**PURPOSE and SCOPE**

The purpose of this worksheet is to provide support for individuals in determining whether Human Research may be approved by the IRB. This worksheet is to be used. It does not need to be completed or retained. (“LAR” = legally authorized representative)

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| **1 Criteria for approval of research** (applies to initial, continuing, modifications).Check if **“Yes”** or **“N/A”**. All must be checked. | | |
|  | Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk. | |
|  | Risks to participants are minimized by using procedures already being performed on the participants for diagnostic or treatment purposes (“N/A”if no such procedures). | |
|  | Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may be expected to result.  (The IRB should consider only those risks and benefits that may result from the research [as distinguished from risks and benefits of therapies participants would receive even if not participating in the research]. The IRB should not consider possible long-range effects of applying knowledge gained in the research [e.g., the possible effects of the research on public policy] among those research risks that fall within the purview of its responsibility.) | |
|  | Selection of participants is equitable taking into account the purpose of the research, the setting in which the research will be conducted, the special problems of research involving vulnerable populations, the selection criteria, and the recruitment procedures. | |
|  | If greater than minimal risk, the research plan makes adequate provisions to monitor data collection to ensure the safety of participants [(see IRB Guidance: Assessing Risk Level Using Magnitude of Harm)](https://research.cc.lehigh.edu/sites/research.cc.lehigh.edu/files/documents/ORSP/LU%20IRB%20Guidance%20Assessing%20Risk_0.pdf). | |
|  | There are adequate provisions to protect the privacy of participants. | |
|  | There are adequate provisions to protect the confidentiality of participants. | |
|  | When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, there are additional safeguards included in the study to protect the rights and welfare of these participants. | |
|  | (For research involving cognitively impaired participants) Research bears a direct relationship to the cognitively impaired participant’s condition or circumstance | |
|  | The additional DHHS and FDA regulatory criteria applicable to research with the following vulnerable populations has been applied: pregnant women (DHHS subpart B), prisoners (DHHS subpart C), children (DHHS and FDA subpart D), neonates of uncertain viability (DHHS subpart B), and non-viable neonates (DHHS subpart B). | |
| **2 Additional consideration** (Check if **“Yes”** or **“N/A”**. Check all that apply.): | | |
|  | Does the research involve no more than minimal risk to participants? [(see IRB Guidance: Assessing Risk Level Using Magnitude of Harm)](https://research.cc.lehigh.edu/sites/research.cc.lehigh.edu/files/documents/ORSP/LU%20IRB%20Guidance%20Assessing%20Risk_0.pdf) | |
|  | Based on risk, is continuing review on an annual basis necessary? Should review take place more often than annually?  If so, specify period: | |
|  | Is verification needed from sources other than the investigator that no material changes have occurred since prior IRB review? (Requires implementation only when the veracity of the information provided is questioned. “N/A” if initial review.) | |
|  | Does information need to be provided to participants because it may affect their willingness to participate? (“N/A” if initial review). | |
|  | Do advertisements conform to the criteria outlined in [IRB Worksheet: Advertisements](https://research.cc.lehigh.edu/irb-forms-and-worksheets)? (“N/A” if none). | |
|  | Do payments to participants conform to the criteria outlined in [IRB Worksheet: Payments to Research Participants](https://research.cc.lehigh.edu/irb-forms-and-worksheets) (“N/A” if none). | |
| **3 Informed consent process** (Check if **“Yes”**. One must be checked.): | | |
|  | Informed consent will be sought from each prospective participant or the participant’s LAR, in accordance with, and to the extent required by §46.116. The process for obtaining informed consent incorporates all of the following:   1. The researcher will obtain the legally effective informed consent of the participant or the participant’s LAR before involving the participant in research. 2. Consent will be sought only under circumstances that provide the prospective participant or their LAR with sufficient opportunity to discuss and consider whether or not to participate. 3. Consent will be sought only under circumstances that minimize the possibility of coercion or undue influence. 4. The information that is given to the participant or LAR shall be in language understandable to the participant or their LAR. 5. The prospective participant or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. 6. The informed consent begins with a concise and focused presentation of the key information that is most likely to assist the participant or their LAR in understanding the reasons why one might or might not want to participate in the research and this part of the consent is organized and presented in a way that facilitates comprehension. 7. The informed consent presents information in sufficient detail relating to the research, and is organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant’s or LAR’s understanding of the reasons why one might or might not want to participate. 8. The informed consent does not include any exculpatory language through which the participant or their LAR is made to waive or appear to waive any of the participant’s legal rights. 9. The informed consent does not release or appear to release the researcher, the sponsor, the institution, or its agents from liability for negligence. 10. The informed consent will disclose the elements in Section 5 below. | |
|  | The informed consent process is waived or altered under one of the following sets of conditions: | |
|  | The most common set of conditions for a waiver or alteration:   1. The research involves no more than minimal risk to the participants. 2. The waiver or alteration will not adversely affect the rights and welfare of the participants. 3. The research cannot practicably be carried out without the waiver or alteration. 4. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. 5. Whenever appropriate, the participants will be provided with additional pertinent information after participating. 6. The research is not FDA-regulated. |
|  | The investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative (either of the following must be true):   1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative. 2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. |
|  | Less common set of conditions for a waiver or alteration (both of the following must be true):   1. The research or demonstration project is to be conducted by or participant to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs. 2. The research cannot practicably be carried out without the waiver or alteration. |
|  | The research is permanently closed to enrollment. | |
| **4 The following information will be provided during the informed consent process and in the documentation of informed consent, unless waived or altered** (check if **“Yes”**. One must be checked.): | | |
|  | The IRB granted a waiver or alteration of the requirements of informed consent, per section 3 above. | |
|  | 1. Required (\**can be omitted if there are none)*: 2. A statement that the study involves research. 3. An explanation of the purpose(s) of the research. 4. The expected duration of the subject’s participation. 5. A description of the procedures involved. 6. \*Identification of any procedures that are experimental. 7. \*A description of any reasonably foreseeable risks or discomforts to the participant. 8. \*A description of any benefits to the participant or to others which may reasonably be expected from the research. 9. \*A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. 10. \*A statement describing the extent, if any, to which confidentiality of records identifying the participants will be maintained. 11. An explanation of whom to contact for answers to pertinent questions about the research. 12. An explanation of whom to contact for answers to pertinent questions about the research participant’s rights. 13. If applicable, an explanation of whom to contact in the event of a research-related injury to the participant. 14. Contact information for the research team for questions, concerns, or complaints. 15. Contact information for someone independent of the research team for problems, concerns, questions, information, or input. 16. A statement that participation is voluntary. 17. A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. 18. A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. 19. A statement that identifiers might be removed from 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 studies without additional informed consent OR 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. 20. For FDA-related research only: 21. A statement that notes the possibility that the FDA may inspect records. 22. For research involving greater than minimal risk: 23. An explanation as to whether any compensation is available if injury occurs. 24. If compensation is available, what it consists of, or where further information may be obtained. 25. An explanation as to whether nay medical treatments are available if injury occurs. 26. If medical treatments are available if injury occurs, what it consists of, or where further information may be obtained. 27. Required for clinical trials: 28. The approval of the IRB. 29. The probability for random assignment into each treatment. 30. The participant’s responsibilities. 31. When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant. 32. The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the participant. 33. When there is no intended clinical benefit to the participant, a statement to this effect. 34. The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the participant’s original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the participant, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the participant or their LAR is authorizing such access. 35. Additional information, to be provided to each participant, when appropriate: 36. A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable. 37. A statement that if the participant is or may become pregnant the particular treatment or procedure may involve risks to the embryo or fetus that are currently unforeseeable. 38. Anticipated circumstances under which the subject’s participation may be terminated by the researcher without regard to the participant’s consent. 39. Any additional costs to the participant that may result from participation in the research. 40. The consequences of a participant’s decision to withdraw from the research. 41. Procedures for orderly termination of participation by the subject. 42. A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant. 43. The approximate number of participants involved in the research. 44. The amount and schedule of all payments to the participants. 45. A statement that the subject’s 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. 46. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions 47. For research involving biospecimens, whether the research will (if know) 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). | |
| **5 Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117** (check if **“Yes”**. One must be checked.): | | |
|  | Long form consent documentation (Check if **“Yes”** or **“N/A”**. All must be checked): | |
|  | The written consent document is accurate, complete, and consistent with the protocol. |
|  | The written consent document embodies the elements in Section 4 above. |
|  | The researchers will provide the participant or their LAR with adequate time to read the document before it is signed. |
|  | Both the participant/the participant’s LAR and the person obtaining consent will sign (and date for FDA-regulated research) the consent document. |
|  | A copy of the consent document will be provided to the person signing the document. |
|  | If there is a LAR or parent signature line, the IRB has approved the inclusion of adults unable to consent or children. (“N/A” if no signature line). |
|  | When a participant or LAR is unable to read: an impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document any other information provided was accurately explained to, and apparently understood by, the participant or LAR, and that consent was freely given (“N/A” if all participants are able to read). |
|  | Short form consent documentation (Check if **“Yes”** or **“N/A”**. All must be checked): | |
|  | The consent document and summary are accurate and complete. |
|  | The consent document states that the elements of disclosure required by regulations had been presented orally to the participant or LAR. |
|  | A written summary embodies the basic and appropriate additional elements of disclosure. |
|  | There will be a witness to the oral presentation. |
|  | For participants who do not speak English, the witness is conversant in both English and the language of the participant. |
|  | The participant or the LAR with sign (and date for FDA-regulated research) the consent document. |
|  | The witness will sign both the short form and copy of the summary. |
|  | The person actually obtaining consent will sign a copy of the summary. |
|  | A copy of the short form will be given to the participant or the representative. |
|  | A copy of the summary will be given to the participant or the representative. |
|  | If there is a LAR or parent signature line, the IRB has approved the inclusion of adults unable to consent or children. (“N/A” if no signature line). |
|  | Proxy consent obtained from cognitively-impaired subject’s LAR or guardian (Check if **“Yes”** or **“N/A”**. All must be checked): | |
|  | The written consent document is accurate, complete, and consistent with the protocol. |
|  | The written consent document embodies the elements in Section 4 above. |
|  | The researchers will provide the LAR or guardian with adequate time to read the document before it is signed. |
|  | A “Verification of Explanation” statement is present and signed and dated by the investigator |
|  | Both the participant’s LAR/guardian and the person obtaining consent will sign (and date for FDA-regulated research) the consent document. |
|  | A copy of the consent document will be provided to the person signing the document. |
|  | If there is a LAR signature line, the IRB has approved the inclusion of adults unable to consent. (“N/A” if no signature line). |
|  | The requirement to document the consent process is waived under the following set of conditions:   1. The research presents no more than minimal risk of harm to participants. 2. The research involves no procedures for which written consent is normally required outside of the research context. 3. The oral or written information provided to the participants includes all required and appropriate elements of consent disclosure. 4. The IRB has determined whether the participant should be provided with written information. | |
|  | The requirement to document the consent process is waived under the following set of conditions:   1. The only record linking the participant and the research will be the consent document. 2. The principal risk will be the potential harm resulting from a breach of confidentiality. 3. Each participant will be asked whether the participant wants documentation linking the participant and the research, and the participant’s wishes will govern. 4. The research is not FDA-regulated. 5. The oral or written information provided to participants includes all required and appropriate additional elements of consent disclosure. 6. The IRB has determined whether the participants should be provided with written information. | |
|  | The requirement to document the consent process is waived under the following set of conditions:   1. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm. 2. The research presents no more than minimal risk of harm to subjects. 3. There is an appropriate alternative mechanism for documenting that informed consent was obtained. 4. The IRB has determined whether the participants should be provided with written information. | |
|  | The research is permanently closed to enrollment. | |
| **6 Limited IRB Review as required for Exempt Determination under §46.104(d)(2)(iii) and (d)(3)(i)(c).** (check if **“Yes”**. Both must be checked): | | |
|  | There are adequate provisions to protect the privacy of participants. | |
|  | There are adequate provisions to protect the confidentiality of research data. | |

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| Comments: |