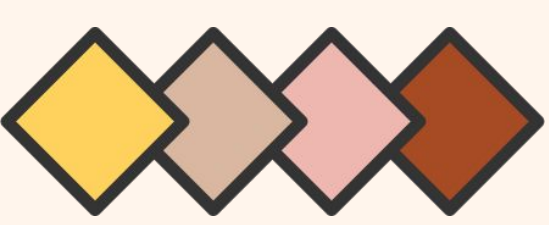


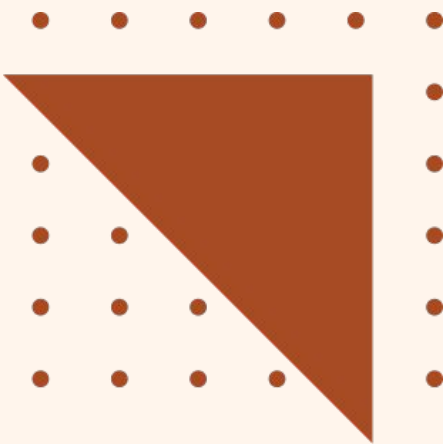


# **Informed Consent Process**



# Agenda

1. REDCap Follow-Up
2. What is the Informed Consent Process?
3. The Informed Consent Quiz
4. Read Through & Develop a Script!



# **What is the Informed Consent Process?**

Informed consent is the process of telling potential research participants about the key parts of a research study and what their participation will involve. This includes explaining their risks, benefits, and rights as a participant to help them decide if they want to take part in the research study.

The individual must be capable of making a voluntary decision about whether to participate in the study

# **Why is this process important?**

Ethical, not just legal, requirement

- Ensure that participants understand the nature of the research activity through all stages of the research study, and that they are voluntarily choosing whether or not to begin or continue participation in the research study
- Protects the rights, safety, and welfare of participants

Can allow for:

- Participants to make choices on what's best for them
- Building trust between the researcher and participant
- Investigators face less risk of legal action

# **Why is informed consent a process?**

- Begins with the first contact and exchange of information but continues throughout the study and even beyond
- Each contact is an opportunity to reiterate information and ensure that the participant continues to be fully informed and understands their participation as voluntary
- The informed consent document is a teaching tool! Covers:
  - Information
  - Comprehension
  - Voluntariness

# **Avoid Undue influence/coercion**

- **Undue Influence-** Use of persuasion, authority figures, or the offer of an excessive or inappropriate reward in order to obtain research participation or compliance.
  - Example - a professor offers to write glowing letters of recommendation for any student that participates
- **Coercion-** when an threat of harm is intentionally presented by one person to another in order to obtain consent
  - Example - research assistant tells participant that they will lose access to the services available at SACHR or SWAN if they don't participate in the study



# **Avoid Undue influence/coercion**

- Subject should feel free to decline participation without fear of repercussion or punishments.
  - When obtaining consent, emphasize that subject can withdraw from study at any time
- They should be reassured that declining participation will not influence the care they would otherwise receive
- Important to provide enough time for consideration
- Avoid leading or overly reassuring statements - just give the facts

# Best Practices

- While obtaining consent, study should be introduced to potential subject and the consent reviewed with them.
- Speak clearly and slowly
- Provide the participant time to read the informed consent document
- Should be given an opportunity to ask questions and have them answered to their satisfaction



# Informed Consent Quiz

*Please answer the following questions to the best of your ability. We will not be grading this quiz – we will use your responses to make sure you know your rights as a participant in this project and understand what the project is about.*

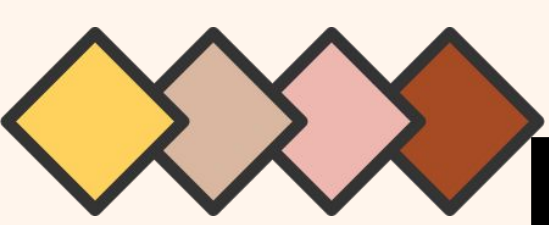
1. Participation in this research study is not my decision. **False**
2. I can decide to leave or walk away from this study at any time without loss of harm reduction services or any other negative consequences. **True**
3. Any information I provide to the study staff can be shared with anyone who asks for it, without my permission. **False**
4. For the first 2 months or so, I will be asked to complete weekly in-person assessments. **True**
5. The follow up includes 3 assessments at 3-, 6-, and 12-months after the main part of the study is completed **True**
6. All study publications will mention me by name. **False**
7. I may contact Dr. Jordan (the study's Principal Investigator), the New York University Langone Health Human Investigations Committee, or other members of the research team if I have any questions about the study or my rights as a participant. **True**

Needs to return correct items and incorrect items so CHR can review.

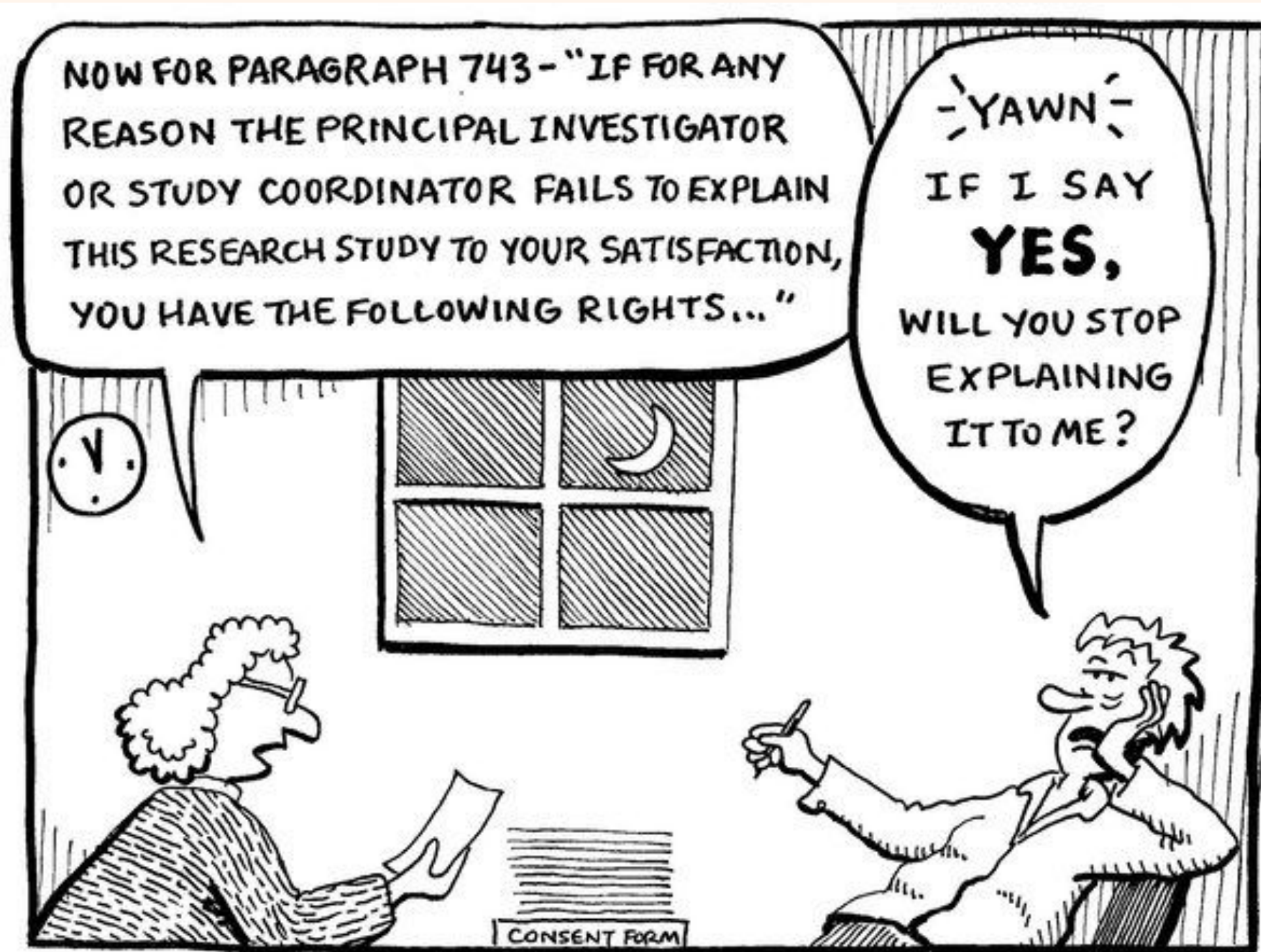
# Documenting

- Informed consent shall be documented by the use of a written consent form approved by the IRB, signed and dated by the subject or the subject's LAR, at the time of consent. A copy shall be given to the person signing the form.





# Developing a Script/Outline Together







Q

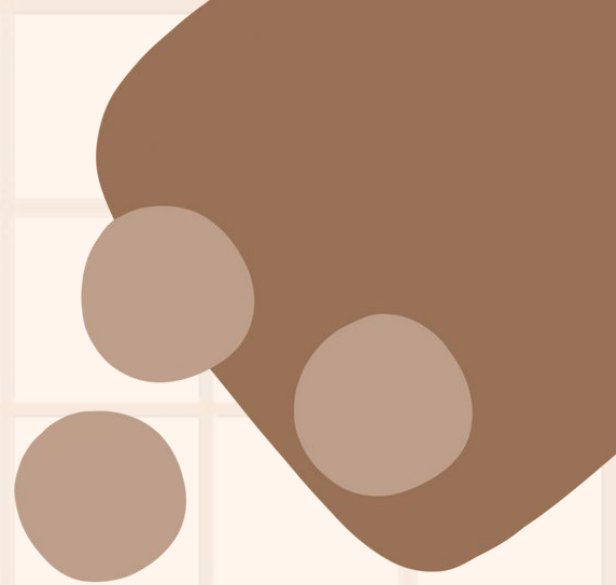
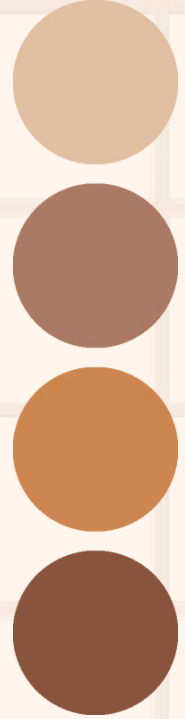


A



**Question  
Time**





THANK YOU  
SO MUCH!

