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

Review Request for Research Involving Human Participants Form

Institutional Review Board Office
Attn: Provost, 1184 W Main St
Millikin University IRB, Decatur, IL 62522
Tel: 217-424-6220 fax:217-424-6653
E-mail: irb@millikin.edu

Please type your response in the boxes or spaces provided. Boxes will expand as you type. **Review requests will be reviewed once all supporting documentation is received by the IRB.**

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:
Street address:	City:	State/Zip:
PS Information – required ONLY IF PI is a student. Attach CITI Certifications in Appendix A.		
Last name:	First Name:	Dept:
Office address:	Phone:	Email:
Street address:	City:	State/Zip:

Co-Investigator(s) (CI): List all co-investigators, including those from other institutions, who will: 1) be directly responsible for the project's design or implementation, 2) obtain informed consent, or 3) be involved in data collection, data analysis, or follow-up.

☐ **No Co-Investigators.** Mark an X and go to Item 2.

Co-I 1 Information - Attach CITI Certification in Appendix A		
Last name:	First Name:	Dept:
Office address:	Phone:	Email:
Street address:	City:	State/Zip:
Co-I 2 Information - Attach CITI Certification in Appendix A		
Last name:	First Name:	Dept:
Office address:	Phone:	Email:
Street address:	City:	State/Zip:

2. **Project Summary** in layperson's terms, describe the project including the aims, research questions, or hypotheses and significance of the proposed research. You may provide a glossary of technical terms necessary to understand the proposed research.

3. **Research Procedures** – Using layperson's terms, specifically describe what the participants (treatment groups and controls) will do and where the research activities will take place. Give approximate dates and durations for specific

activities, including the total number of treatments, visits, or meetings 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 include an electronic copy of each Non-Millikin site's IRB approval letter.

Site Name	Site Contact Information (Name, phone, email)	Site IRB Letter
1.		Attached Defer MU N/A
2.		Attached Defer MU N/A

4.1 **Illinois K-12 Schools-based Research** – If participants will be recruited from Illinois public or private elementary or secondary schools, additional deadlines and procedures may apply. Special consideration must be given to the exclusion of vulnerable populations.
☐ **No** Illinois schools are used in this study**.** Mark an X and go to Item 5.
☐ **Yes** Illinois schools WILL be used in this study. Mark an X and complete items 4.2-4.3 explaining who will and will not qualify for participation (inclusion/exclusion criteria), and how that determination will be made.

4.2	List specific criteria for inclusion and exclusion of study participants, indicating treatment and control groups.
4.3	Describe procedures to assure equitable selection of participants. Justify the use of any special or vulnerable groups marked in item 8 below. Selection criteria that target one gender, race, or ethnic group require a clear ethical rationale.

Participants

5. **Anticipated participants -** Describe the participants in this study below. How many participants will you need? If you plan to study disproportionate numbers of a given gender, race, or minority group, provide a rationale.

5.1 Are any of the researchers associated with the participants in a possible power relationship (e.g., participants are students, employees, patients)?
☐ **No** Mark an X and go to Item 6
☐ **Yes** Mark an X and describe ethical safeguards that will be used to protect the participants in the box below.

6. **Recruitment Procedures** – In the box below, specifically describe how you will find and recruit participants. Indicate who will contact the prospective participants. Describe the solicitation process (e.g., posters, flyers, announcements, newspaper, radio, television, internet, face-to-face interaction, direct mail, phone contact, classrooms, etc.) as applicable.

7. **Recruitment Materials** Will recruitment materials be used to solicit participants?
   - ☐ **No** Mark an X and go to Item 8.
   - ☐ **Yes**, Mark X and provide copies of each type of recruitment material to be used in your research (e.g., posters, flyers, newspaper ads, internet messages, direct mail letters, etc.). Either cut and paste the content here, OR create Appendix G – Recruitment Materials and submit electronic/typed/scanned copies of these recruitment materials with the review request.

8. **Special or Vulnerable Populations** Federal regulations require IRBs to give special consideration to protecting the welfare of vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons**.** Please consider whether you may have anyone in your sample of participants that might fall under any of the special or potentially vulnerable categories below, even if you are not intentionally soliciting them or exclusively targeting that particular population. Then consider these individuals when responding to item 18 regarding risk.
   Might special or vulnerable populations be included among your research participants?
   - ☐ **No** Mark an X and go to Item 9.
   - ☐ **Yes** Mark an X and answer Items 8.1-8.2. If appropriate, submit the additional CITI certifications for working with the specific vulnerable populations in Appendix A. If children are exposed to *more than minimal risk in this study*, create Appendix D: Documentation of Benefits and include a written rationale and documentation of benefits for the children to be used in this research.

8.1. Special or Vulnerable populations – Mark an X in all boxes below that apply.			
	Children (age < 18yrs)		Individuals with impaired decision-making capacity (e.g., those living with Alzheimer's Disease) *
	Neonates		Terminally Ill
	Fetuses (in utero)		Comatose or Traumatized Patients
	in vitro fertilization participants		Intellectually disabled*
	Pregnant or Lactating women		Prisoners
	Specific racial or ethnic groups (describe participants in this space):		
	Economically or educationally disadvantaged persons (describe participants in this space):		
	Other:		
8.2 If you have checked any boxes in Item 8.1, describe additional safeguards included in your research procedures that will be used to protect the rights and welfare of the special or vulnerable populations in your study, if necessary.			

*** A few additional questions may be added to your consent form to help you determine whether your participants are cognitively capable of consenting to participate in your study. An example of these additional questions can be found on the IRB webpage under Consent Form Instructions, Additional Consent and Assent Form Elements.**

9. **Participant Inducements** Will participants receive inducement or rewards before, during, or after participation?
   - ☐ **No** Mark an X and go to Item 10.
   - ☐ **Yes** Mark an X and answer Items 9.1 – 9.2.

9.1	Provide the form of the inducement/reward (e.g., $, course extra credit, gift certificate, or other) for each participant and its approximate value.
9.2	Explain the inducement plan, including whether and how prorating will be made for partial participation.

10. **Participant Costs** – Will participants incur costs for research-related procedures (e.g., extra tests, longer hospitalization), use of equipment, lost compensation, or transportation (over 50 miles)?

☐**No** Mark an X and go to Item 11.

☐**Yes** Mark an X and describe the costs to participants in the box below.

Informed Consent Process

Researchers must obtain the informed consent and assent, as applicable, of participants, using language the participant and/or the participant's legally authorized representative can easily understand. See Appendix I for a discussion and examples of consent/assent types and informed consent requirements.

11. **Consent Form –** Will this study obtain the consent of participants?

☐ **No** Mark an X and explain in the box for "Waived Consent" below

☐**Yes** Mark an X here and in each box that applies to study participants. Create Appendix I Informed Consent & Assent. Attach one copy of each type of labeled assent form or verbatim script that will be read to participants.

	Adult participant, written consent with signature
	Parent/legal guardian, written consent with signature
	Adult participant, oral consent with detached signature page
	Parent /legal guardian, oral consent with detached signature page
	Implied consent (e.g. return of anonymous surveys)
	Waived consent: Provide a full justification for requesting a waiver of consent.

12. **Assent Form** – Persons with diminished autonomy (e.g., children, adults with legal guardians) may not give informed consent and can only provide their assent to participate. Will this study obtain the assent of participants?

☐ **No** Mark an X and go to Item 13.

☐ **Yes** Mark an X and complete Item 12.1 below. Create Appendix I Informed Consent & Assent. Attach one copy of each type of labeled assent form or verbatim script that will be read to participants.

12.1	**Type of Assent –** type an X in each box that applies to study participants
	8-17 year old child participant written assent with signature verification.
	≤ 8 year old child participant oral or passive assent
	Participant with diminished autonomy oral or passive assent
	Oral or passive assent with no signatures.
	Oral or passive assent justification: When the researcher cannot or does not plan to obtain written assent, a justification should be provided. Provide the Oral Assent script, which must be read verbatim to participants here.

13. **Informed Consent/Assent Process** Describe the informed consent/assent process in the boxes below. Describe when and where voluntary informed consent/assent will be obtained, how often, by whom, and from whom. If

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 Items that will be asked or actions that will be taken to assess their understanding of the research.

14. **Parental/Legal Guardian Consent for Children**: Does the research involve children?
    - ☐ **No** Mark an X and go to Item 15.
    - ☐ **Yes** Mark an X and answer Items 14.1

14.1	Indicate whether consent will be obtained from: the legal guardian, both parents, unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child; or from one parent regardless of the status of the other parent.

15. **Waiting Period**: Will there be a waiting period between informing the participant about the study and obtaining informed consent/assent?
    - ☐ **No** Mark an X and go to Item 16.
    - ☐ **Yes** Mark an X and answer Items 15.1

15.1	Describe the waiting period between informing the prospective participant and obtaining the consent/assent and steps taken to minimize the possibility of coercion or undue influence.

16. **Pregnant Women, Fetuses, or Neonates**: Does the research involve pregnant women, fetuses, or neonates?
    - ☐ **No** Mark an X and go to Item 17.
    - ☐ **Yes** Mark an X and answer Item 16.1

16.1	Indicate whether consent will be obtained from the mother, father, or both.

17. **Withheld Information** Will information be withheld from participants prior to or during their participation in the study?
    - ☐ **No** Mark an X and go to Item 18.
    - ☐ **Yes** Mark an X and answer Items 17.1-17.2

17.1	Describe what will be withheld, justify the withholding of this information (address risks, provide rationale), describe the debriefing process.
17.2	Type the script that will be used for debriefing the participants in this space.

18. **Participant Risk Assessment** Describe the risks and any benefits to participants below.

18.1	**Potential participant benefits** - describe any expected benefits of the study for participants
18.2	☐ **No more than minimal risk –** type X if applicable and go to Item 20. Minimal risk means the probability and magnitude of harm or discomfort anticipated for participation in the proposed study are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

18.3	☐ **More than minimal risk –** type an X if applicable and complete Items 18.3a – 18.3c. Researchers planning to include children in research projects involving more than minimal risk must provide written documentation of the benefits that are likely to accrue to a child participating in the project.
18.3a	**Participant risks -** Describe all probable risks from the proposed research procedures and activities that exceed minimal risk standards, particularly noting risks to the participant's physical well-being, privacy, dignity, self-respect, psyche, emotions, reputation, employability, and criminal and legal status. These risks must be described on the consent forms.
18.3b	Describe the procedures that will be used to minimize risks to participants as well as the procedures for monitoring participants to ensure their safety.
18.3c	Indicate what criteria will be used to stop the research based on monitoring the risk level of the participants.

19. **Risk-Benefit Analysis** – For studies potentially involving more than minimal risk to participants, present a risk-benefit analysis for the proposed study.

Data to be Gathered

20. **Secondary Data only** (e.g., Archival, Retrospective Chart Review, Recorded data). Will the proposed research only involve the analysis of data that has already been collected from human participants for other purposes and no new data collection will occur?
    ☐ **No** Mark an X and go to Item 21
    ☐ **Yes** Mark an X and complete 20.1-20.4 below

20.1	Provide the contact person, address, and name of the Agency or Institution giving permission to use or have access to the record data. Create Appendix C and attach electronic copies of the Record Data Permission letters
20.2	Describe the procedures to be followed for requesting pre-existing data or materials.
20.3	Address how you will safeguard this information.
20.4	Using layperson's terms, specifically describe how the records will be used by the researcher.

21. **Individually Identifiable Information** – Will any individually identifiable data (e.g. name, address, phone number, email, birth date, etc.), images, or recordings of participants be published or shared?
    ☐ **No** Mark an X and go to Item 22.
    ☐ **Yes** Mark an X and identify the individually identifiable data below. Be aware that participants must provide written consent, with explicit details about what, how, and who will have access to these data and how these data will be used. This information must also be contained within the signed, written consent form.

22. **Protected Health Information** The IRB must address the privacy and use of health information that is created, received or housed by health care providers, health plans, or health care clearinghouses and that identifies or could be used to identify an individual. During *either recruiting or data collection,* will you use or have access to such information that is related to the past, present or future health or conditions of a *living or deceased individual*, provision of health care to the individual, or payment for the provision of health care to the individual?
    ☐ **No** Mark an X and go to Item 23.
    ☐ **Yes** Mark an X and indicate how you will safeguard this information in the space provided below.

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.	
	23.5 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)?
23.6	☐**Yes** ☐ **No**	Will the biological samples be destroyed after being used in this project? If Yes, mark an X and go to Item 24. If No**,** mark an X and answer Items 23.6 a-i below.	
	23.6a	How long will the samples be stored?	
	23.6b	Where will the samples be stored?	
	23.6c	Will the stored samples be used for other purposes before being destroyed? If yes, describe the other uses of the stored samples here.	
	23.6d	Will any participant receive information from the analysis of their samples? Describe who will inform participants, how and when they will be informed, and what they will be told about their analyzed samples in this space.	
	23.6e	Indicate who will "own" the samples and the data derived from them here.	
	23.6f	Indicate whether the researcher in charge of the project will remain in control of the samples and the data here.	
	236g	Indicate whether the samples and /or data will be shared with other investigators, identifying the investigators and the nature of sharing of the samples here.	
	236h	Indicate whether the participants will have the option of specifying future use or non-use of these stored samples here.	
	23.6i	Indicate whether all of this information about the stored samples is clearly explained in the consent form here.	

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 to maintain student research data.

30. **Project Funding –** Mark an X in each box that applies and name the funding source below. If there is a Funding Contract create Appendix J – Funding Contracts and provide a copy of the contract with each funding source. Is there funding for this project?
    - ☐ **No** Mark an X and go to Item 31.
    - ☐ **Yes** Mark an X in each appropriate box and provide a description below

Mark X for each funding source		**Name of Source**
	Millikin	
	Federal	
	State	
	Commercial Sponsor	
	Gift / Foundation	
	Other (describe):	

31. **Researcher Financial Interests:** Indicate below if any researchers or members of their immediate families have any relationships, commitments, or activities with the sponsor of this research that might present or appear to present a conflict of interest with regard to the outcome of the research. If a financial conflict of interest exists, create Appendix K – Financial Interest Documents and include an electronic copy with your proposal. If you have questions about a potential conflict of interest, contact the Provost at 217-424-6220. Are there any potential financial conflicts of interests associated with this research?
    - ☐ **No** Mark an X and go to Appendix Checklist.
    - ☐ **Yes** Mark an X in each appropriate box and provide a description below.

	Ownership, equity or stock options.
	Personal compensation (royalties, consulting fees, etc.).
	Intellectual property (patents, copyright, licensing, etc.).
	Other conflict of interest.

Appendix Checklist
Mark an X by each appendix submitted with the review request. Include appendices as an email file attachment**.** At least one type of CITI certification from **Appendix A is mandatory.** Appendices B-K may also be required.

	Appendix A – CITI Certifications for PI, PS, CI		**Appendix B** – Non-MU Site Permissions
	Biomedical Research Investigators		**Appendix C** – Records Data Permissions
	Biomedical Responsible Conduct of Research		**Appendix D** - Documentation of Benefits
	Humanities Responsible Conduct of Research		**Appendix E** – Drug/Biological Agent Descriptions
	Physical Science Responsible Conduct of Research		**Appendix F** - Human Origin Materials Permissions
	Responsible Conduct of Research for Administrators		**Appendix G** – Recruitment Documents
	Social & Behavioral Research Investigators		**Appendix H** - Tests/Measurements Permissions
	Social & Behavioral Responsible Conduct of Research		**Appendix I -** Consent & Assent Forms
			Appendix J - Funding Contracts
			Appendix K - Conflict of Interest Contracts

INVESTIGATOR 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 safety.
- no change will be made to the human subjects protocol or consent form(s) until approved by the Millikin IRB.
- legally effective informed consent or assent will be obtained from human subjects as required.
- Unanticipated problems, adverse events, and new information that may affect the risk–benefit assessment for this research will be reported to the IRB, irb@millikin.edu and to my Faculty/Staff Project Supervisor (if student PI).
- student and co-investigators on this project are knowledgeable about the regulations and policies governing this research.
- I agree to meet with the investigator(s), if different from myself, and co-investigators on a regular basis to monitor study progress.
- if the Faculty/Staff Project Supervisor will be unavailable during the study, as when on sabbatical or other leave, including vacation, an alternate faculty/staff sponsor will be arranged to assume responsibility during my absence. I will advise the Millikin IRB by letter of such arrangements.

I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until IRB approval has been obtained.

Signatures

Principal Investigator	Date	Faculty/Staff Project Supervisor	Date
Co-Investigator	Date	Co-Investigator	Date

Millikin IRB Use Only

MU IRB Protocol No. _____ Date Submitted:_____

Expedited Review _____ Full Board Review _____ Renewal _____ Date_____ _____

IRB Committee Decision: ___ Approved ___ Revisions Needed __ _ Approved

_____PI & PS Notified Date **_____ Copy to Provost's Office Date _____**

IRB Chair Signature _____ Date_____