M2P2 #	QUESTION/TITLE
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?
2	What is Good Documentation Practice?
3	What information should be included in the narrative summary when reporting an AE to the IRB or IND/IDE sponsore?
4	What does building “wiggle room” into your protocol procedure time points really mean?
5	Why should a Nurse have a Curriculum Vitae (CV)?
6	How can I stay current with regulations, guidances, and other news from OHRP and the FDA?
7	Why do I get so many different emails about required training and how do I keep up with them?
8	When do I submit a Reportable Event Form (REF) to the IRB and what happens after the submission?
9	RETIRED: Since the printed pocket version of CTCAE v.4 is not available, how can I have CTCAE at my fingertips?
10	How do I submit a MAJOR protocol deviation to the IRB and what do I include in the submission?
11	What should I do if I find incorrect or missing information on ClinicalTrials.gov (CT.gov)?
12	You submitted a SAE/AESI to the sponsor, what else needs to happen with the event information?
13	What are the responsibilities of the research team when CCR is the coordinating center for a multi-site clinical trial?
14	What is off-treatment versus off-study?
15	How do I create, modify, or deleate a protocol order set in CRIS?
16	When are credentials verified and what do I need to do to maintain my privileges?
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?
18	Who should be included as a sub-investigator on the FDA Form 1572?

M2P2 #	QUESTION/TITLE
19	What is the Monitoring Committee/Board and what are my responsibilities as a Clinical Research Coordinator (CRC)?
20	RETIRED: Documentation of protocol-specific training and the impact for the Research Nurse
21	Who can write an order for IND agents (i.e., drugs & biologics)?
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)
23	What should the Research Nurse do if there is an ineligible subject who was enrolled on a clinical research study?
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
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
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?
27	If consenting is an ongoing process, what does re-consenting mean?
28	I made an error when entering information on a paper form, now what?
29	Where did the Cooperative Groups go?
30	Why does the FDA inspect IRBs and what do they review?
31	What should you do if you notice that there is something missing on the signed informed consent document?
32	What is a Corrective and Preventative Actions (CAPA) Plan?
33	RETIRED - see M2P2 #11: What should I do if I find incorrect or missing information on ClinicalTrials.gov (CT.gov) or NIH Clinical Research Studies?

M2P2 #	QUESTION/TITLE
34	My patient has had labs drawn outside of the CC. What do I need to do as the research nurse besides ensuring that we get the results and they are scanned into CRIS?
35	How does the protocol information get onto the CCR Clinical Trials website?
36	RETIRED: Did you know that you can use the ATV system to obtain a Clinical Center (CC) medical record number (MRN)?
37	You learn that one of your patients, who is not an inpatient, has died. What documentation is required?
38	What are baseline symptoms and how do I capture them?
39	What does it mean to take a patient/participant off-study?
40	What does it mean to close a study with the IRB?
41	What is the primary completion date (PCD) and the anticipated completion date (ACD)? Why are these dates important?
42	What is an unexpected adverse event (AE) and how is it be reported to the IRB?
43	Who needs to be listed on the Delegation of Tasks Log?
44	RETIRED: What happens if a patient signs an informed consent document with dates outside of the approved date range?
45	There are several email boxes used in the CCR. How do I know what to send to which email?
46	RETIRED: How to respond to a Reportable Event Form (REF) Stipulation
47	RETIRED: A potential study participant cannot come to the Clinical Center to sign the informed consent. Can I obtain informed consent via telephone?
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)
49	Data Management FAQs
50	What are the expedited reporting requirements for “events” that happen during research?

M2P2 #	QUESTION/TITLE
51	RETIRED: What research “events” need to be reported at the time of continuing review?
52	RETIRED: I thought that a witness signature is no longer required on the information consent document but now I have an audit finding for lack of witness signature. What gives?
53	My patient had genetic testing for inherited cancer risks and a Variant of Uncertain Significance was identified, what is that?
54	What should I do to get biologic material (e.g., pathology samples) from outside the U. S to the NIH?
55	What exactly is a CRIS order?
56	What are the different types of CRIS orders?
57	What is the difference between an order set and a research order set?
58	I want to use a patient survey in my clinical research study, do I have to do anything first?
59	What are my options to send secure email?
60	What is the NIH Form 527-1?
61	Where can I find Patient Education materials to teach my patient?
62	What does it mean for a research participant to be lost to follow-up?
63	When is it appropriate to enroll the participant onto protocol 01C0129?
64	When is it appropriate to enroll the participant onto protocol 04C0165?
65	How do we interact with the Protocol Services Section (PSS)to register a protocol with clinicaltrials.gov?
66	Is there anything special that needs to be done when conducting remote consenting?
67	What is Serious Adverse Event (SAE) reconciliation?
68	I know what a Curriculum Vitae (CV) is, but are there any particulars that I need to know related to CCR requirements?

M2P2 #	QUESTION/TITLE
69	What is iMedConsent™?
70	What is an Expanded Access Use IND/IDE (also called “Single Patient” or “Compassionate Use”) ?
71	What is Embedded Agreement Information in PRES?
72	What do I need to know about ThinkAndor®?
73	What needs to be done for a monitoring/audit visit and who is responsible?
74	What should you do if you have a protocol modification/amendment that impacts one of CCR’s databases?
75	What is the Clinical Center’s Office of Patient Recruitment (OPR)?
76	Who should be notified when a primary completion date (PCD) is met for one of my clinical trials?
77	What is a Good Cause Extension (GCE) for reporting results in ClinicalTrials.gov?
78	Is it mandatory to redact certain information from a protocol and/or consent for results reporting to clinicaltrials.gov?
79	What is compensation for research participants?