Informed Consent

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Adapted from “The Consent Process: It’s More Than Just A Form” by Cyndi Long, MS, RD, CCRC
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Definition

"Informed consent is a vital part of the research process, and as such entails more than obtaining a signature on a form. Investigators must educate potential subjects to ensure that they can reach a truly informed decision about whether or not to participate in the research. Their informed consent must be given freely, without coercion, and must be based on a clear understanding of what participation involves."*

The *documentation* of informed consent (*i.e.*, signing of the consent form) is also a vital part of the research process.

*Partners Healthcare: Founded by Brigham & Women's Hospital & Massachusetts General Hospital

Why?

- Legal and Ethical Principles
  - Nuremburg Code (Nuremburg Code, 1949)
    - Individuals must voluntarily consent to participation.
  - Declaration of Helsinki (Declaration of Helsinki, 1964)
    - The well-being of the individual is most important
  - Belmont Report (The Belmont Report, February 1976)
    - Individuals should be knowledgeable about what the research entails

Who?

- Who is consenting?
  - Consent needs to be obtained from participating therapists AND the families of the students participating
- Who is obtaining consent?
  - SSCs will obtain consent from the therapists
  - Therapists will obtain consent and HIPAA forms from families of students

What?

8 Required Elements of Informed Consent:

1. **Research** – statement that study involves research, its purpose, duration, procedures, & identification of experimental procedures.
2. **Risks** - or discomforts, that are reasonably foreseeable.
3. **Benefits** – to subject or others, that are reasonably expected.
4. **Alternative** - procedures or treatments available, if any.
5. **Confidentiality** - of records identifying subject, though may be inspected by authorized entities (*i.e.*, FDA, IRB, UCD/UCH, Sponsor).
6. **Research-Related Injury** – available treatment & compensation (if study is greater than minimal risk).
7. **Contact** – person for questions regarding the study, subject's rights, or research-related injury.
8. **Voluntary** – no penalty or loss of benefits for choosing not to participate & may discontinue at any time.

FDA 21 CFR 50.25 & 45 CFR 46.116

When?

- Before any data collection begins!
- Use the IRB approved form
- Be available to discuss in person or by phone

How?

- Verbally go over the consent with each individual.
  - Invite questions and be open to discussion
  - Allow extra time for the individual if desired
- Sign and date form the same day as the participants

I agree to participate in this study:

PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative*)	Printed Name	Date
SIGNATURE OF PERSON OBTAINING CONSENT	Printed Name	Date

- Provide a complete copy to the family and keep a complete copy for our record.

How-HIPAA?

- HIPAA forms are not required for the therapist participants
- Verbally go over the HIPAA with each family.
  - Invite questions and be open to discussion
  - Allow extra time for the individual if desired
- Have the family print the students name and sign and date form.

Patient/Participant Name (Print): _____

_____ _____

Signature of Patient-Participant
or Parent if Participant is a minor

Date

- Provide a complete copy to the family and keep a complete copy for our record.

Summary

- Consent is an ethical obligation governed by federal regulation, which requires the use of current IRB approved consent forms.
- Consent must be informed and voluntary.
- Consent must be completed prior to any study-related activity.
- Documentation of the consent process (by signing the consent form) is required.

For Additional Support

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