Lancaster General/Penn Medicine

Template and Instructions for Verbal or Implied Consent in Non-Exempt and Exempt Research

This form is a template for construction of verbal or implied consent in non-exempt and exempt research studies.

A summary explanation for verbal or implied consent may be appropriate when:

- The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research. (For example, simple surveys about non-sensitive issues.)
- Research, which is not FDA-regulated, in which the consent document would be the only record linking the individual to the research and the principal risk would be potential harm resulting from a breach of confidentiality. (Each individual will be asked if he/she wants documentation linking to the research and his/her wishes will govern.)

Instructions:

- Instructions are provided below in italics, with example wording.
- This model is flexible based on the type of research (include applicable sections where appropriate).
- Use language and simple sentences understandable to the average 8th-grade lay person.
- Delete the instructions before printing.
- There is an outline for non-exempt research (section A) and one for exempt research (section B).

A. Consent Outline for Non-Exempt Research: Reviewed and determined to be non-exempt from IRB requirements – must be IRB approved and reviewed annually.

Title of Project: *{Complete title of the project as it appears on the protocol and protocol summary}*

Protocol Number and Protocol Date:

Principal Investigator: *{only one person may be named as principal investigator}*

Other Investigators:

You are being invited to volunteer to participate in a research study. Research studies include only people who voluntarily choose to take part. This summary explains information about this research. You are urged to ask questions about anything that is unclear to you.

- *Briefly summarize the purpose. (i.e.,* The purpose of this research is …)

- *Identification of any procedures that are experimental*
- *List any appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.*
- *Briefly describe the procedures in lay terms. What will the research involve?*
- *Use lay terms to explain the risks of participating in the research.*
- *Explain the potential benefits to participants, if any, or to society. (i.e.,* The possible benefit to you from participating… **OR** You will not benefit from taking part in this research study.; The results of this research may guide the future treatment of… **OR** [Medical] science may gain further understanding of ….)
- *Explain the expected duration of the participant's participation and the time commitment (i.e., the time needed to complete questionnaires, etc.)*
- *Explain the extent, if any, to which confidentiality of records identifying the participant will be maintained. (For FDA-regulated research, a statement that noted that the possibility that the FDA might inspect the records.)*
- *Clarify the participant's right to have questions answered and indicate who may be contacted in case of further questions about the research or the participant's rights or privacy issues. (Example wording provided below.)*
- *Address the issues of payment and costs associated with participation, if applicable.*
- *Clarify the funding status of the research and disclose any sources, if applicable.*
- *Disclose any consultative or financial relationships the investigators may have related to the research, if applicable. (See example wording in the consent form template on the IRB web site.)*
- *Include the following wording regarding voluntariness and the participant's decision.*

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have been harmed from participating in this research, you should contact *[Principal Investigator]* at 717-544-XXXX.

The Human Research Protection Program (HRPP) provides oversight of all research activities involving human subjects at Lancaster General Health. If you have any questions about your rights as a research participant, or if you have complaints or concerns, you may send an e-mail to the HRPP (SM-HRPP@lghealth.org). You also may call the Chair of the Institutional Review Board at Lancaster General Hospital, at 717-544-5091.

Your participation in this study is voluntary. This means it is your choice whether or not to take part. You may refuse to take part in this study, or you may withdraw from this study at any time. You will not lose benefits you would otherwise receive or suffer any penalty if you do so.

Tell the researcher your decision regarding whether or not to participate in the research. *[For verbal consent]* **OR** Your completion of the questionnaire implies your voluntary consent to participate in the research. [*For implied consent*]

B. Consent Outline for Exempt Research: Reviewed and determined to be exempt from IRB requirements.

Title of Project: *{Complete title of the project as it appears on the protocol and abstract}*

Principal Investigator: *{only one person may be named as principal investigator}*

Other Investigators:

You are being invited to volunteer to participate in a research study. Research studies include only people who voluntarily choose to take part. This summary explains information about this research. You are urged to ask questions about anything that is unclear to you.

- *Briefly summarize the purpose. (i.e.,* The purpose of this research is …)
- *Briefly describe the procedures in lay terms. What will the research involve?*
- *Use lay terms to explain the risks of participating in the research.*
- *Explain the potential benefits*
- *Explain the expected duration of the participant's participation and the time commitment (i.e., the time needed to complete questionnaires, etc.)*
- Explain the extent, if any, to which confidentiality of records identifying the participant will be maintained.
- *Address the issues of payment and costs associated with participation, if applicable.*
- *Clarify the funding status of the research and disclose any sources, if applicable.*
- *Disclose any consultative or financial relationships the investigators may have related to the research, if applicable. (See example wording in the consent form template on the IRB web site.)*
- *Include the following wording regarding voluntariness and the participant's decision.*

You must be 18 years of age or older to take part in this research study.

If you have questions, complaints or concerns, you should contact *[Principal Investigator]* at 717-544-XXXX.

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Your participation in this study is voluntary. This means it is your choice whether or not to take part. You may refuse to take part in this study, or you may withdraw from this study at any time. You will not lose benefits you would otherwise receive or suffer any penalty if you do so.

Tell the researcher your decision regarding whether or not to participate in the research. *[For verbal consent]* **OR** Your completion of the questionnaire implies your voluntary consent to participate in the research. [*For implied consent*]