

Wittenberg University

Research Ethics and Compliance

Informed Consent Template

All human subjects' research at Wittenberg University must include Informed Consent documentation. Informed Consent shows respect for persons and ensures that subject participation is voluntary. Wittenberg's IRB review will look for the following elements in Informed Consent documentation.

Informed Consent Checklist - Basic and Additional Elements

- 1) A statement that the study involves research
- 2) An explanation of the purposes of the research
- 3) The expected duration of the subject's participation
- 4) A description of the procedures to be followed
- 5) Identification of any procedures which are experimental
- 6) A description of any reasonably foreseeable risks or discomforts to the subject
- 7) A description of any benefits to the subject or to others which may reasonably be expected from the research
- 8) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- 9) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- 10) For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- 11) **Research, Rights or Injury:** An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- 12) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
- 13) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility
 - b) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies

- 14) Add this statement to the bottom of the informed consent: For questions regarding your rights as a participant in this research or IRB approval, contact Dr. Darby Hiller, Associate Provost for Academic Affairs and Institutional Research, IRB Chair, at 937-591-1024, or by email at hillerd@wittenberg.edu.

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