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Rating Scale Guide

A. Basic Coding Technique for the Rater or Observer

1. Review the rating sheet prior to listening to each encounter (reminds you of what you will be "looking for").
2. You should be able to rate items 1 - 4 (Greeting) within the first three minutes of the encounter.
3. Many of the items can be rated as soon as you see the behavior performed. They may not, however, follow the order on the rating sheet.
4. For the items that require the rater to assess multiple examples of that concept (for example "The RA handles tough questions well") we are looking for a "preponderance of evidence". In other words, the RA may not have done it perfectly throughout the entire encounter but if they mostly did it well we would give them credit. For example:
 - a. What if RA handles one tough question well and another one poorly?
 - o Rater should think "big picture". Keep in mind we are looking at a 15 minute encounter. No RA is perfect. On the whole did s/he answer the questions well? If so, rate it "Yes".
 - o What if RA answered 5 tough questions beautifully and then one tough question poorly. The obvious answer is to rate this "Yes". HOWEVER, if the one question that was answered poorly was so serious it might harm the patient or harm the informed consent process, then it should be rated, "No". An example of a "poor" answer that is very serious is as follows:
 - "You shouldn't worry about the risks. It hardly ever happens." This is a terrible answer because the RA is NOT here to tell the PRP what they should or should not worry about.
 - b. If most of the time the RA provided information in small chunks but once or twice went a little long, if you believe that generally the RA provided information in small chunks then it should be rated as a "yes". The same would hold for the following items: "Handling tough questions well" and "Allowing the PRP to speak without interruption", etc.
 - c. Regarding using "nonjudgmental words and phrases" or avoiding the use of "specific judgmental, disrespectful, or unprofessional words" consider the following:
 - o If mostly the RA performed well on these items and had a minor slip up that could still be acceptable.
 - o If the RA had made a major mistake where the PRP is likely to feel belittled, disrespected, etc. then that would not be acceptable even if there were 10 other instances where the RA used "appropriate" wording.

B. Item Specific Questions

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GREETING

1. **States name and function.**
 - a. Points awarded for:
 - o RA states their first AND last name AND their function or role
 - b. Points should NOT be awarded if:
 - o RA does not state all 3 components
2. **Greets the PRP in an appropriate way based on age, gender, familiarity, setting, etc.**
 - a. See "CULTURE" below
3. **Correctly pronounces PRP's name**
 - a. Points awarded if:
 - o RA pronounces the PRP's name correctly (it is okay for RA to ask if they are pronouncing name correctly)
 - b. Points should NOT be awarded if:
 - o RA does not pronounce PRP's name correctly
4. **Describes the purpose of the encounter in the first three minutes**
 - a. Points awarded for:
 - o RA explains they are there to see if the PRP wishes to enroll in a research study AND
 - o RA gives a brief summary of the study. For example,
 - "This is a study to see if we can diagnose a heart attack using ultrasound faster than we can by using blood tests."
 - "This is a study to see whether patients are more effective at reducing their blood pressure if they join a group of other people with hypertension to discuss ways of reducing their blood pressure."
 - "This is a study to see if we can develop better, more specific treatment for people with certain kinds of cancer if we target that treatment based on the patient's genetic makeup."
 - b. Points should NOT be awarded if:
 - o RA does not have both of the components above.

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INFORMED CONSENT CONTENT

- 5. States that "consent is voluntary" at least once during the conversation and included in the wrap-up.**
 - a. Points awarded for:
 - o RA must state that "consent is voluntary" at least twice during the encounter.
 - o It should be very clear to you that the PRP understands that "consent is voluntary"
 - o If voluntary consent has been discussed a number of times AND it is very clear to you that the PRP understands that, then points should be awarded even if it was not reiterated in the wrap up.
 - b. Points should NOT be awarded if:
 - o The RA only states "consent is voluntary" once during the encounter.
 - o You are not sure if the PRP understands that "consent is voluntary"
- 6. States that PRP can withdraw from the project at any time.**
 - a. Points awarded for:
 - o RA stating at least once that the PRP can withdraw from the project at any time.
 - b. Points should NOT be awarded if:
 - o The RA does not state that the PRP can withdraw from the project at any time.
 - o The RA states that the PRP can withdraw from the project at any time but said it in a way that was confusing or ambiguous.
- 7. States that PRP's decision will not affect care in any way**
 - a. Points awarded for:
 - o A clear statement by the RA that the PRP will continue to get good care or the usual care even if they decide not to participate in the study.
 - b. Points should NOT be awarded if:
 - o The RA does not make it clear that if the PRP decides not to participate in the study, their routine care will not change. In other words, there should be no threats or pressure on the PRP to join the study.
- 8. States that PRP does not need to decide immediately**
 - a. Points awarded for:
 - o RA makes it clear that the PRP can take their time to decide.
 - o If the case is such that the PRP needs to make a decision at this visit then the RA should carefully explain the reason for this.
 - o If the case is such that the PRP needs to make a decision at this visit they still do not have to make the decision the second. They should still be given some time to think about it or even the opportunity to discuss it with a support person or a physician.
 - b. Points should NOT be awarded if:
 - o The RA pressures the PRP to consent right now
 - o The RA does NOT say specifically that the PRP does not need to decide immediately

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- 9. Explains in detail "loss of personal information" under "Confidentiality"**
- a. Points awarded for:
 - o a clear discussion about the possibility that the participant's personal information can be lost and this conversation must include:
 - The risk or negative effects that that could cause AND
 - What the researchers do to minimize that possibility AND
 - The RA does NOT inappropriately minimize the possibility that it could happen or minimize the negative effects it could have on a person
 - b. Points should NOT be awarded if:
 - o The RA fails to do each of the above bullets.
- 10. Reviews each section of the informed consent as required by the protocol**
- a. Points awarded for:
 - o All sections must be covered in order to rate this "yes".
 - b. Points should NOT be awarded if:
 - o Any section of the informed consent document is not presented to the patient
- 11. Appropriately discusses risk(s) per study protocol, without minimizing**
- a. Points awarded for:
 - o RA must discuss the risks and must NOT minimize those risks
 - It is okay to say, "That is not likely to happen (or that is a rare event)." PROVIDING it is a true statement.
 - b. Points should NOT be awarded if:
 - o RA minimizes the risks, for example:
 - "You shouldn't worry about that."
 - "That never happens."

ASSESSES UNDERSTANDING

- 12. Encourages questions after relevant sections of the informed consent, as appropriate**
- a. Points awarded for:
 - o RA makes sure the PRP gets to ask questions.
 - o RA MUST pause after asking a question so that the PRP has time to think.
 - o RA MUST ask the question in a way that really invites the PRP to ask. For example:
 - "I've just given you a lot of information, I'm wondering if I've been clear?"
 - "Most people have questions now. I'm wondering if you do?"
 - o It is NOT necessary to ask for questions after every item.
 - By the end of the encounter, we want the RA to verify the PRPs understanding of at least three of the areas below: What the study is all about
 - What their role in the study is
 - What the potential risks might be
 - Consent is voluntary
 - After any part of the consent process that is long, complicated, confusing,

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or potentially risky

- Rate this item “yes” only if the RA verifies understanding of at least three of the areas above

- a. Points should NOT be awarded if the RA asks for questions in a way that makes it unlikely a PRP will ask. For example:
 - o "Do you have any questions?"
 - o "You don't have any questions, do you?"
 - o "Do you understand?"

13. Provides information in understandable chunks

- a. Points awarded for:
 - o RA providing information a little bit at a time so that the PRP has time to think and process the information. The more complicated the information, the smaller should be the chunks.
- b. Points should NOT be awarded if:
 - o The PRP has no time to think about or process the information.
 - o The RA moves from one topic to another without pausing.

14. Addresses PRP's questions AND concerns, without minimizing

- a. Points awarded for:
 - o RA answers PRP's questions AND does so clearly and respectfully.
 - "That is a really good question." The RA then proceeds to answer the question.
 - "I'm glad you're asking questions. It helps me make sure I cover everything that is important to you."
 - o RA does NOT minimize their questions or their concerns
 - The PRP should feel respected
 - o AND the RA addresses the PRP's concerns. Sometimes these concerns are directly stated by the PRP but at other times they are shown by nonverbal communication. For example, if the PRP is clearly worried then the reason for the worry should be elicited and addressed.
- b. Points should NOT be awarded if:
 - o RA does NOT answer PRP's questions clearly and respectfully
 - "Like I already told you..."
 - o It is difficult to follow the RA's explanation
 - o RA does NOT answer concerns
 - "Don't worry about that."

15. Assesses PRP's understanding of the risks of the study using one of the methods outlined in the Rater's guide

- a. Points awarded for:
 - o **Teach back method:** The **Teach-Back Method**, also called the "show-me" **method**. The purpose of this method is to confirm whether or not a patient understands what is being explained to them. The patient is asked to summarize what was just discussed. If the patient understands, they are able to "**teach-**

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back" the information accurately to the RA using their own words. Examples of how an RA might ask this:

- "We just covered a lot of information. I want to make sure that I did a good job explaining everything. Could you please summarize the main points about what we just discussed?"
- "It is common for people to be a little overwhelmed by the amount of material we just went over and I want to make sure that you have all the information you need. Could you please tell me in your own words the important points?"
- "I'm required to make sure that I explained the material well so I need to ask you a series of questions. Is that OK with you?" Then the RA asks specific questions, e.g., "Please tell me what you understand about the risks of this study."

- o In these informed consent protocols there are so many parts that if you just ask someone to summarize everything at the end there is almost no way they can do that. Therefore, one can ask for these summaries after each section of the informed consent process, e.g., after discussing risks, after discussing possible benefits to the participant, etc. Or, the RA can ask the participant a series of questions.

b. Points should NOT be awarded if:

- o The RA says, "Do you understand?"
- o The RA says, "Do you have any questions?"

16. Handles tough questions well (for example, addresses all questions, answers clearly, and ensures PRP feels their questions/concerns were appropriately addressed; it is okay for RA to say they are unsure and will get back to them with an answer).

a. Points awarded for:

- o What if RA handles one tough question well and another one poorly?
 - Rater should think "big picture". Keep in mind that this is an informed consent study. No RA is perfect. On the whole did s/he answer the questions well? If so, rate it "Yes".
 - What if RA answered 5 tough questions beautifully and then one tough question poorly. The obvious answer is to rate this "Yes".

b. Points are NOT awarded if:

- o If the one question that was answered poorly was so serious it might harm the patient or harm the informed consent process, then it should be rated, "No". An example of a "poor" answer that is very serious is as follows:
 - "You shouldn't worry about the risks. It hardly ever happens." This is a terrible answer because the RA is NOT here to tell the PRP what they should or should not worry about.
- o If the RA's answers are confusing or if they are off the mark (not really answering the PRP's question).

SHOWING RESPECT

17. After greeting, ask permission to continue with conversation about the research study

- a. Points awarded for:
 - o "Is this a good time for us to talk?"
 - o "May I tell you about the study?"
- b. Points are NOT awarded if:
 - o RA merely continues talking to the PRP without asking permission

18. Provides two or more elements of "positive speak" strategy (see Raters guide)

- a. Points awarded for:
 - o **Positive speak:** The interviewer demonstrates interest for the patient's personal situation or behavior or provides praise, support, or a pat on the back for the patient. Examples include the following:
 - Any **personal** individualized statements of interest for example, "How's work going?" or "What are you reading?"
 - Statements of individualized interest in the patient that go beyond professional, social conversation.
 - **"Pats on the Back."** If the patient describes an accurate knowledge of diabetic complications and the interviewer says, "You've really learned a lot." or "I'm impressed with what you know." or "You're working very hard to get your weight under control." or "You handle your diet changes very well."
- b. Points are NOT awarded if:
 - o Less than two of the above elements are present

19. Uses PRP's name and appropriate number of times throughout the encounter.

- a. Points awarded for:
 - o Using the person's name to whom you are speaking is a sign of respect. It is not the only way to show respect, however. RA must use the PRP's name at least once.
- b. Points are NOT awarded if:
 - o RA never uses the PRP's name.

20. Elicits PRP's personal perspectives relevant to their participation in the study

- a. Points awarded for:
 - o Asking the PRP why they are concerned about [said reason] or attempts to get at the reasons for the concern
 - o Inviting the PRP to talk about what is important to them. This could include:
 - Barriers to participate
 - Reasons they may want to participate
 - Reasons they may be skeptical about participating
 - o RA might ask, "You seem like you are unsure (or hesitant, or concerned, etc.) about participating. Could you talk to me about that?"
 - o If the PRP brings these issues up spontaneously and the RA acknowledges them the item would still be marked "yes"

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- b. Points are NOT awarded if:
 - o RA never asks about or discusses the PRP's personal perspectives.

21. Appropriately responds to the PRP's personal perspectives relevant to their participation in the study.

- a. Points awarded for:
 - o RA discusses the PRP's personal perspectives that are relevant to their participation in the study. This must go beyond merely asking for them. It could include:
 - Asking more questions relevant to the thread
 - Giving further information relevant to the thread being discussed
 - Clarifying what the PRP means by a certain term or phrase, for example, if the PRP says, "I don't have time for participating in a study", the RA might respond, "Can you tell me more about that? Are there times of the day or times of the week where you could participate in a two hour group session?"
- b. Points are NOT awarded if:
 - o There is no follow-up questions or discussion on any personal perspective that is brought up by the PRP.

COMMUNICATION SKILLS – VERBAL

22. Uses nonjudgmental words and phrases.

- o This is different than Q27 "AVOIDS use of SPECIFIC judgmental, disrespectful, or unprofessional words". These words or phrases (Q27) are words that are egregious. The words or phrases in Q22 are disrespectful but not egregious.
- b. Points awarded for:
 - o "I'm glad you asked. This is a difficult concept."
 - o "Many people find it is hard to get to appointments. Do you think that will be a problem for you?"
 - o "I see where you are coming from."
- c. Points are NOT awarded if:
 - o "Like I already told you..."
 - The reason for this is that it belittles the PRP. It makes it sound like they were not paying attention.
 - o "You need to figure out a way to get to appointments"
 - The reason for this is that it takes away the PRP's autonomy, and is dismissive.
 - o "We have to hurry this along."
 - o "You ask a lot of questions."

23. Allows PRP to speak without interrupting

- a. Points awarded for:
 - o RA does not speak over the PRP
 - o RA pauses at times to allow PRP to speak

24. Speaks clearly and at a pace which is easily understood

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- a. Points awarded for:
 - o RA speaks "clearly". Interpret "clearly" to mean *both* pronunciation as well as the explanation itself. The explanation should be easily understood.
 - o If some jargon creeps in but the RA explains it, that is acceptable.
- b. Points are NOT awarded if:
 - o RA speak so quickly that is difficult to process the information especially if it is a complicated or emotional topic.
 - o The explanation is roundabout, indirect, poorly organized, or otherwise difficult to understand.
 - o Jargon is used limiting the PRP's ability to understand the information.

25. Pauses to allow participant to absorb information or ask questions.

- a. Points awarded for:
 - o RA pauses periodically to allow the PRP to absorb and process the information or to ask questions.
- b. Points should NOT be awarded if:
 - o The PRP has no time to think about or process the information.
 - o The RA moves from one topic to another without pausing.

26. Uses vocabulary and phrasing appropriate for the PRP

- a. Points awarded for:
 - o RA uses language at an educational level that is commensurate with the PRP's.
 - o This does not require the RA to ask the PRP how far they've gotten in school. It requires initially speaking in the "Goldilocks zone", not too high and not too low. The RA then judges the level of language needed based on the language used by the PRP. For example:
 - o The RA might start a conversation with, "I would like to discuss a study with you about seeing whether or not an ultrasound machine, which takes pictures of your heart using sound waves, can help us diagnose a heart attack sooner than blood tests can". If the PRP responds, "I had atherosclerotic heart disease a couple of years ago leading to an MI resulting in a three vessel CABG", the RA could increase their use of medical terminology. Caution still must be maintained. For example, one might ask the PRP, "it sounds like you're very knowledgeable about medicine. Do you have a background in medicine?" Without such a background it could be that the patient has a good medical vocabulary specifically for things that have happened to him already but that doesn't mean he has other medical terminology. This may require a little "dance" between the RA and the PRP. With this in mind, as a rater, use your judgment as to whether the PRP understands the RA.

27. AVOIDS use of **SPECIFIC** judgmental, disrespectful, or unprofessional words

- a. This is different than Q22 (Uses non-judgmental words or phrases)
 - o The words or phrases in Q22 convey judgment or disrespect but not to the degree that Q27 does. Q27 are words that are egregious.
- b. Points awarded for:

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- o Having NO derogatory language or insults.
- c. Points are NOT awarded if RA:
 - o "You people"
 - o Uses derogatory language

COMMUNICATION SKILLS - NONVERBAL

28. Appears nonthreatening

- a. Points awarded if RA:
 - o Sits down to stay at eye level with the PRP
 - o Uses open, warm, friendly body language
 - o Smiles
 - o Uses a calm, warm tone of voice
- b. Points are NOT awarded if RA:
 - o Towers over the patient
 - o Gets too close to the PRP (in his or her space)
 - o Points or uses other "aggressive" gesticulations or body language
 - o Uses words like, "you need to" or "you should"

29. Conveys interest using nonverbal cues appropriate for PRP

- a. Points awarded if:
 - o RA Maintains eye contact
 - o RA Uses "facilitative" gestures and vocalizations in order to encourage the PRP to say more, for example:
 - Nodding head
 - "Uh Huh"
 - Attentive silence
- b. Points are NOT awarded if:
 - o RA looks away from the PRP more than minimally
 - o RA not looking at PRP when they are speaking
 - o RA appears cold, emotionless, appears to just try to get through the checklist

30. AVOIDS distracting behavior

- a. Points are NOT awarded if RA:
 - o Clicking pen
 - o Shaking foot
 - o Playing with an object
 - o Cleaning glasses
 - o Tone and affect

RESPONDING TO EMOTION

31. When appropriate to the informed consent process, RA **elicits** PRP's emotions or feelings

- a. Points awarded for:
 - o **Eliciting Potential feelings or responding to PRP's emotions or clues:** There are times when the RA should be alert to PRP's feelings. One is when the patient's verbal or non-verbal language suggests that emotions are at play. The second is when it would be *expected* that emotions would be at play, e.g., when told that we are going to put a needle in your heart, it would be normal and expected that a PRP might be frightened or worried.
 - The RA could say, e.g.,
 - "Many of the patients get a bit worried about this part of the study. I'm wondering how you are feeling about this?"
 - "Tell me what you're thinking now."
 - "Can you tell me more about what makes you nervous about this?"
- b. Points are NOT awarded if:
 - o The PRP is demonstrating emotion or gives a clue that they are feeling and emotion and it is ignored by the RA. Examples of demonstrating emotion:
 - Named:
 - "There's no way I would do that."
 - "That's scary" or "That sounds horrible"
 - Non-verbal Cues:
 - Sighs
 - Looks away

32. **Addresses** PRP's feelings, emotions, or concerns

- a. Points awarded for:
 - o RA names or validates, the patient's emotional reaction
 - o RA makes it clear that he or she heard or notices the emotion
 - o RA tries to understand where that emotion or concern is coming from
 - o Examples include:
 - "You sound very busy"
 - "It sounds like you're going through a lot right now"
 - "It's hard to concentrate on the study when you're worried about your heart"
- b. Points are NOT awarded if:
 - o RA says, "I understand" or "I understand how you feel".

33. **Meets emotion with emotion.** Does NOT provide information as response to an emotional reaction UNLESS it is needed to alleviate the concern.

- a. Points awarded when:
 - o PRP asks a question that is filled with emotion OR PRP demonstrates a strong emotion and the RA comments on, or otherwise addresses the feelings or emotions.
- b. Points are NOT awarded if:

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- o PRP asks a question that is filled with emotion OR PRP demonstrates a strong emotion and the RA answers with more information. It is unusual for information to satisfy someone with an emotional reaction although it can happen when there's merely a misunderstanding. Therefore, if the PRP appears completely satisfied by the information given then it was appropriate. If the PRP does not calm down, or in fact escalates, then this was not a good response and points should not be awarded.

34. Responds appropriately to feelings or emotions expressed by PRP.

- a. Points awarded when:
 - o "I can see that you are worried about this. How can I help you with this?" OR "Tell me what is most concerning."
- b. Points are NOT awarded if:
 - o If RA ignores the question or concern.

TIMING

35. Finishes the consent within the allocated time frame as set forth by the case

- a. Points awarded when:
 - o The consent process is completed by the time the simulation has been called to an end

GLOBAL RATING SCALES

36. Establish Rapport

- a. It is likely that no single anchor will be a perfect fit. Raters should choose the one that fits the best.

37. Responding to Emotions

- a. It is likely that no single anchor will be a perfect fit. Raters should choose the one that fits the best.

CULTURE

We are getting at “Cultural concordance” or “cultural perspective”, for example:

- Concordance in responses, reactions, and gestures aligned with PRP’s cultural or personal preferences
- Responds appropriately to PRP’s cultural preferences

Cultural perspective: To understand this term in the context of this study some background is helpful. One of the goals of this study is to improve the number of people from under-represented minorities who participate in research projects related to healthcare. This has been challenging because of a number of factors related to people’s perspective.

Everyone interprets information through different lenses which represent their world view. One’s world view is shaped by past experiences. Past experiences are shaped by many factors, some of which are cultural. The way one interprets information has a huge impact on the decisions one makes.

In addition to world view and cultural perspective, one’s individual living circumstances may play a key role in deciding what one chooses to do or what options are even available to the individual.

- i. Now let’s relate this back to our study. Shake hands; or women do not shake hands.
- ii. In some cultures it is not polite (or even dangerous) to make eye contact.
- b. We do not expect our RA’s to know what is expected in every culture. In addition, even if they knew what was typical, in say, Rwanda, one does not know what the particular Rwandan person in front of you actually prefers. They may have lived in the US for 15 years. Etcetera.
- c. POINT:
 - i. We expect the RA to have “**situational awareness**”. We expect them to be observant of the person in front of them. The RA should take their cues from the person in front of them.
 1. If the person does not reach out to shake the RA’s hand then maybe the RA should not initiate this gesture. Etcetera.
 2. If the RA says something and the PRP changes body language, tone of voice, or the way they are communicating, there is a good chance that what you said was not received well if the body language, etc. became closed, or may have made a positive impact if the body language, verbal language, etc., became more open.

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2. “Cultural Perspective”
 - a. There have been a number of healthcare studies in history (some quite recent) where Black Americans were treated unethically and actually harmed. It would be expected that some Black Americans could be very skeptical about agreeing to participate in a research study.
 - b. People living below the poverty line (or near the poverty line) may not have a car. They may need to work and many low wage jobs have no set hours. People can be given their weekly schedule a few days in advance. These people may have a very hard time getting to a clinic, meeting center, or whatever is needed by the study.
 - c. POINT:
 - i. It is important for the RA to understand the patient’s cultural beliefs and their living situation when those are relevant to their participation in the study.
 - ii. The only way to “know” that perspective is either to ask directly, or to listen intently for clues. The latter is very helpful but may not be sufficient.

SUMMARY RE: CULTURAL PERSPECTIVE

We expect our RA’s to:

1. Take their cues from the patient regarding cultural preferences, shaking hands, eye contact, etc. The rater should look for concordance (“Yes”) or discordance (“No”).
2. Be aware of the effects of their own words, body language, etc., on the PRP. If rater sees that the RA changes what they are doing in response to negative body language, tone of voice, etc., mark “Yes”
3. Ask the PRP for their perspective. We do not expect them to ask all of these questions but here is a sample of questions that get at the patient’s perspective:
 - a. “What would you need to hear to make you feel more comfortable?”
 - b. “You seem a little hesitant. Can you help me understand why that is?”
 - c. “As I described the study for you, what thoughts first came to mind?”
 - d. What information would you need to see or receive before making a decision to participate?”
 - e. “Who would you talk to and ask for advice when considering whether or not to participate in this study?”
 - f. “Are there certain details about the study that would be most important to your decision to participate? For your most important concerns, what could we do to address those concerns in a way that would make you feel more comfortable about participating/?”
4. Respond appropriately to issues raised with regards to the patient’s “perspective”.