THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

What is the "Key Information" Section in the Informed Consent Form?

Under the 2018 Common Rule/Revised Common Rule (effective January 21, 2019), informed consent must include discussion with prospective participants and an initial presentation of "key information" for **minimal risk studies undergoing expedited review** and **greater than minimal risk studies**.

What constitutes "key information" varies due to the specific nature of the study. The key information that a prospective participant needs in order to decide whether to enroll in a biomedical study will be different from the key information a prospective participant needs in order to decide whether to enroll in a social/behavioral study.

Consent templates with the key information section can be found here: https://humanresearch.gwu.edu/research-tools

*The "key information" is designed to facilitate prospective participants' or a legally authorized representative's understanding of the research and the **reasons why one might wish to participate or not participate in the research study**.*

Elements of the Key Information Section

There are **five required elements**, per the 2018 Common Rule:

- That the prospective participant's consent is being sought for **research** and that participation is **voluntary**
- The **purpose(s)** of the research, the expected duration of participation, the research procedures to be followed, and any other important information about the research
- The reasonably foreseeable **risks** or discomforts to the prospective subject
- The **benefits** to the prospective participant or others that may reasonably be expected
- Appropriate **alternatives** to the research, if any

Note: Key information provided to participants is not limited to these five elements. Researchers may include other types of information that they deem necessary and appropriate to include in the key information.

Changes to the Elements of Informed Consent

- If the research involves the collection of identifiable private information or identifiable biospecimens, a statement on whether the identifiers might be removed from the data/biospecimens and information that data/biospecimens that are not identifiable could be used for future research or distributed to other researchers

- When applicable:
  - A statement that biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
  - A statement about whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so under what conditions
  - For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)