CRITERIA FOR IRB APPROVAL:
Reviewer Checklist

Primary Reviewer: _____ IRB #: _____ PI: _____
Title of Projec t: _____

Instructions: Review the criteria below which applies to the proposed research. IRB approval should only be issued if all criteria are met. Check the applicable box to document your determination, and sign and date on the line provided.

Reviewer Determ ination
‰ (1) Approved -- the research proposal meets all of the applicable criteria for approval listed below.
Informed Consent: † The IRB agreed with the PI's written informed consent document and has recognized that the form includes the 8 required elements of informed consent (see attached guidance document " 6 N L G P R U H Informed Consent & K H F"N O L V W

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Primary Reviewer: _____ IRB Protocol #: _____ PI: _____

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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).**

☐Yes ☐No

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Risks to subjects are minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk.

☐Yes ☐No

When possible, risks to subjects are minimized by using procedures already being performed on the participants for diagnostic or treatment purposes.

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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.

8. **The research setting (e.g., location of research, facilities, etc.) supports adequate safeguards for protection of human subjects.**

☐Yes ☐No ☐N/A

9. **Additional safeguards have been included in the study to protect the rights and welfare of participants vulnerable to coercion or undue influence (e.g., children, prisoners, adults with impaired consent capacity, etc.)**

☐Yes ☐No ☐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 participants. Where applicable, the following may be considered in evaluating whether the data and safety monitoring is adequate.**

Is the proposed plan commensurate with the nature, size, and complexity of the research as well as the degree of risk involved?
☐Yes ☐No ☐N/A

Does proposal include procedures for promptly detecting harm and mitigating potential injuries?
☐Yes ☐No ☐N/A

What safety information will be collected? How will safety information be collected (e.g. at study visits, by monthly telephone calls, etc.)?
☐Yes ☐No ☐N/A

What data will be monitored and who will monitor the data?
☐Yes ☐No ☐N/A

What is the frequency of review or analysis of cumulative safety data to determine whether harm is occurring?
☐Yes ☐No ☐N/A

Are there procedures for ensuring appropriate reporting of findings to the IRB?
☐Yes ☐No ☐N/A

Are there any conditions or criteria that could trigger an immediate suspension/ termination of the research and if so are their procedures for reporting the suspension/ termination to the appropriate entities?
☐Yes ☐No ☐N/A

Is establishment of an independent individual or data and safety monitoring board (DSMB) warranted? If so, is there a plan for providing DSMB reports, (routine and urgent), to the IRB?
☐Yes ☐No ☐N/A

11. **If the proposal is a multicenter study in which Skidmore 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).**

☐Yes ☐No ☐N/A

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Federally Required Elements of Informed Consent

DHHS 45 CFR 46

Yes	No	N/A	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

Consent \Assent Checklist

Federally Required Elements of Informed Consent

DHHS 45 CFR 46

Yes	No	N/A	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:
			(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.

Yes	No	N/A	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 specime