# Informed Consent: Best Practices

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# Most important elements of informed consent process?

# Key aspects

- **Explanation of**
  - Purpose
  - Duration of pt's involvement
  - Procedures involved
  - Whom to contact for questions/concerns
  - Risks/discomforts and how research team intends to protect pt against those risks/discomforts
    - Confidentiality and how we protect it
  - Benefits (if any); and if none, a statement about that
  - ****voluntary****
  - ****pt can change their mind at any time****
  - Compensation

# Key aspects continued

- **Explanation of**
  - Discontinued/terminated participation without consent
    - E.g., safety reasons; inappropriateness
  - Additional costs to pt e.g., clincard
    - Not using the card or having funds for extended period of time
    - ATM withdrawals
    - Requesting paper statement
    - Requesting a replacement card through Greenphire's Customer Service
- You **must** understand every section of the consent form and why it is in there
- Before consenting participants, you **must** complete mock consents with other staff (or family/friends)
- The goal is the pt is making this decision **free of coercion or undue influence**
- IC is an **ongoing** process

# Do's

- DO view consent form as informational and instructional document
  - It should be a **conversation** to the extent possible
  - Staff member pausing along the way to ask if pt has any questions/concerns
- DO review all information on the form
- DO give them opportunity/choice to review form on their own
- DO ensure minor understands it is their decision even if parent/guardian consents
- BE brief/concise yet thorough

# Dont's

- DON'T make statements that suggest a pt is waiving their rights in any way
- DON'T rush through the process
- DON'T be in a public place
- DON'T assume pt's understanding
  - **DO** check for their understanding along the way (e.g., "can you explain back to me what you're being asked to do today?")
- DON'T be coercive

# Consent templates/e-consents

- Penn provides consent templates for different types of research (e.g., Biomedical, Behavioral, etc)
- Reach out to Nina Laney with any IRB questions related to consent
- For creating new e-consent projects in REDCap // modifying existing projects, see here: https://github.com/upenn/BIT/wiki/Electronic-Consents
- For e-consent administration guidelines, see Virtual Research Reference Guide (section on e-consenting)


ANY
QUESTIONS?