IRB Continuation Review
Primary Reviewer Checklist

Primary Reviewer: _____ IRB #: _____ PI: _____

Title of Project: _____

Review Type: ◯ **Expedited** ◯ **Full** **Level of risk as currently approved**: ◯ **1** ◯ **2** ◯ **3** ◯ **4**

REQUIRED DETERMINATIONS

Please check the applicable boxes:

◯ **Yes** ◯ **No**	1. The research meets the criteria for IRB approval (refer to Criteria for IRB Approval checklist if necessary).
◯ **Yes** ◯ **No**	2. **The risk/benefit ratio has changed.** If "Yes" to the risk/benefit ratio changing, select the category that describes what the risk/benefit ratio has changed to and describe in the space below why it has changed: ☐ **Category 1** Not greater than minimal risk; ☐ Expedited Category 8: The IRB agreed that this research, previously reviewed by the convened IRB, meets the Expedited criteria set forth in 45 CFR 46.110(a)(8); therefore an Expedited review was conducted. ☐ Expedited Category 9: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented **at a convened meeting** that the research involves no greater than minimal risk and no additional risks have been identified. ☐ **Category 2** Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects; ☐ **Category 3** Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition; ☐ **Category 4** Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects. ========== **Why the risk/benefit ratio has changed:**
◯ **Yes** ◯ **No**	3. Significant new findings (*e.g., from scientific literature; a procedural change; PI disclosure of financial interest; privacy/confidentiality issues, etc…*) that might relate to the subject's willingness to continue participation need to be relayed to the subject. ***If "yes"*, describe** what should be relayed to the subjects and how the subjects should be informed (e.g., revise consent/assent document & re-consent subjects; send letter to subjects):
◯ **Yes** ◯ **No**	◯ **N/A** 4. The consent/assent document(s) are complete and accurately describe the research [The consent/assent form(s) include the required elements of informed consent (see guidance document "Federally Required Elements of Informed Consent")]. *If "No"*, provide related comments in space provided on page 2.

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Reviewer's Recommendations **Review Date:**

- ◯ Approve
- ◯ Approve pending minor revisions/additional information (you review)
- ◯ Withhold approval for major revisions/additional information (committee reviews response at meeting)
  - ◯ PI does *not* need to attend meeting
  - ◯ PI needs to attend meeting
- ◯ The protocol needs verification from sources other than the investigators that no material changes have occurred since the previous IRB review.
- ◯ *For expedited continuation review:* Review by full committee required.
- ◯ Disapproved: Determination made at a convened meeting.

Recommended period of Approval: ◯ **12 months** ◯ **Other - specify period:**

If recommended period of Approval is other than 12 months, provide justification:

Some of the following may or may not apply to the research. You only need to provide comments/recommendations for items deemed to involve controverted issues.

[MINOR concerns include, but are not limited to: typographical errors, grammar, pagination, headers/footers, template language, signatures; MAJOR concerns include, but are not limited to: risk/benefit ratio, ethical concerns, cognitive ability, failure to obtain consent, waiver of consent, etc.]

Area to Address	Page	Specific Requests/Questions
Consent/Assent Document(s)/ Process For Minor concerns regarding the consent/assent document submitted for approval, you may write the corrections on your copy of the consent/assent document(s) and return it to the ORI staff person. For other minor or major concerns about the consent/assent document(s)/process, please describe in the space to the right.		
Study Personnel Changes:		☐ Human subject protections training has **not** been completed by each individual listed as study personnel.
		☐ Other (e.g., expertise not appropriate). **Please describe**:
Unanticipated problem(s)/Adverse Event(s) or other New Safety Information (e.g., data and safety monitoring report, new relative literature, etc.)		
Subject Withdrawals		
Deviations/Exceptions/Violations		
Other (e.g., unanswered question,form missing):		

University of Kentucky Institutional Review Board Criteria for IRB Approval

1.	• Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result (achieved from research interventions).		
	• Risks to subjects are minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk.		
	• When possible, risks to subjects are minimized by using procedures already being performed on the participants for diagnostic or treatment purposes.		
	• The research proposal addresses the likelihood of harm and magnitude of harm (encompassing potential physical, psychological, social, and/or economic risks to the subjects).		
	• The research is likely to achieve its proposed aims.		
	• The importance of the knowledge expected to result is clear.		
2.	• Subject selection is equitable (in relation to:)		
	• Objectives of the research;		
	• The setting in which the research is to take place;		
	• The special problems of research involving special populations;		
	• Recruitment methods		
	• Inclusion/exclusion criteria		
* If N/A for any of #3 below, a request for waiver/alteration of the informed consent process must be completed by the PI and the criteria met.			
3.	• Adequate provisions are in place for seeking informed consent from each prospective subject ("subject), or the prospective subject's legally authorized representative ("subject's LAR").	N/A*	■
	• The proposed consent process provides the subject/subject's LAR with sufficient opportunity to consider whether to participate.	N/A*	■
	• The proposed consent process minimizes the possibility of coercion or undue influence.	N/A*	■
	• The information to be relayed during the consent process is in a language understandable to the subject/subject's LAR.	N/A*	■
	• The information being communicated during the consent process does not include exculpatory language through which the subject/subject's LAR waives or appears to waive any of the subject's legal rights.	N/A*	■
	• The information being communicated during the consent process does not include exculpatory language through which the subject/subject's LAR releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.	N/A*	■
** If N/A for #4 below, a request for waiver/alteration of documentation of informed consent must be completed by the PI and the criteria met.			
4.	The provisions for documenting informed consent/assent are appropriate.	N/A**	■
5.	The research proposal describes adequate provisions for protecting the privacy of subjects.		
6.	The research proposal describes adequate provisions for maintaining confidentiality of the data.		
7.	The credentials and/or described qualifications of the research staff/ investigators are representative of the appropriate expertise needed to perform their responsibilities in the study.		
8.	The research setting (e.g., location of research, facilities, drug/device controls & accounting) supports adequate safeguards for protection of human subjects.		
9.	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence (e.g., children, prisoners, adults with impaired consent capacity, economically or educationally disadvantaged persons, etc.).	N/A	■
10.	For greater than minimal risk research or NIH funded/FDA regulated clinical investigations, adequate provisions are in place for monitoring the data collected to ensure safety of subjects. Where applicable, the following may be considered in evaluating whether the data and safety monitoring is adequate:	N/A	■
11.	If the proposal is a multicenter study in which the lead PI or UK is the coordinating institution, the plans for communication among sites are adequate to protect the participant (e.g., consider communication of protocol modifications, data and safety monitoring reports, and unanticipated problems).	N/A	■
12.	Proposed payment to participants and/or cost to subjects for participation is appropriate.	N/A	■
13.	If PI/research staff conflict of interest is identified, the conflict of interest in relation to human research protections is appropriately minimized or managed (e.g., limit who obtains informed consent; add disclosure(s) in informed consent	N/A	■
14.	Review and approval by other committees/units, as applicable for medical research (e.g., RDRC, IBC, RSC, MCC PRC), has been conducted.	N/A	■
15.	Approval from external institutions has been obtained from an authorized official.	N/A	■
16.	**A signature assurance statement signed by the Principal Investigator and his/her Department Chairperson (or appropriate equivalent) is on file.**		

Federally Required Elements of Informed Consent
DHHS 45 CFR 46 & FDA 21 CFR 50

General Informed Consent Requirements:
(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
✶ (4) The prospective subject or the legally authorized representative 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.
✶ (5) (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
✶ (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Basic elements of informed consent - unless the IRB has approved a waiver or alteration of informed consent, the following information must be provided to each subject or the legally authorized representative:
(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
(2) A description of any reasonably foreseeable risks or discomforts to the subject;
(3) A description of any benefits to the subject/others that may reasonably be expected from the research;
(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
(6) 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;
(7) 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;
(8) 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; and
✶(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (i) 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; **or** (ii) 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.

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Additional elements of informed consent - the following elements of information, when appropriate, must also be provided to each subject or the legally authorized representative (if applicable)**:**
(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
(3) Any additional costs to the subject that may result from participation in the research;
(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
(6) The approximate number of subjects involved in the study;
✶ (7) 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;
✶ (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
✶ (9) For research involving biospecimens, whether the research will (if known) 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).

Additional FDA Related Statements (include in addition to the above, if applicable):
Purpose should indicate if study will test or collect data on an FDA regulated product. (e.g., test safety and effectiveness). Proof of concept or early feasibility research may test “how something works” instead of “how well it works”. Indicate if results will be shared with FDA;
Description includes reference to FDA approval status or specific use in study (i.e., FDA has approved ___ for some uses but not for your specific disease). Listing approval status is more meaningful than ambiguous terms like “investigational”;
Sections discussing confidentiality should indicate that FDA may look at or copy pertinent portions of records;
Applicable FDA regulated clinical trials statement regarding registration and results posting on Clinicaltrials.gov- Exact statement from 21 CFR 50.25(c); and 3/7/2012
For FDA studies, (if not covered in HIPAA Authorization section of consent), indicate that if subject withdraws from study early, the data collected until that point remains in the study database and may not be removed.

Other Statements Required by UK IRB (if applicable)
Information concerning payment including but not limited to amount and schedule of payment.

Sample Statements Required by Sponsors
For studies with a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH), FDA or other agency – include language informing research participants of the protections and the limits to protections provided by the CoC. 12/13/2016
Studies subject to the NIH Genomic Data Sharing (GDS) Policy (i.e., NIH-funded projects that generate large-scale genomic data) NIH expects investigators to obtain consent to share participants' genomic and phenotypic data broadly through databases. Include language to specify if the data will be shared via unrestricted- or controlled-access databases, or both. 1/25/2015
NIH Funded Clinical Trials clinical trials statement regarding registration and results posting on Clinicaltrials.gov 1/18/2017

✶ = Not enforceable until the new Common Rule goes into effect 2019