M2P2s

M2P2s #1-25

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 (GDP)? *(REVISED 12/2021)*
M2P2 #3: What information should be included in the narrative summary when reporting an expediate AE to the IRB, or IND/IDE sponsor? *(REVISED 01 /2023)*
M2P2 #4: What does building "wiggle room" into your protocol procedure time points really mean? *(REVIEWED 12/2021)*
M2P2 #5: Why should a Nurse have a Curriculum Vitae (CV)? *(REVIEWED 12/2021)*
M2P2 #6: How can I stay current with regulations, guidances, and other news from OHRP and the FDA? *(REVISED 12/2021)*
M2P2 #7: Why do I get so many different emails about required training and how do I keep up with them? *(REVISED 12/2021)*
M2P2 #8: When do I submit a Reportable New Information (RNI) form to the IRB and what happens after the submission? *(REVISED 03/2024)*
M2P2 #9: Since the printed pocket version of CTCAE v.4 is not available, how can I have CTCAE at my fingertips? **RETIRED 2/2022**
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 #11: What should I do if I find incorrect or missing information on *ClinicalTrials.gov*? *(REVISED 12/2023)*
M2P2 #12: You submitted a SAE/AESI to the sponsor, what else needs to happen with the event information? *(REVISED 02/2022)*
M2P2 #13: What are the responsibilities of the research team when CCR is the coordinating center for a multi-site clinical trial? *(REVISED 01/2023)*
M2P2 #14: What is off-treatment versus off-study? *(REVISED 01/2022)*
M2P2 #15: How do I create, modify, or delete a protocol order set in CRIS? *(REVISED 02/2022)*
M2P2 #16: When are credentials verified and what do I need to do to maintain my privileges? *(REVISED 12/2021)*
M2P2 #17: What information needs to be reported to the IRB at the time of continuing review (CR)? *(REVISED 02/2023)*
M2P2 #18: Who should be included as a sub-investigator on the FDA Form 1572? *(REVISED 03/2024)*
M2P2 #19: What is the Monitoring Committee/Board and what are my responsibilities as a Clinical Research Coordinator (CRC)? *(REVISED 12/2023)*
M2P2 #20: Documentation of protocol-specific training and the impact for the Research Nurse **RETIRED 01/2023,** see CCR SOP PM-5 *Research Protocol Training Requirements* and PM-9 *Research Team Amendment Training*
M2P2 #21: Who can write an order for IND agents (i.e., drugs & biologics)? *(REVISED 02/2022)*
M2P2 #22: How to handle Personally Identifiable Information (PII) in a report submitted to the IRB or IND/IDE sponsor? *(REVISED 02/2022)*
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 #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)*