTAs on behalf of the University. Please work with ORSP.	UM Data Office Data & Biospecimen Sharing webpage Policy for the Transfer of Human Data & Biospecimens … ORSP Unfunded Agreement Types
Section 3 UM Site Functions:	Adding/Deleting additional functions/responsibilities to UM-site • Based on the functions that are being changed, numerous other changes may apply. For example, if "recruitment" or "Interaction" is being selected for a Secondary Use application, it will impact the overall IRB application and the IRB application type will need to be changed. • Answers in this section do not trigger additional sections or questions.	
Section 3 Changes to Participating Sites	When UM is not the coordinating center, • In Section 03-1, list the coordinating center(s) and upload the IRB approval letter. • It is not required to list other participating sites When U-M is the coordinating center • Section 03-1, list the participating sites individually in eR for a standard application type. This should be done via a spreadsheet for the Multi-Site Research application type. • Section 03-1, upload the IRB approval letters for all participating sites if it is the responsibility of the UM as a coordinating center to track the IRB approvals for each site. • NOTE: For Federally-funded multi-site studies, there is a possibility that Single IRB policy may be applicable. Contact IRBMED for additional information and guidance on this topic.	IRBMED Guidance Multi-Site Research U-M HRPP Single IRB-of-Record (sIRB) Process Authorization Agreement Process

	External Sites that are determined to be **not** engaged in human subject research • Section 03-1, add participating sites • Section 03-1, describe the activities that will be conducted at these sites • Section 03-1, upload a confirmation/permission letter from the site for the proposed research activities • Section 03-1, if available, upload a confirmation letter from the site IRB that their site is not engaged in human subject research For any of these scenarios, if there will be any transfer of data or samples, link the UFA ID in Section 2 of the IRB application.	
Section 5 Protocol:	• Based on the type of changes that are being made, numerous other sections might be impacted. • Generally, avoid including in the protocol document text that is also submitted as a separate document (*e.g.* recruitment emails or phone scripts that belong in section 08-1; survey questions that belong in section 29)	ITS Reference Materials Uploading, Editing, comparing and deleting documents IRBMED Document Revision
Section 05.6 Age Range: Expanding or decreasing the age range. Also, see Section 09 below.	• Section 5.1 Protocol • Section 09-1 Subject Populations • Section 10-1 Informed Consent Document(s) • Section 10.1 For Adults • Section 10.2 For Children • Section 33 Children	
Section 6 Risks and Benefits: changes to risks and/or benefits	• Section 5.1 Protocol • Section 10-1 Informed Consent Document(s) • Section 14 Healthcare Treatments and Procedures • Section 15 Drugs (Investigator Brochure or other similar documents) • Section 16 Medical Devices (instructions For Use or other similar documents) • Section 21 Radiation	
Section 08 Subject Enrollment: increasing or decreasing the total number of subjects to be enrolled.	• Section 5.1 Protocol • Section 10-1 Informed Consent Document(s) • Section 15-1 Total Number of Subjects, if drugs are applicable • Section 16 IDE approval letter, if Devices are applicable • Section 21-2 RDRC/SHUR, if administering radioisotopes NOTE: The change in the enrollment numbers must be communicated with the Sponsor. If U-M PI is the IND/IDE holder, these changes may trigger additional requirements (for example, reports to FDA).	U-M HRPP IRB Enrollment Definition

Section 9 Subject Populations: • Children	• Section 5.1 Protocol • Section 5.4 Eligibility Criteria • Section 5.6 Age Range • Section 06 Benefits and Risks • Section 10.2 Assenting Process • Section 10-1 Informed Consent Document(s) • Assent and Oral Script • Section 33 will be triggered automatically	U-M HRPP Operations Manual (OM) Part 7 IRBMED Guidance Children in Research Who May Consent …
Section 9 Subject Populations: • Cognitively Impaired Adults	• Section 5.1 Protocol • Section 5.4 Eligibility Criteria • Section 10.1 Assenting Process and waiver of assent as applicable • Section 39 will be triggered automatically	U-M HRPP Operations Manual (OM) Part 7 IRBMED Guidance Who May Consent …
Section 13 Payments • Changing the type of payment method • Increasing or decreasing the amount	• Section 5.1 Protocol • Section 8-1 Recruitment • Section 10-1 Informed Consent Document(s)	IRBMED Guidance Payment to Research Subjects Human Subjects Incentive Program (HSIP) Incentive v. reimbursement
Section 15 Investigator Brochure (IB)	• Section 05 Protocol • Section 06 Risks, if risk information is being updated • Section 10-1 Informed Consent Document(s), if risk information is being updated	MICHR IND/IDE Assistance Program (MIAP)