Proposal # _____ Date Received by IRB _____ New _____ Revised _____

Review Request for Research Involving Human Participants Form

Project Title

Project Personnel

1. Principal Investigator (PI): The PI is the faculty, staff, or student who conducts the project at Millikin. If the PI is a student, a Millikin Project Supervisor (PS), who is either Millikin faculty or a staff member must be designated. Attach CITI Certification for each PI, PS, & CI in Appendix A: CITI Certifications for PI, PS, & CI.

PI Information – Create Appendix A and attach CITI Required Certifications.		
Last name:	First Name:	Dept:
Office address:	Phone:	Email:

activities, including the total number of treatments, visits, or meet ings required and the total time commitment. For studies conducted in school or college classrooms where class time is used, describe in detail the activities planned for nonparticipants and explain where (e.g., classroom, in a private area) both participants and nonparticipants will be located during the research activities. Include a concise description of procedures, locations, time commitments, and alternate activities on the relevant consent forms.

Research Setting

4. Only Millikin Campus sites will be used in the proposed research. Mark an X and go to Item 5.
   Off Campus sites will be used in the proposed research. Mark an X and complete information below.

For each Non-Millikin site to be used, provide the following information: 1) site name and 2) site contact person information, if applicable. In the box to the right of each site listed, bold the correct response to indicate whether or not the site's IRB has reviewed the research or intends for Millikin's IRB to review it. Create Appendix B: Non-MU Site Permissions and includean electronic copy of each Non-Millikin site's IRB approval letter.

Site Name	Site Contact Information (Name, phone,

9.1 Provide the form of the inducement/reward (e.g., $,

participants with diminished autonomy or children under age 8 will be involved, explain how the participant's understanding will be assessed and how often; include the Item

23. Materials of Human Origin Will this research involve the collection, analysis or banking of human biological materials (e.g., cells, tissues, fluids, DNA, etc.)?

No Mark an X and go to Item 24.

Yes Mark an X and complete sections 23.1 to 23.6 below

23.1	Describe the materials that will be collected, analyzed, or banked.		
23.2	Indicate the intended use of the biological samples.		
23.3	Describe how and from where (name the entity) or from whom (describe the participant population) the biological samples will be obtained.		
23.4	No Yes	Biological samples are **unidentified** – identifying information was not or will not be collected, or if collected by a repository, was not maintained and cannot be retrieved by the repository.	
23.5	No Yes	Biological samples are **identified** – links to identifying personal information exist somewhere, or will be collected and maintained. Answer Items 23.5a-c.	
23.6	23.5 a, b, c Answer if samples are identified.	a. No Yes	a. If the biological samples are identified, are the samples unlinked (samples have no identifiers or codes that link to identifiers) ?
		b. No Yes	b. If the biological samples are identified, are the samples coded (samples have codes that are linked to identifiers?
		c. No Yes	c. If the biological samples are identified, are the samples identified – (samples have identifying personal information)?

Create Appendix F – Human Origins Materials and attach necessary permissions / agreements

Research Measures

24. Measurement Instruments – The IRB must review all measurement instruments participants will complete for the study including surveys and psychological tests. It is the researcher's responsibility to obtain any necessary permission to use copyrighted materials. Does the proposed study include use of measurement instruments?
    - No Mark an X and go to Item 25.
    - Yes Mark an X and list them below (add lines as needed). Create Appendix H – Measures, and include in this appendix a complete copy of each measure used in your study.

	Name of Measure
Measure 1	
Measure 2	

25. Audio-Visual Data – If you collect any of the types of data listed below, please describe the methods that will be used to ensure the confidentiality of participant's identifiable data. Confidentiality is required unless participants give express, written permission to have their identifiable information published, presented, or shared. Does the proposed research include gathering audio, video, or photographic data?
    - No Mark an X and go to Item 26.
    - Yes Mark an X and provide explanations in the boxes below

Audio	
Video	
Photographs	
Other (describe):	

26. Equipment – Will any physical stimulation or physiological data acquisition equipment be used with participants?
    - No Mark an X and go to Item 27.
    - Yes Mark an X and provide a description of the equipment in the box below.

27. Drugs and biologics – Will any drugs, chemicals, or biological agents be used with participants?
    - No, mark an X and go to Item 28.
    - Yes, mark an X and create Appendix E - Drug / Biological Agent Descriptions by including a list and description of the drugs, chemicals, or biological agents used in your study. This information should also be disclosed and included on the consent form.

Confidentiality

28. Data Collection Confidentiality

28.1	Explain how the data will be collected and stored to safeguard confidentiality. If anonymous data collection is proposed, provide details of how investigators *will not have the ability to trace responses to participant identities.*
28.2	For multiphase data collection OR if multiple contacts will be made with participants, specifically explain the participant tracking and coding systems.
28.3	If data are collected via email, databases, websites, computer servers, and other networked information, address how confidentiality will be protected.

29. Data Retention - Indicate how long the data will be kept, where it will be stored, and, if applicable, how and when it will be destroyed. The IRB requires that study data and consent forms be retained for 3 years after the study closes. Project Supervisors may request

IN VESTIGATOR ASSURANCES

Your study will not be reviewed until ALL supporting documents are received by the IRB. The signature of the Principal Investigator and Faculty/Staff Project Supervisor (if the PI is a student) is required (Electronic, scanned or faxed signatures are acceptable). Other investigators are also responsible for these assurances and are encouraged to sign. My signature on this form assures that:

- I certify that the information provided in this application, and in all attachments, is complete and correct.
- I understand that I have ultimate responsibility for the protection of the rights and welfare of human subjects, the conduct of this study, and the ethical performance of this project.
- I agree to comply with all Millikin policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human subjects in research.

My signature certifies that:

- the study will be performed by qualified personnel according to the Millikin IRB-approved protocol.
- the equipment, facilities, and procedures to be used in this research meet recognized standards for sata.