Dordt University Informed Consent Checklist

1) A statement that the project is research

_____ Opening statement should state that it is a research study

2) A summary of research include

_____ Purpose

_____ Duration of participants' participation

_____ Description of procedures

_____ Identification of any procedures that are experimental [45 CFR 46.116(b)(1)]

3) Reasonable, foreseeable risks or discomforts AND Reasonable, expected benefits

_____ Description of any reasonably foreseeable risks or discomforts to the subject [45 CFR 46.116(b)(2)]

_____ 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 [45 CFR 46.116(b)(6)]

_____ Description of any benefits to the subject or to others that may reasonably be expected from the research [45 CFR 46.116(b)(3)]

_____ Description of any incentives or compensation provided to participant, such as extra credit that may be extended by course professor if applicable, and an explanation of the extent that incenitves or compensation are dependent on completion of study

_____ 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 [45 CFR 46.116(b)(8)]

4) Confidentiality and Possible Continued use of information

_____ Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained [45 CFR 46.116(b)(5)]

_____ Statement that the subject's information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies -OR - Statement that identifiers might be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or their authorized representative, if this might be a possibility [45 CFR 46.116(b)(9)(i)and (ii)]

5) Contact information

_____ For researchers

_____ For supervisors (if student research)

_____ 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 [45 CFR 46.116(b)(7)]

6) Signature OR Waiver of documentation request*

_____ End with a statement of agreement

_____ Space for participant & researcher signatures **OR**

_____ Waiver of documentation of informed consent

The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality. For example, for research on sensitive topics, such as domestic violence or illegal activities; **OR**

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online; **OR**

Where the participants are members of a cultural group in which signing forms is not a normal/acceptable practice.

*Even in situations where the IRB may waive the documentation (signature) requirement, investigators are expected to present participants with the required key elements of informed consent and with a copy of the written consent document.

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7) Additional Possible Elements

_____ Statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable [45 CFR 46.116(c)(1)]

_____ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent [45 CFR 46.116(c)(2)]

_____ Any additional costs to the subject that may result from participation in the research [45 CFR 46.116(c)(3)]

_____ Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject [45 CFR 46.116(c)(4)]

_____ Approximate number of subjects involved in the study [45 CFR 46.116(c)(6)]