Did you know… ***therapeutic misconception*** often occurs during the consent process and can rise to the level of ***coercion***?

It happens when participants think the study is designed to provide personalized treatment or that enrolling is the best or only option. Because clinicians, as well as research staff, are seen as authority figures, even subtle comments can sway decisions. To protect voluntariness and prevent undue influence, research staff should ***stick strictly to the facts*** in the IRB-approved consent form, avoid personal opinions, explicitly reinforce that participation is voluntary, and ***focus on helping participants understand the study rather than guiding their choice***. Clear, factual communication ensures participants make informed, unpressured decisions about participating in a research study.

Why this matters:

The informed consent process requires that participants make fully voluntary decisions, free from coercion or undue influence. Both the Belmont Report and 45 CFR 46 make clear that investigators and research staff must avoid statements that could pressure, persuade, or guide a participant toward enrollment.

Because clinicians are often viewed as trusted authority figures, even subtle comments can unintentionally sway a participant's decision. This creates the risk of **therapeutic misconception,** where participants mistakenly believe a study is designed for their personal clinical benefit simply because a clinician presents it.

There is also a concept described as the "white coat effect", where the presence of a researcher in a white coat influences participants' behavior. Participants naturally change their behavior to meet the *perceived* expectations of the authoritative researcher, just because the researcher is wearing a white coat and formal attire.

Best Practices to Prevent Undue Influence:

To protect voluntariness and maintain compliance, keep the following principles in mind during the consent conversation:

- Stick to the facts. Only present information included in the IRB-approved consent form or study materials.
- Avoid personal opinions. Do not say whether you like the study, believe it's important, or think the participant should join.
- Avoid "what would you do?" statements. If asked, respond neutrally "If I were in your position, I would review the form carefully, discuss it with family or trusted people,

an ask questions before deciding". This keeps the focus on the decision-making process rather than the decision outcome.

- Reinforce voluntariness. Make it clear that participation is 100% voluntary and that declining will not affect their care or relationships with providers.
- Remain neutral. Focus on explaining the study; do not recommend or discourage participation.

Example of a Compliant Approach:

> *"My role is to explain the study and answer any questions so that you can decide whether participating feels right for you. Participation is voluntary, and choosing not to take part will not affect your care. I encourage you to review the consent form, take time to think about it, and discuss it with your family or friends if you'd like. Please let me know if you have any questions."*

This approach supports informed, unpressured decision, protects participant autonomy, and ensures compliance with ethical and regulatory standards.