INFORMED CONSENT INSTRUCTIONS

Once you have carefully defined your research question, created a valid design, and developed your protocols for a research project, it is time to plan for the ***informed consent*** for those invited to participate. Planning involves deciding:

- What information is important to provide potential participants, both in writing and in discussions
- Who will present the information
- When, or at what point in the interactions with participants, to provide the information
- How to assess the participant's understanding
- Who will obtain the participant's signature or agreement

This plan must be reviewed and approved by Bentley's Institutional Review Board (IRB) before approaching potential participants.

Informed consent, as a legal, regulatory, and ethical concept, has become widely accepted as an integral part of research. Current requirements for informed consent owe much to the legal system, but the underlying values are deeply embedded in American culture and the American character. Fundamentally, informed consent is based on **respect for the individual**, and, in particular, the **individual's autonomy or capacity and right to define his or her own goals and make choices designed to achieve those goals in life.** This right is well-established in American jurisprudence and medical practice, and applies to all types of medical interventions and clinical research.

Informed consent in research means more than simply obtaining the signature of the potential research participant. It is a process that involves (1) conveying accurate and relevant information about the study and its purpose; (2) disclosing known risks, benefits, alternatives, and procedures; (3) answering questions; and (4) enabling the potential participant to make an informed decision about whether to participate.

General requirements for informed consent in federally funded research are spelled out in the *Code of Federal Regulations*, 45CFR.46.116.

Elements of Consent:

In order for consent to be valid, it should be based on the following critical elements:

- The participant must be **COMPETENT** to begin the informed consent process. If the participant is not competent because of age, illness, incapacity, or any other reason, special provisions apply, or the participant may not be included in the research.

- The research team must **DISCLOSE** all relevant information to the potential participant. The information must be sufficient to allow the potential participant to decide whether to participate. It is generally accepted that the potential participant must be given the following information: **the purpose of the study; nature of the procedure; how the data will be used; how confidentiality will be maintained; and risks, benefits, and uncertainties associated with the research**.

- The participant must **COMPREHEND** the information. The research team must evaluate the potential participant's ability to understand the proposed intervention in the study.

- The participant must **AGREE** to the proposed intervention in the research study.

- The participant's agreement must be **VOLUNTARY** and free from coercion.

Finally, participants must be informed that even after they have made a voluntary agreement to participate in the study, they may **WITHDRAW** such agreement at any time without penalty.

For questions, please contact:

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