M2P2s

M2P2s #1-25

M2P2 #1: What is the impact on C3D when your protocol has the following optional language (or something similar) which is taken from the NCI IRB protocol template?

M2P2 #2: What is Good Documentation Practice?

M2P2 #3: What information should be included in the narrative summary when reporting an AE to the IRB, sponsor, FDA, or IBC/OBA?

M2P2 #4: What does building “wiggle room” into your protocol procedure time points really mean?

M2P2 #5: Why a Nurse should have a Curriculum Vitae (CV)?

M2P2 #6: How can I stay current with regulations, guidances, and other news from OHRP and the FDA? (revised 10/29/18)

M2P2 #7: Why do I get so many different emails about required training and how do I keep up with them?

M2P2 #8: When do I submit an “NIH Problem Form” to the IRB and what happens after the submission? UNDER REVISION

M2P2 #9: Since the printed pocket version of CTCAE v.4 is not available, how can I have CTCAE at my fingertips?

M2P2 #10: How do I submit a protocol deviation to the IRB and what do I include in the submission? UNDER REVISION

M2P2 #11: What should I do if I find incorrect or missing information on ClinicalTrials.gov (CT.gov)?

M2P2 #12: So you submitted an expedited adverse event (AE) report - now what?

M2P2 #13: What are the responsibilities of the research team when CCR is the coordinating center for a multi-site clinical trial?

M2P2 #14: What is off-treatment versus off-study?

M2P2 #15: How do I request a Protocol Order Set to be developed in CRIS?

M2P2 #16: When are credentials verified and what do I need to do to maintain my privileges?

M2P2 #17: What adverse events (AEs) need to be reported to the IRB at the time of continuing review (CR) and what format needs to be used? UNDER REVISION

M2P2 #18: Why should the Research Nurse be added as a sub-investigator on the FDA Form 1572?

M2P2 #19: What is the Safety Monitoring Committee (SMC) and what are my responsibilities as a research nurse

M2P2 #20: Documentation of protocol-specific training and the impact for the Research Nurse

M2P2 #21: Who can write an order for IND agents (i.e., drugs & biologics)?

M2P2 #22: How to handle Personally Identifiable Information (PII) in a report submitted to the IRB, sponsor, or any other regulatory agency (e.g., FDA, OBA)? (REVISED 1/6/17)

M2P2 #23: What should the Research Nurse do if there is an ineligible subject who was enrolled on a clinical research study?

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: Seeking IRB Approval & Securing Translator (REVISED 01/2020)

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 01/2020)