M2P2 By Topic

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Informed Consent

M2P2 #24: You learn that your patient doesn't speak English and you don't have an IRB-approved protocol consent in the patient's native language. What do you do? Part 1: Ensuring RB Approval, Obtaining Short Form & Securing Interpreter *(REVISED 04/2024)*
M2P2 #25: You learn that your patient doesn't speak English and you don't have an IRB-approved protocol consent in the patient's native language. What do you do? Part 2: Consent Discussion and Documentation*(REVISED 04/2024)*
M2P2 #26: You learn that your patient doesn't speak English BUT you have an IRB-approved protocol consent in the patient's native language (i.e., the full English version translated). How does the consenting process differ when not using the short-form consenting process? *(REVISED 04/2024)*
M2P2 #27: If consenting is an ongoing process, what does re-consenting mean?*(REVISED 08/2023)*
M2P2 #31: What should you do if you notice that there is something missing on the signed informed consent document?*(REVISED 01/2023)*
M2P2 #48: A patient that is blind wants to enroll in a study. How do I enroll someone that cannot read the informed consent document? *(includes information about patients that cannot sign the document)* *(REVISED 08/2023)*
M2P2 #66: Is there anything special that needs to be done when conducting remote consenting? *(REVISED 04/2024)*
Guidelines for Adobe Signature
M2P2 #69: What is iMedConsent™? *(REVISED 04/2024)*
M2P2 #71: What is Embedded Agreement Information in PRES? *(12/2022)*

CCR Frequently Asked Questions on Informed Consent

IRBO FAQs: General and Short Form Consent Processes

Reportable Events: Sponsor/SAEs and IRB/CR

M2P2 #3: What information should be included in the narrative summary when reporting an AE to the IRB, or IND/IDE sponsor? *(REVISED 01/2023)*
M2P2 #8: When do I submit a Reportable New Information (RNI) form to the IRB and what happens after the submission? *(REVISED 05/30/2023)*
M2P2 #10: How do I submit a MAJOR protocol deviation to the IRB and what do I include in the submission? *(REVISED 01/2023)*
M2P2 #12: You submitted a SAE/AESI to the sponsor, what else needs to happen with the event information? *(REVISED 02/2022)*
M2P2 #17: What information needs to be reported to the IRB at the time of continuing review (CR)? *(REVISED 02/2023)*
M2P2 #23: What should the Research Coordinator do if there is an ineligible subject who was enrolled on a clinical research study? *(REVISED 01/2023)*
M2P2 #42: What is an unexpected adverse event (AE) and how is it be reported to the IRB? *(REVISED 06/2023)*
M2P2 #50: What are the expedited IRB reporting requirements for "events" that happen during research? *(REVISED 02/2023)*
M2P2 #67: What is Serious Adverse Event (SAE) reconciliation? *(Developed 03/2022)*

Documentation and Data Management

M2P2 #1: What is the impact on C3D when your protocol has the following optional language (or something similar)? *(REVISED 12/2021)*
M2P2 #2: What is Good Documentation Practice? *(REVISED 12/2021)*
M2P2 #14: What is off-treatment versus off-study? *(REVISED 01/2022)*
M2P2 #28: I made an error when entering information on a paper form, now what? *(REVISED 02/2022)*
M2P2 #37: You learn that one of your study patients, who is not an inpatient at NIH, has died. *(REVISED 01/2023)*
M2P2 #38: What are baseline symptoms and how do I capture them? *(REVISED 02/2022)*
M2P2 #39: What does it mean to take a patient/participant off-study? *(REVISED 01/2022)*
M2P2 #62: What does it mean for a research participant to be lost to follow-up? *(REVIEWED 01/2022)*

ClinicalTrial.gov Reporting

M2P2 #41: What is the primary completion date (PCD) and the anticipated completion date (ACD)? Why are these dates important? *(REVISED 01/2023)*
M2P2 #76: Who should be notified when a primary completion date (PCD) is met for one of my clinical trials? *(07/2023)*
M2P2 #77: *What is a Good Cause Extension (GCE) for reporting results in ClinicalTrials.gov? (09/2023)*
M2P2 #78: *Is it mandatory to redact certain information from a protocol and/or consent for results reporting to ClinicalTrials.gov? (10/2023)*