**An Observational Descriptive Study of IRB Practices**
**Topic Codes for IRB Meetings**

**0.** ***No topic***

**1. Risk**

**a. Risks to Subjects**

**i. Biomedical Side Effects**: Effects from the specific drug or technique being studied. Also use topic code *research study, response to safety issues* [8h] if a stopping rule is discussed because of a risk to the research participant.

Examples:

- *162-Chair: … and there are some potential harms from all the medications, non-placebo medications…*
- *15-PR: So, again, it may add to the risk of the patient if they have to undergo all these biopsies to confirm what really is going on with this area that has metabolic activity in this patient…*

**ii. Psychosocial Risks:** Code psychosocial risks (loss of employment, loss of insurance) here.

Examples:

- *5 – chair & PR: They do say that the* ***Sponsor*** *is gonna have your identifiable information which might say that if you have 3 car crashes, you won't be able to be in the driver's pool anymore.*
- *Subject won't be in the driver's pool anymore…*

**b. Risks Inherent in the Overall Research Design:** Over-arching risks, (e.g. placebos, wash-outs, double-blind). Effects from how the study itself is structured. This includes risks of including severely ill people in the research study.

Examples:

- *155: … it may be very difficult to start them out without having some kind of a washout period.*

- *13-PR: … I've got a couple of concerns about the severity of disease that they're willing to include in the study.*

**c. Risks From Deviation From Routine Care:** Code when there are specific discussions of how risks to subjects are different from "routine care", "standard care", "usual care".

Examples:

- *21-2nd: … And then they make the bland statement here that 'there's no increase in risk by having it done this way.' I don't agree when they're asleep for another 20 minutes and getting extra shocks. I think they should be upfront about it and say that there's gonna be a bit more anesthesia time, intubation time, a little more* ***central nervous system drug*** *dose, but we're gonna watch you carefully by the following criteria if they want to. But, they need to say that it is going to be added time exposed to risks.*

**d. Assessment of Risk Level:** Use this code when members of the IRB panel are trying to categorize a protocol's risk level, (e.g., minimal, minor increase over minimal etc) or there is a discussion of the level of risk that was assigned by an investigator.

- *108 - Staff: … that I think needs to be resolved before we can approve it, but if everyo-, if after we've discussed it we agree that it's minimal risk we can defer it back to the chair…*

- *138-PR: Ok I just, I didn't, wasn't, it's not a high high risk study, I mean…*

**e. Harms:** Use this code when there are mentions of a harm that has actually occurred in a study or in a study of direct relevance. The exact damage that was done or how AE's are dealt with in the protocol. Examples are Adverse Events (AEs), Severe Adverse Events (SAEs), Sentinel Events.

Examples:

- *5-Chair: …this was something we saw earlier and it was not deferred but we had questions about the adverse events….*

- *Reporting increased liver enzymes as the AEs, as opposed to hepatic injury which is the real AE.*

**2. Benefits to subjects**

**a. Reduction/Avoidance of Risk:** Code benefits that accrue to research participants from the reduction or avoidance of a risk; in order to distinguish this from a direct benefit of the study, this is a statement with a negative cast or valence.

Examples:

- *15-PR: They mention that the scans for the CT scan maybe may include more images, I imagine they need to cover a larger area to overlay these images. So, it could add to the increased radiation dose, on the other hand, if they po- position the needle with a bit more pre- precision it may lower the radiation dose.*

**b. Follow-Up After Completion of a Study:** Any clinical follow-up for a research participant after a study has been completed. This does not include clinical follow-up that is part of the research study.

Examples:

- *178-PR: So they just, they don't say that they just send you back to the primary care provider with no directions…*

**c. Potential Benefits of the Research Study:** Code here when there are potential treatment benefits to subjects from the research intervention. To distinguish this from a benefit accrued by avoidance/reduction of risk, this is a statement with a positive cast or valence. This code includes discussions of closer follow-up, higher quality of medical care, free treatment, additional tests that would not otherwise be done, and finding clinical problems.

Examples:

- *21-2nd: But they're not actually looking to see if the battery lasts longer or if some other benefit accrues clinically as part of the research question…*

**d. Other Benefits:** Use when there are mentions of undifferentiated benefits. Do not use this code if you can use topic code *benefits, reduction/avoidance of risk [2a], benefits, follow-up after completion of study* [2b], or *benefits, potential benefits of the research study [2c].*
Examples:

- *178-PR: I mean, I thought it sounded like, what are the benefits, I mean there are no benefits.*

**3. Risk/Benefit:** Code when risks and benefits are mentioned together. This includes weighing risks and benefits.

Examples:

*49 – Chair & PR: There's a third issue that we may want to come back and revisit. We asked about the risk/benefit, but he's come back with an argument that looks reasonably cogent to my eye.*

**4. Informed Consent Procedures**

**a. Disclosure:** Use this code when subjects are given information about the study being conducted. This code is used when consent is discussed as a process, or when reviewers require that participants be given more or clearer information. This code is used only when the PI or study team discloses information about the study. Use of translators is coded here as is translations of consent forms.

Examples:

- *21-2nd: They've just said, we're gonna put a device in so we're asking you to test the lead in a particular way, they've not actually explained to the patient there's another way of doing it, the routine way, and giving them an option…*

**b. Comprehension/Capacity (Competence):** Any effort to describe or assess decision-making, or any effort that should be made for the participant to reach a decision about being part of the research study.

Examples:

- *163-2nd: That some of these, some of these are gonna have a degree of cognitive impairment, although they say not to the degree that they could not give consent.*

**c. Coercion/Pressure/Influence**

**i. Natural:** Code when coercion is recognized/identified by the coder, but not by the person speaking.

Examples:

- *67: The one other thing that bothered me, I don't know if it bothered anybody else, was the repeated referral to the study and drug as treatment. And particularly in the opening, 'You're not gonna benefit from standard chemotherapy, so we're gonna treat you in this study.' You know, I just think it's kind of promising too much altogether.*

**ii. Described:** Code when the coercion is recognized/identified by the person speaking.

Examples:

- *137-PR: . . . Or at least make sure there's not disincentives associated with this study that would discourage such testing.*

- *163-PR: Another minor point probably is on the consent form; they have this big word 'volunteer' on the opening page and to me that's a little bit coercive.*

**d. Obtaining Assent (including assent forms)**

Examples:

- *49-chair & PR: We asked him to delete surrogate consent since none of these kids can provide consent, they'll provide assent.*

- *129: Well, if they're gonna be 50% 7 or younger we assume they're not capable of assent…*

**e. Obtaining Surrogate Consent (including surrogate consent forms):** Obtaining consent from parents, guardians and adult children for the research subject.

Examples:

- *37: So, that would prompt us to say that we probably should get consent from both parents, because there would be no benefit at all to the placebo kids, would there?*

- *5-Chair: They also check the box that they would get surrogate consent and I don't think that's appropriate for this study nor really necessary to it.*

**f. Obtaining Consent**: Use this code for there is discussion about the event or act of obtaining a signature for the consent form. Signing the form, "doing consent", consent discussed as an event rather than a process. The process of informed consent is coded under its elements: *informed consent procedures, disclosure* [4a], *informed consent procedures, comprehension/capacity* [4b], *informed consent procedures, coercion/pressure/influence* [4ci or 4cii]. Do not code here when the consent is a mere time marker (e.g. "we do x, y, z after the consent". This is a discussion that is not focused on the consent).

Examples:

- *22-2nd: The parts of the protocol summary are worded gives me some but not a lot of concern about whether the investigators fully understand the nature of securing the informed consent of a participant. For example the protocol summary in the section of the study states "the initial website serves as an electronic informed consent." Oh no it doesn't, you know it's an elective, electronic means to show consent.*

**g. Consent for Future Contact/Future Studies**

Examples:

- *45-PR: The they're gonna be doing genetic testing and I have questions in the consent form and I would have to defer to the experts on whether or not those are all appropriate, but whether or not the patients can be contacted in the future etcetera.*

**5. Consent Forms**

**a. Norms and norm violations:**. Use this code when there is a discussion about conceptual issues raised by the consent form; consent form rules that are explicitly stated, or evaluations of types of behavior (or norms) expected in the form. Use this code when there are mentions about the content that is or is not being disclosed. Code here for translation of the consent form, readability of the consent form, risks described in the consent form, benefits in the consent form, and more information needed in the consent form. Coercion (namely, coercive language) does not get coded in this topic, instead it gets coded for the topic *informed consent procedures, coercion/pressure/influence* [4c].

Examples:

- *20-PR: Well, I expected something more in terms of an understanding of what the additional risk is for having this done. And if there's none, say there's none. If there is some, say there's some. I mean it's only fair that you <u>put that also in some understandable fashion for the consent form as well</u>.*

- *11-PR: I found a discrepancy in the reimbursement described in the consent form versus the protocol, so I just wanted clarification on that.*

**b. "Form" Requirements:** Norms or applications of norms concerning how the consent form should be presented on the written page. Code here when there is a discussion about the consent form's mechanics and/or grammar. Code when there is a discussion about the way words are presented on the written page. Do not use this code when someone is talking about whether or not the consent form is doing what it is supposed to be doing, instead use *consent forms, norms and norm violations* [5a].

Examples:

- *171: Yeah, on page 39 first page of the consent form …it's not a complete sentence.*

**c. Other:** General mentions of the consent form (not content). Use this code when above topic codes *consent forms, norms and norm violations* [5a] and *consent form, form requirements* [5b] are not applicable.

Examples:

- *5-Chair: Ok,* ***20*** *do you have a comment?*
  *20: No, just the paragraph, fourth paragraph of the consent form the third paragraph in the consent form.*

**6. Application:** This is an evaluative code specific to what is right or what is wrong with the application or protocol. Only use this code when statement is not referring to another topic. If there is a statement about debriefing norms in the application, for example, code under "debriefing" and not under this topic. Use this code when there are general statements about the research study or research application the is being reviewed by the IRB. If reviewers need more data about feasibility or safety as background, code here as an application code, not as a subcode of *information sources* [18] (not as a data resource consulted). This code differs from topic code, *standards, rules and procedures pertinent to the IRB* [24] in that this code addresses norms of the application, not the norms that the IRB uses to make decisions or do their work.

**a. Norms and Norm Violations**: Use this code when there is a discussion about conceptual issues raised by the application or protocol itself; rules that are explicitly stated, or evaluations of types of behavior (norms) expected in the application. Discussion of continuity, consistency, and precedence are coded here. Statements about the norms of the protocol summary and checklist are coded here.

Examples:

- *102-PR: . . . the protocol is actually well-written*

- *102-PR: . . . In my understanding the patients will come with the diagnosis already and they're going to endoscopy as part of their treatment and biopsy's part of the treatment. But that's not totally clear in the protocol if the biopsy's actually part of the study or if they're just gonna use that as that, so they need to clarify that.*

**b. "Form" Requirements:** Norms or applications of norms concerning how the application should be presented on the written page. Code when there is a discussion about the application's mechanics and/or grammar.

Examples:

- *30-2nd: The application needs to be signed…*

**7. Auxiliary documents:** Examples of auxiliary documents are the Investigator's brochure, the Sponsor's protocol, HIPAA forms, contracts and subcontracts, general appendices and conflict of interest forms.

**a. Norm and norm violations**

Examples:

- *49-Chair & PR: The most prominent problem potentially for these folks is a prolongation of gastric emptying which could predispose these folks to aspiration especially if the patient is getting coincident tube feeds which these people are capable of having. They actually have a reasonable paradigm of handling that issue with an appendix to the protocol that's a standard approach to looking for potential tube feeds, which they'll implement in this as well.*

**b. "Form" requirements**

Examples:

- *263-Chair &PR: They need to add the title for the HIPAA form, and oh the department chair signature, PI FOR 26B5 I guess is the acting chair so he signed for himself, so we will need to get somebody else to sign that…*

**c. General**

Examples:

- *13-PR: It's not in the literature they gave us, but it's in the investigator's manual…*

**8. Research Study**

**a. Initial Presentation of Study:** This code is a marker for the introduction of a review of a protocol; a Reviewer is making their initial presentation of a study. If there is Secondary or Tertiary Reviewer, code here when that person is making their initial presentation as well. Keep using this code if a Reviewer gets interrupted in their introductory presentation. If the interruption causes a change in the topic of discussion, however, move on to other more specific codes.

Examples:

- *18-PR: So a study from Radiology for evaluation of multi-detector CT scan's role in evaluation of atrial thrombi in patients who are undergoing cardioversion. They want to compare the performance of CT scan in diagnosis of atrial thrombus to the standard of care which is transesophageal echo. So, the, my general comment is the protocol and the consent form are a little abbreviated; I was looking for some details, especially like for the CT scan, for what to have in the original protocol is that the patient will undergo CT scan, but there is like inclusion exclusion criteria as would expect to see what to see what tests would be done for the patient before they go to CT scan, because they are excluding patients with high creatinine.*

**b. Specific Description of Intervention** (drug, device, technique): Use this code when the intervention that is the focus of the research is being discussed. Use this code any time the intervention is mentioned.

Examples:

- *180-PR: So a study from Radiology for evaluation of multi-detector CT scan…*

- *162-Chair: Yeah. So, and is the fMRI machine the same configuration as the clinical machine?*

**c. Research Design:** General, over-arching design; not the discussion of an intervention or a procedure. Types of research designs: cohort, case series, case-control, randomized clinical trial (RCT), placebo control, Phase I-IV, double blind, cross-over, open label, single-blind, intent to treat, treatment as usual (TAU). Also code when there is a description of the study's timeline or when reviewer identifies when things are done in a study (check-ins, phone calls, appointments). To code here, however, times of check-ins/appointments should be related to overall design, not safety or specific research issues. Use this code

when dosage issues (e.g., changes, switches related to design) are discussed. This code includes extension studies and pilot studies. Code research subcontracts here when who is doing the research is evidence of multi-site design.

Examples:

- *138-PR: . . . there are 3 different asthma control strategies and everybody is going to be taking one and 2 placebos.*

- *138-PR: . . . In the original protocol it was multi-center RCT.*

- *102-PR: . . . That there'll be also chart review of course to see the the follow-up of these patients after the procedure and to compare with the the blood tests.*

- *162-Chair: You can say that's the point of which the six month clock starts ticking but…*

**d. Procedures:** Use this code when there are mentions/discussions of a medical technique. Giving participants medication is a medical technique unless the intervention is the investigational drug itself, then code under *research study, specific description of intervention [8b].* Code here when there is a mention of drugs being combined. This includes hospitalization as a procedure. Code specific data collection methods here. Do not apply this when someone mentions testing in general and does not specify what type of test is being done.

Examples:

- *134-PR: He wants to draw blood on anyone who comes to his clinic,*

- *108-Staff: … It's a blood draw and it's also eye photography which I I don't…*

- *102-PR: … and they're gonna do biopsies of the esophagus.*

**e. Purpose of Research:** Use this code when there are mentions of why the research is being done (broad purpose including specific aims). Use topic code, *research study, outcomes* [8k] *when there are mentions of* specific outcomes expected.

Examples:

- 134-PR: … *you know this is a repository study. He wants to draw blood on anyone who comes to his clinic; the underlying goal is that he says he's gonna find genes for new, inherited eye disorders*

- *102-PR: The purpose of this study is to see how related serum gastrin levels are significantly elevated in patients with esophageal adenocarcinoma and compare them with patients with Barrett's esophagus.*

**f. Importance:** This topic code applies only when someone states that something is "important or "not important" (or equivalent phrasing) about the research study.

Examples:

- *22-2nd: … like I said I wouldn't stand in the way of something like this which I think is probably quite useful.*

**g. Quality Issues**: This code is used when there are statements about the quality of the research (not about the design features of the study, but a "well-designed" study is a quality comment) – whether the research is "good" or "bad". This code refers to the quality of what takes place in the research investigation itself.

Examples:

- *The research won't generate the results they want*

- *138-PR: It's a good study.*

- *163-PR: Otherwise I thought it was a reasonable study.*

**h. Response to Safety Issues (minimizing risks):** Code here when there is a proposal of what to do under situations of increased risk. This includes not only stopping the study, but also what is done in response to undesirable effects on the research participant (checking lab values, performing an EKG). Stopping rules are also included here if they are relevant to safety.

Examples:

- *137-PR: . . . I asked the coordinator if they knew during the 24 week participation if there would be a time when you would be reevaluated for, let's say, viral load or some way to know that it wasn't time to get onto treatment.*

- *… and there are beta blockers that will be given if the patient has tachycardia.*

**i. Statistics:** Mention of statistical evidence/data analysis is coded here. This code includes discussions of sample size and power.

Examples:

- *8: I didn't see that sample size calculation.*
  *22-2nd: You mean x percentage of all people working, something like that?*
  *5-Chair & PR: Probably, we can ask.*
  *22-2nd: It's just that I can't figure out how these things happen. I mean that sounds like a little more than you might need to have something sufficiently powered to get something out of it.*

**j. Future Data/Storage:** Code when there will be future research on and/or storage of samples/tissue.

Examples:

- *134-PR: … you know this is a repository study.*

- *134-PR: … so this is just basically permission to bank the bloods.*

**k. Outcomes:** Planned endpoints or outcomes of the research study. Must be explicit. This code does not include the termination of the study.

Examples:

- *36-PR: So I think what you'd change there is the eligibility criteria and they'd need to refocus their outcome as well…*

- *36-PR: … they indicate that that's not what they want to do because they are interested in collecting efficacy data.*

**9. Routine Care:** Use this code when there is discussion of expected clinical care for the condition under investigation.

**a. What Routine Care Is:** Stating/discussing what routine care is. Included here is how routine care is different from the research being done.

Examples:

- *138-PR: . . . Right now, apparently, the way that people's dose of asthma medication, particularly steroids, is adjusted there are these guidelines and you know every month or you know without exacerbations it gets better, it gets worse you just go down on the dose, but these are just sort of very general guidelines.*

- *140-Chair: But the big question- question is whether the biopsy is part of the…*
  *102-PR: Right. Yeah.*
  *140-Chair: … standard procedure for this condition…*

**b. Comparisons to Routine Care:** Code here any assertions that the research is clearly superior or inferior to the current clinical care. Also code here any discussions of research being different from clinical care e.g., because it is not yet proven or it is not focused on an individual's best interest.

Examples:

- *20-2nd: … they oughta have something in the consent form that says, 'This is not what we normally how we treat people who have this problem or issue that we are concerned about' and that oughta be in there, so the people understand that this is somewhere out there and we think it might work but we don't really know if it will.*

- *36-PR: I guess you'd need to argue to me that, and maybe that's what the trial would show, that it was that much better at doing that.*

**c. Routine Care for Another Condition:** Code here when the Investigational drug is the approved routine care for another condition.

Examples:

- *44-2nd: Yeah, other indications that the drug was given to kids for what it's approved for.*

**10. Subjects:** When using this code there must be a specific reference to population, not just a reference to a disease or group with a disease.

**a. Recruitment:** This code includes how participants gets picked to be in a study (e.g., approached by their clinician who is not involved in the research, by advertising, announcements, leaflets etc.). Do not use this code when there is a mention of inclusion/exclusion criteria, but instead use code *subjects, inclusion/exclusion* [10c].

Examples:

- *15-PR: So they will recruit those patients that are referred to an interventional radiology service for biopsy of a tumor…*

**b. Enrollment:** The point at which a participant joins the study; the point where recruitment ends. Use this code when there is a mention of how many participants are in a study.

Examples:

- *11-PR: It's a multi-centered study that plans to enroll 80 subjects in total. 8 of which would be enrolled at the* ***Name of Hospital 1.***

**c. Inclusion/Exclusion:** Use when there are explicit criteria that describe the subject population.

Examples:

- *102-PR: If after the first, very first, section you are found not to be eligible because of poor asthma control…*

- *102-PR: What they're gonna do is to study patients who are receiving partial pump inhibitors.*

**d. Refusal:** When a participant refuses to be in a study at enrollment.

Examples:

- *455-PR: You know, request to withdrawal will be submitted, should be submitted to so and so, I didn't see language like that in the consent. And maybe I missed that. 454: I don't know if they have to have it.*

*455 & PR: Don't they have to?*
*454: I think they just say "hell no I'm not coming back". I think that's sufficient.*

**e. Retention/Withdrawal:** The withdrawal of a participant unrelated to safety issues/adverse events (likely because of participant burden or ineffectiveness).

Examples:

- *5-Chair & PR: Yeah but remember, I mean, people are going to say 'oh yeah I'll do this,' they're gonna sign on, you know then like 2 months into it they're gonna go, 'oh geez I don't wannna do this anymore.' So, you know, probably you're gonna have an attrit- a huge attrition rate here.*

**f. Special Populations:**

**i. Subparts B, C, D of the Federal Regulations (45CFR46):** Code here when something special, different, unusual is being done or is being considered for research participants because of their membership in a vulnerable population (pregnant women, children, prisoners). Do not code here when there is simply a mention of these groups.

Examples:

- *44-2nd: Background on efficacy is based on 20 patients and not very many of them have received this dose, so it's potentially giving 15 milligrams to a 6 year old child with essentially no drop criteria…*

**ii. All Other Special Populations:** Code here when there is a special concern or a special protection being made for the population being studied. Examples include persons diagnosed with mental illness, students, blind persons, the military, those economically disadvantaged, developmentally disabled, participants unable to consent. Use topic code, *subjects, vulnerable populations* [10fi] when the discussion is about pregnant women, children, prisoners, or neonates.

Examples:

- *61-PR: The study summary said also, just to protect undue influence including **Site 77** employees, it occasionally allows cognitively impaired persons*

*but there's not comment on that in the protocol or anywhere nor in the statement as to how detriment occurs so I assume we have a standard language template for that…*

**g. General Description of Subjects:** Use when there is only a general term to describe the research population. Code when words such as "appropriate", "large", "treatment naïve", or "very sick" are used when referring to a population.

Examples:

- *5-Chair & PR: So, I don't understand why that would need to be. I mean it seems to me that with this <u>huge number</u> of people, what is the rationale for having **Name of Sponsor** get that identifiable information?*

**h. Third Parties:** Use when there is a reference to people related to subjects (partners, family, affected third parties).

Examples:

- *45-PR: I mean, they're looking for first degree relatives but they're not necessarily gonna be contacting the relatives…*

**11. Sponsorship**

**a. IRB Expectations of the Sponsor**

Examples:

- *5-Chair: …there should be some commitment on the part of the sponsor to pay for that.*

**b. Sponsor's Expectations of the Research Project and/or the Investigator:** What the sponsor wants done in the research project or by the investigator. Information about data storage by a sponsor is coded here.

Examples:

- *108-Staff: … it's a multi-site protocol. They won't be able to do it without getting approval from the sponsor and…*

**c. Sponsor's Intentions/Motives:** Use this code when there is a mention/discussion of the reasons that the sponsor wants the research done or wants certain procedures followed.

Examples:

- *50-PR: Those 2 addition to the entry study the entrance study I believe will probably be paid for as part of their current care but any studies, but the other 2 studies will clearly be paid for by the sponsor and if I I presume if the first one's not covered the company would cover that as well, they they said they will cover all all study-related procedures.*

**d. General Mention of the Sponsor:** Code when reviewers state who is funding a research study.

Examples:

- *162-Chair & PR: . . . They have federal support, they're asking for a waiver of HIPAA.*

**e. Investigator Initiated:** Use this code when there is mention of a study being initiated by the Investigator himself/herself, regardless of funding source.

Examples:

- *157-PR: This is a investigator-initiated study involving young adults, not older adolescents as they're stating on the title.*

**f. Internally Sponsored:**

Examples:

- *362-PR: Okay, so this is an investigation from two people in the department of surgery and it's department funded, and I love the name of this person,* ***name of PI for 8B3 (neck).***

**g. Action Taken by a Sponsor:**

Examples:

- *21-2nd: And they went back to the manufacturer and the manufacturer said fine, make it 4.*

**12. Debriefing**

**13. Conflict of Interest**

**a. Of the Reviewer (Monies, interests, relationships with PIs)**

Examples:

- *63-Staff: He dropped **77A1 (Leukemia)** and (unclear) **77A4 (Bypass grafting)** 78-Chair: **77A4 (Bypass grafting)**, Ok. So, he did drop **77A1 (Leukemia)**. So, I and I but I did that one so let's go ahead. Let's go ahead because of the conflict of interest. Ok. **68**, **68** why don't you go ahead first and I'll put this on.*

**b. Of the Research Team** (includes the PI): Code here the research team/PI has a conflict of interest.

Examples:

- *15-PR: Now, I think the bigger risks that are not particularly mentioned in this consent form is that the decision as to which part of the patient will be biopsied, is totally left to the intervention radiologist who is also part of the research team. I'm sure there's interesting areas that one would want to biopsy that are difficult and compelling, and I think that sometimes they may choose an area that is more of interest for the research, rather than clinically relevant. So I would like to see that the site of the biopsy will be determined by an independent radiologist, or an independent oncologist who has nothing to do with the research…*

**c. Of the Institution**

Examples:

- *372-chair: There is, my concern about this and I tried to get it clarified in talking to **PI of 81A7 (glioblastoma)** yesterday, who's by the way a member of the **site 81 location** committee. So, there is a very vague and loose relationship between **study sponsor** and **site 81** in here. Who's the coordinating center? Well it's not us, it's them. What are they gonna do? What he finally said was, "We do everything, we have this one person from **study sponsor** come over once a week and help me*

*understand the science about this stuff". I was, still somewhat concerned about it. The main concern I had was that the DSMP, the DSMB committee is the **site 81's cancer center** committee, and because of that they wanted to keep it blinded. And, to me that's not acceptable at this point. They can't be blind to the randomization and there's no point to have a DSMB. He said that he would be willing to make it unblinded, which I think we must. This is really too important.*

**14. Confidentiality**

**a. Confidentiality Certificates**

Examples:

- *5-Chair & PR: They do have a certificate of confidentiality…*

**b. General Confidentiality/Privacy:**

Examples:

- *22-2nd: … the consent form is a nightmare and they mix up confidentiality and privacy all over the place.*

- *5-Chair & PR: They do say that the sponsor is gonna have your identifiable information…*

**15. Costs:** Code when there is mention of insurance payments or ways in which costs of an intervention or a related need will be covered. An example of a related need is transportation costs, related treatment, and the use of translators.

Examples:

- *162-Chair & PR: So, one question that I had is for cancer patients in, in, in **country#1,** is there a state health insurance that pays for their care or is it private?*

**16. Remuneration**

**a. Costs to Participants**

**i. Actual Costs to the Subject:** Reimbursement for actual cost incurred to the participant (e.g. travel, parking).

Examples:

- *138: Will there be, is there reimbursement for this study?*

- *171: They will reimburse the participant 30 dollars for travel and other expenses though it's probably the caregiver who's more likely to incur those expenses as… I wondered if either it could be shared or whether…*

**ii. Payments for Participants' Time, Effort, Pain:** Examples are incentive payments, inducements to the research participant.

Examples:

- *48-PR: So, and then they'll pay 250 dollars plus parking plus transportation if everything is completed in the study.*

**iii. Unspecified Remuneration**

Examples:

- *33-PR: For all of this the patients are paid 150 dollars. It seems a reasonable amount.*

**b. To the Investigators**

**17. Laws, Regulations and Issues of Meeting Federal or State Regulations**

**a. HIPAA**

Examples:

- *162-chair & PR: . . . They have federal support, they're asking for a waiver of HIPAA.*

**b. 45 CFR 46/Common rule (also subsections 404/405/406)**

Examples:

- *250: Because I think, as of now, we can't approve this under 404, um, because it has more than minimal risk. They do not claim any benefit so we can't approve it under 405.*

**c. Belmont Report**

**d. State Laws/Regulations**

Examples:

- *20-2nd: (unclear) segue into that. If you read the statement of confidentiality, it's pretty clear that almost any type of legislative proceedings do not being brought against this person, the only way they can get the information and it would not be able to be used against the person is if they were investigating the investigator for some kind of conduct (unclear). But they they talk about you know there's civil, criminal, legislative, administrative, or these other you know there's always different…*

**e. Other Federal Laws/Regulations (including Executive Orders) Including 51 FDA 52.**

Examples:

- *250: Which falls under the uh inv, investigational device regulations.*

**f. Other:** Including international documents (e.g. The Declaration of Helsinki).

Examples:

- *267-PR: There is an interesting thing here that I have a note about, says that the investigators that find, that a subject with sleeping sickness will be given Pafuramidine if they do not respond to the study drug, we should be sure if this is a legal requirement. In other words it states straight out that they will be given Pafuramidine.*

**18. Information Sources:** Code here when information sources *other than the research protocol* are considered, used, and/or suggested. Any reference to an information source

that provides factual, normative or evaluative information will be coded here**.** Consider the context and setting.

**a. An Individual's Personal Research Expertise/History:** An individual's own research. Research given/described to the IRB to help them make an informed decision.

Examples:

- *15-PR: having worked in this field and knowing how interesting it can be to take a sample of an interesting area…*

**b. Books, Articles:** Journals and texts. Any online application that is linked to journal articles or academic literature is also coded here (PubMed, Medline) instead of topic code *information sources, internet [18c].*

Examples:

- *36-PR: … and as I picked through what's out there in the literature, references that they cite, I guess I learned more about it than I ever imagined I would…*

**c. Internet**

Examples:

- *162-Chair: … and and so that they're trying you, you know, so that people are already trying, it but I really looked to see if there were it was like one abstract that they quote in in here that I couldn't find and that's it for any of these agents. And and I really think that that's a…*

**d. IRB Consultants**

Examples:

- *5: Well, we got our lawyer here today.*

**e. Other Reviewer**

**f. Principal Investigator**

Examples:

- *47-PR: … So I called Dr. **PI of 11B2 (pediatric vocal fold)** and it rapidly became apparent that when I repeated the questions to him that most of the driving force for this was coming from the otolaryngologist, Dr. **Name of otolaryngologist of 11B2 (pediatric vocal fold)**, and Dr. **PI of 11B2 (pediatric vocal fold)** really didn't know some of the answers to the questions.*

**g. IRB Staff**

**h. IRB Members**

**i. IRB Chair**

**j. Other Colleagues**

Examples:

- *5-Chair: I actually referred it to an oncologist and they agreed with me that no, you can't just do this, you need a real protocol.*

**k. Other Studies**: Relevant/past studies that are used to assess the study being reviewed. Do not code when information from another study comes from the investigator's research application itself. Unless the person indicates where they got their information about another study, treat the information as coming from the investigator's research application. Use only when another study is used to inform the current study. Do not code when another protocol is mentioned in passing.

Examples:

- *36-PR: There is a study that they point to a lot called the **Previous Study** that supports doing that. And so with that as background, what this study proposes to do, at least in theory, is look at a device that will help with that.*

**l. Research Staff**

Examples:

- *74-Pr: I asked the project manager about this – she basically said as a department they are trying to put that in all the time because essentially **Manufacturer of the MRI** sends them these new pulse sequences and they wanna give **Manufacturer of the MRI** back some of the data.*

**m. Other, specify**

Examples:

- *76-2nd: I agree with **61**'s comments and actually had most of the same ones I guess my (?) comment or question is I saw some references throughout to potentially needing to have ophthalmology exams and that there could be some ophthalmologic lesions that were representative of toxicity, but I didn't, I didn't quite get it and I asked **not sure who she is refereeing to here** and I didn't get a call back from him.*

**19. History of Investigators and Research Staff:** Use when the investigator's and/or staff's history or the protocol's history is commented on, not just who the PI is. Included in this code is any mention of the background and training that is necessary to carry out their research. Use when value judgments are made about the investigator (personal judgments about the investigator or research staff arise here). Also code here when there is a mention of an organization that the investigator belongs to. For resubmissions, deferrals, or tabled protocols, or which department the protocol comes from (not just for "new" protocols).

Examples:

- *This is a resubmission*.

- *Seems like we often have these problems with this department…*

**20. Local and Institutional Interests:**

**a. Importance:** This code is used when assessing the protocol's importance to the community. Code here if reviewers explicitly say the study is important for the institution, for the locale, or persons/organizations known to them.

Examples:

- *262-SR: I thought it was a very ah good app- application, I think its worthy.*

**b. Liability**: Legal liability (being at risk for a lawsuit). Do not code here when there are conversations about compensation, instead code as *remuneration* [16].

**i. Of an Institution**

**ii. Of the PI**

**iii. Of the IRB**

**c. General:**

**21. Other Triviality and Importance:** Statements concerning the importance of research protocols specific actions or issues not related to the community or to the importance of the overall study or its potential results.

Examples:

- *402-PR: That needed to be clarified. Other than that I think it's an important study and should move forward and I recommend approval.*

**22. Roles:** Use when there is a mention of role expectations. This code is for any description of responsibilities and/or expectations for what someone is doing or should be doing. Use this code for general role expectations. Code when appropriate role-specific behavior is mentioned. This code does not include other behavioral descriptions, e.g. "At this point, the nurse practitioner enrolls the subject." This code is not applied when there is an action taken. It is not about a specific person, but about a person's role. It is job-specific, not task-specific.

**a. Role and Function of the IRB**

Examples:

- *165-Staff & 2nd: I believe the investigator felt, you know, that we were sort of looking at this more from a compliance standpoint than from a from just an IRB review standpoint so I sat with them other day and went through that sort of*

*laundry list, gave them a little bit of of advice of one, if you don't understand really what the the issues are of why something gets deferred really, please do ask us and not just make assumptions based on our letters if they're not clear enough and then number 2 I just walked 'em through the process, getting 'em some hints and and in general I think they answered everything that then Dr.* ***180*** *would you please….*

**b. IRB Chair**

Examples:

- *162-Chair: So, so, um, so about once every other meeting or so I, I lay in wait for, for a protocol, um and, and let the reviewer go on…*

**c. IRB Members**

**d. IRB Staff**

Examples:

- *357-chair & SR: I think it's ok.* ***351-staff****,* ***351-staff****is sort of the liaison with the-is the liaison with the Cancer Center and um, you know I'm concerned about the, this consent, so could you, did they you know run this, has* ***Name of person (we do not know who 357 is referring to, either someone from the cancer center or a staff at the Human Research Committee)*** *been schooled on consent 101 for phase I? She's very good but I think this is a new field for her.*

**e. Principal Investigator**

Examples:

- *119: … that kind of stuff, so I can't, I don't think we can say that just 'cause the PI is going to be much better. The PI is really looking at the science of it…*

**f. Research Staff:** Anyone involved in research being reviewed, except the PI.

**g. Institution**

Examples:

- *132-PR: …at the medical school our role is patient-subject protection, not whether research…*

*140-Chair: Right*
*132-PR: … has a purpose or not, correct?*

**h. Other**

Examples:

- *119: All of 'em, But that's my job, role as a director of…*

**23. Actions Proposed or Taken:** Use when there is a description of a specific action taken, especially votes, motions, proposed changes. There must be a discrete activity described as a one-time event (even if the event is going to be repeated). An explicit statement of action needs to be made. Code explicit statement that somebody will not complete an action, as an action. "We tabled this" is coded here. If the speaker adopts or asks about another member's proposed action, it is coded as the speaker's own action or proposal (emphasis is on the role of the person speaking).

**a. Actions Proposed or Taken by the IRB**: Use this code when there are votes and motions. Also use this code when summary statements are made by the chair. When chair speaks and uses "we", use this code. If there is mention of a past action <u>also</u> use topic codes *history of investigators and research staff* [19].

Examples:

- *140-Chair: Alright. So, defer to chair. All in favor? It's fine if you want to abstain or whatever. Anybody abstaining? Not in favor? Ok.*

- *108: … that I think <u>need to be resolved before we can approve</u> it but if everyo-, if after we've discussed it we agree that it's minimal risk <u>we can defer it back to the chair</u> but you know there's…*

- *108-Staff: I wasn't sure <u>if we could actually approve</u> the protocol,*

- *162-Chair: So they just <u>have to tell us how</u> they're gonna screen.*

- *162-Chair: So that, probably <u>we need some sort of</u> a simplification of the consent form…*

**b. Actions Proposed or Taken By the Chairperson:** Use when there are actions proposed or taken by a Chair. This code is used when there is a directive by a

Chair. This code includes deferrals and tabling of protocols. Code here when the chairperson uses "I" statements. Use this code when statements such as, "They should do that" and "I think they should do that" are used.

**i. Protocol Related Actions Proposed or Taken:** Proposals made by the Chair about the action the IRB should take regarding a protocol.

Examples:

- *162-Chair: … Dr **163** I think that probably this should be deferred, and then the response is sent to the investigator…*

**ii. Non-Protocol Related Actions Proposed or Taken:** Individual actions taken by the Chair unrelated to the actions of the IRB regarding a protocol. Use this code when the chair is suggesting a new topic, direction, or task. Use this code when the chair talks about "housekeeping" issues, or makes teaching comments. Use this code when the Chair is directing the flow of the IRB meeting, (directing traffic) even when the Chair is just being conversational (e.g. "I know I'll pay for this later", "I feel much better about this").

Examples:

- *140-Chair: Ok, **102 (Primary Reviewer)**, **98A3 (Esophagus)**. [Let's move on to the next study.]*

**iii. Agreement (generic):** Used when an agreement word is found alone (*yeah; OK*). Use this code when the Chair is agreeing, but if the coder cannot discern whether the word is an agreement or directing traffic, then code *actions proposed or taken by the chairperson, non-protocol related actions proposed or taken* [23bii]. When the chair says "Okay", "Alright", "Mm hmm", "Yeah", "Yep" and nothing else follows, use this code. However, use a more specific code if the agreement is in response to a question.

Examples:

- *162-Chair: Yes okay, alright, yep, sure.*

- *179-PR: I think this is probably FDA [language] but this is maybe taken from a protocol.*

*?: Cut and paste it.*
*162-Chair: Okay, alright.*

**iv. Chair as Primary Reviewer/Secondary Reviewer:** Use this code when there is a statement, action, or agreement made by the Chair when the Chair is serving as the primary or secondary reviewer.
Examples:

- *49-chair & PR: So, I would make a motion with the aforementioned changes to the protocol that this is an approvable protocol.*

**c. Actions Proposed or Taken by the Reviewer:** Code here when the Reviewer proposes something be done with the protocol. This code includes proposed actions, suggestions, any type of action except for an actual vote. If chairperson is the reviewer; during the presentation of the review, and when answering questions about the reviewed protocol and in the review itself, code as *actions proposed or taken by the chair as primary/secondary reviewer* [23biv] above (the Chair's role and actions receive special attention in this codebook). Do not code when a Reviewer is directing traffic.

**i. Protocol Related Actions Proposed or Taken:** Proposals made by the Reviewer about the action the IRB should take regarding a protocol. Code here even if the Reviewer says the word "we" – do not code as an *action proposed or taken by the IRB* [23a]. Use this code when statements such as "They should do this," and "I think they should do that" are made. Also use this code when a reviewer is actively agreeing to something specific.

Examples:

- *42-2nd: The only thing I would like clarified is whether the **Hospital 2** is a sit. It says so in the protocol summary, but nowhere else.*

**ii. Non-Protocol Related Actions Proposed or Taken:** Individual actions taken by the Reviewer unrelated to the actions of the IRB regarding a protocol.

Examples:

- *35-2nd: She said she called someone and said that I was going to do it.*

**d. Actions Proposed or Taken By the Research Team:** Use when the research team or PI responds to the IRB's formal requests. Use this code when there is discussion of the research team's response to the IRB that has already occurred. Do not use this code when there is a discussion of procedures that the research team will carry out in their study. Do not code *potential* responses by the research team.

**i. Protocol Related Actions Proposed or Taken:** Actions made by the research team that are in response to an IRB request.

Examples:

- *108-Staff: …I'd be more comfortable seeing a subcontract…*
  *140-Chair: Mmm Hmm.*
  *108-Staff: … but she [Investigator] hasn't been able to provide us with that.*

- *134-PR: He's [Investigator] chosen not to heed our strong suggestion of collaborating with a geneticist and, you know, setting himself up for real ability to do this.*

**ii. Non-Protocol Related Actions Proposed or Taken:** Actions made by the research team that are unrelated to an IRB request. Do not use this code when there is a discussion of the procedures that the research team will carry out for the research study.

Examples:

**e. Actions Proposed or Taken By the IRB Staff:**

**i. Protocol Related Actions Proposed or Taken:** Proposals made by the IRB Staff about actions the IRB should take regarding a protocol. Use this code when statements such as "They should do this" and "I think they should do that" are made.

Examples:

- *108-Staff: Well, so I had, I had a question as to whether we could approve it.*

**ii. Non-Protocol Related Actions Proposed or Taken:** Individual actions taken by the IRB Staff that are unrelated to the actions of the IRB regarding a protocol.

Examples:

- *108-Staff: Yeah, I'm sorry Dr.* ***138,*** *I emailed you today just so you could…*

**f. Actions Proposed or Taken By an IRB Member:** Use this code when an action/proposal/suggestion is made by a member of the IRB who is not a reviewer of the protocol being discussed, and is not the Chair, or a staff person.

**i. Protocol Related Actions Proposed or Taken:** Proposals made by an IRB member about actions that the IRB should take regarding a protocol. Use this code when statements such as "They should do this" and "I think they should do that" are made.

Examples:

- *5–Other IRB Member: So, I think we could, we should at least talk about that and and make that determination.*

**ii. Non-Protocol Related Actions Proposed or Taken:** Individual actions taken by an IRB member that are unrelated to the action of the IRB regarding a protocol.

Examples:

- *67: There's a comment this, I did I did that review, and there's a comment in the discussion that the duration of the study is 30 years, that was a joke. What I was commenting on was the fact that they were only accruing one patient a year and I thought their accrual was very slow to…*

**24. Standards, Rules and Procedures Pertinent to the IRB:** Use this code when there is recognition of an IRB standard: how things are done on the IRB, the culture of the IRB, or how they should be done. Use this code when a discussion of templates/boilerplates occurs, or whether a study can be expedited. But this is different from a discussion of the application. Do not code an action that is *motivated* by a rule here. If there is an action that is governed by a rule, this code requires a clear reference to the rule that is being applied. This code also applies to rules/standards of

the individual IRB members, and how they apply their rules/standards to the investigators.

**a. Of the IRB**: Use this code when there is mention of established rules or an absence of rules of the IRB. The rules and procedures of the administrative structure of the IRB are included here. Use topic code, *consent forms, norms and norm violations* [5a] or *application, norms and norm violations* [6a]when there is mention of how a consent form or application is suppose to look.

Examples:

- *180-PR: … the language in the consent form is a little advanced for an eighth grade level <u>that we agree on</u>.*

  *"That's not our boilerplate." "That's not how we do it."*

**b. Of the University or Hospital**

**c. Standards of another IRB/Other IRBs**

Examples:

- *5-Chair & PR: And then I guess, my the other comment that I forgot to make is the issue of **name of occupational group that may be subject to coercion** IRB review. I mean I can't imagine an occupational site allowing these additional things to go forward without at least running it past their IRB, so I expect that's in the cards for the future. They would have to either review it or say 'we elect not to review it, you're just doing this stuff on our site.' But, one of those 2 things would have to happen I think. **Occupational group that may be subject to coercion** has a pretty, you know, serious IRB system and I can't imagine them not wanting to look at this.*

**d. Precedents:** The IRB's historical precedents. Code here when there is a specific discussion of how things have been done in the past**.**

Examples:

- *49-chair & PR: This **Name of PI for 11B5 (Burn patients)**, we've seen these kinds of studies before…*

**e. Other:** Use this code when there are mentions of deferring to a decision made by another IRB

Examples:

- *I wasn't sure how that worked; I know the VA has its own processes.*
- *I wasn't sure how that works. I know the VA has their own process.*

**25. Principles and Values:** General statements of principle. Use this code for broad mentions of ethics, not when there are mentions of internal workings of the IRB.

**a. Fairness/Justice:** This code includes mentions of duties/obligations (including due diligence) to research participants (also their rights), institutions, society.

Examples:

- *162-Chair & PR: There, there the paragraph 'what are my rights as a participant?' is that consistent with what their rights would be in in* ***country #1****, cause that's sort of our standard kind of legal language but is that…*

**b. Beneficence/Nonmaleficence**

Examples:

- *49-chair & PR: Well, in order for us to approve surrogate consent we have to assume beneficence on the part of the person, the surrogate.*

**c. Autonomy/Respect for Persons:** Use when a participant's choice or free will is mentioned.

Examples:

- *267-PR: Well, they give them a choice, see that's what this choice is all about. They can you know go home and with the blister pack and take the 10 days of treatment.*

**d. Equipoise**

Examples:

- *36-PR: So, suddenly not only does there not seem to be equipoise, but I think based on this we would argue that there's reason to think that there's actually some risk of injury here.*

**e. Other** (e.g., respect for the IRB process and Zeno's Paradox.)

**f. Therapeutic Misconception:** The discussion of participant misunderstanding about research being for his/her best interest.

Examples:

- *272: Yeah, that is how they have advertised all of their stuff before.*
  *272: …Yeah, well it's a hook…*
  *266-SR: Can we boost your child's brain power.*
  *263-Chair: Um, so the ad needs to be retitled.*

**26. Self Referential Codes:** Used when someone is describing himself/herself (e.g. education, experience, age, etc.) Do not code when someone mentions what they do for the review process.

Examples:

- *49-Chair: I'm gonna go to **53** first, **53** is joining the committee, he's a pediatric nephrologist. Is that right?*
  *53: Mmm Hmm*

**27. Reference to the UMass Interviewers and/or the UMass IRB Study**

Examples:

- *903: This is an observational, descriptive study of the IRB process and this consent form allows us to tape the meeting. If you'd like to be interviewed at a separate time…*

**28. Non IRB Oversight Procedures:** This topic code has to do with oversight procedures outside the IRB holding the discussion. This includes references to OHRP, radiation safety committees, grants and contracts, DSMBs, FDA (including IND applications), accreditation bodies (e.g., AAHRPP), and HRPPs. Subcontracts that indicate multi-site design should also be coded with topic code *research study, research design [*8c].

Examples:

- *108-Staff: There's still this other thi- I mean, the other thing is there's no DSMB…*

- *162-Chair: So, so that raises… the question of the DSM- is there a DSMB process for this?*

**29. Genetics Studies:** Use this code for genetic studies and for discussions of genetics issues within a research study.

Examples:

- *140-Chair: Right. It if they use any, do any genetic testing, they're not doing any now, they're just…*
- *151-PR: … Also keeping the blood samples for doing other potential genetic studies um, if the patient gives consent so their, their blood will be used by the company potentially for other genetic studies…*

**30. Discussion of Stem Cells**

Examples:

- *5-Chair: Alright. Ok, why don't we do the* ***11A2 (a special medium for growing stem cells)*** *study, another another little stem cell thing. Let me just give a little background on this one. This is a study that initially came in to us as a a discarded materials thing. So, they wanted to use these fallopian tissues to as supported tissues for embryonic stem cell research, and we kind of went through a variety of institutional sort of look-sees at this thing and decided that it would not be appropriate to do this study in which the person's tissues would be directly involved in embryonic stem cell research without a full consent form and a full IRB review.*

**31. General Agreement:** Use this code when an agreement is being made, but there is no explicit connection to what the person is agreeing to. Do not use this code if the speaker is a Chairperson, instead use *actions proposed or taken by the Chairperson, agreement* [ 23biii]. If coder cannot tell who is agreeing, use topic code, *no topic* [0].

Examples:

- *49-chair: If the risk in a patient population could be defined as de minimis however one describes that, then a feasibility study that has as its major risk fluid overload…*
  *?: Right*
  *49-chair: … which doesn't seem to be a huge risk and the risk associated with a Foley catheter…*
  *36- PR: Right*

**32. Agreement with Previous Statements:** Use this code when a speaker is agreeing with all of the previous statements of another speaker. This code is used when there is a generic statement accepting all of the statements of another speaker prior to the reviewer's own assessment.

Examples:

- *161-2nd: Um, well, I, I agree with what, with what's been said…*