

# Obtaining Consent from Research Participants

One of our most **fundamental ethical obligations** as researchers is to ensure that we treat prospective participants as individuals worthy of basic dignity and respect – not merely as a means to accomplish our research objectives.

US Federal Code 45 CFR 46, or “The Common Rule”, provides some guidelines on the information researchers should provide prospective participants to ensure that they are given the opportunity to make an informed decisions for themselves whether to participate in research. This document simplifies the federal code to help researchers operate ethically and within the requirements of federal code.

## Informed Consent Documents **MUST** include:

- A clear affiliation with UNI (i.e. university letterhead)
- A concise KEY INFORMATION section near the top of the document
  - Risk level and associated risks if any
  - The basic procedures
  - A brief description of the nature of the research - what you hope to learn and why it's important
- **NO** exculpatory language. This includes anything that could be construed as waiving the participant's rights or releasing the research team from liability for negligence.
- A statement that participation is voluntary and will have no impact on grades, services, standing, etc. whether the person decides to participate or not.
- Whom to contact for information or questions about the research. (The research team)
- Whom to contact for information or questions about research subjects' rights or compensation for injury resulting from the research. (The IRB administrator)
- Expected duration of the participant's engagement in the research (*may be covered in the key information section*).
- Purpose of the research (*may be covered in the key information section*).
- Description of the procedures to be followed (*may be covered in the key information section*).

Informed Consent Documents MIGHT include the following elements as appropriate:

- Any clear benefits to the subject or others that might be expected from the research.
- For research that collects personally identifiable information (PII):
  - Measures taken to maintain the confidentiality of PII.
  - A statement that PII could be removed and the deidentified data shared with other researchers in the future **OR** that data will never be used outside of this specific research project.

### Other Requirements:

- The participant must be given sufficient opportunity to consider, ask questions, or discuss the research with the research team before consenting to participate.
- The consent process must minimize the possibility of real or perceived coercion.
- Information must be provided in language that is understandable to the person giving consent.
  - Translated consent documents as necessary
  - 8<sup>th</sup> grade reading level

\*We recommend that researchers review guidance at [ConsentTools.org](https://www.consenttools.org)

\*\*For research that involves medical devices, procedures or clinical trials, consult 45 CFR 46.116 for additional requirements.