PROTOCOL APPROVAL APPLICATION

Institutional Review Board (IRB) for Research with Human Subjects

Easy to Use Template Instructions:

Simply tab to the gray blocks and type in your information. The box will expand as you type

PROJECT TITLE				
INVESTIGATOR INFORMATION (must be a faculty or staff not a student)	**Name:**		**Dept.:**	
	Title:		**Status:** Select one:	
	Degree(s):		**Phone:**	
	Complete Mailing Address:		**Email:**	
Student Investigator	**Name**		**Dept.:**	
	Title:		**Phone:**	
	Degree(s)		**Email:**	

List all co-investigators below, including those from other institutions.

Simply tab to the gray blocks and type in your information. The box will expand as you type.

Name	Degree(s)	Responsibility on Research Project	Department (provide address if off-campus)	Contact Information
				Ph: **Email:**
				Ph: **Email:**
				Ph: **Email**

:

Anticipated Start date _____ **End Date** _____

Investigator's Agreement:

I certify that myself as well as all co-investigator has accepted their role in this study. I agree to a continuing exchange of information with the Institutional Review Board (IRB). I agree to obtain approval before making any changes or additions to the project. I will provide progress reports at least annually, or as requested. I agree to report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. A copy of the informed consent will be given to each subject if applicable and a signed original will be retained in my files.

Signature of Investigator

_____ **Date** _____

Responsible Faculty Member's Agreement: (If a student investigator is involved) I certify that, as the student's responsible faculty, I have:

- read and endorsed the materials submitted; and

Signature of Responsible Faculty

_____ **Date** _____

1. Conflict of Interest

Will members of the research team have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this study or otherwise have a potential conflict of interest regarding the conduct of this study? If so, please provide explanation below.

2. Purpose of Project

Provide a **brief summary (i.e. 300 words or less)** of the purpose of the project in layman's terms including: background information as necessary, research question(s), and explanation of why the study is needed. Provide the full name/title at least once when using acronyms.

3. Vulnerable Populations

	Yes	No
Children:	☐	☐
Non-English speaking:	☐	☐
Decisionally impaired or mentally incompetent :	☐	☐
Prisoners, parolees and or other convicted offenders:	☐	☐
Pregnant women: Select "Yes" if study is about pregnancy, pregnant women and/or the fetus or neonate.	☐	☐
MSU Students:	☐	☐

4. Characteristics of the Study Population

List required characteristics of potential subjects and those that preclude participation.

- **Inclusion Criteria:** Describe the characteristics of the study population(s). What characteristics make someone an ideal candidate to participate in your study? (e.g., age, occupation, M/F, etc.)
- **Exclusion Criteria:** What characteristics would make someone ineligible for participation in the study?

Inclusion Criteria:	☐
Exclusion Criteria:	☐

5. Health Information

The Health Information Portability and Accountability Act (HIPAA) Privacy Rule governs disclosure of personally identifiable health information (deemed "protected health information" or PHI) by hospitals, physicians, and other HIPAA-defined Covered Entities. PHI is broadly defined to include data on a person's physical or mental health, health care, or payment for health care. PHI includes, for example, a list of a person's current medications or a person's weight, smoking status or date of surgery.

As part of this research study, will you obtain any protected health information (PHI) from a hospital, health care provider, insurance agency or other HIPAA-defined Covered Entity?

No ☐ Yes ☐

6. Summary Checklist – Are any of the following involved?

The items listed below ARE NOT an all-inclusive list of methods or procedures but are intended to provide 'triggers' or reminders for you to provide appropriate information in subsequent questions in the application or to provide supplemental materials necessary for the review process.

	Yes	No
a) Will research include use of existing data, research records, patient records, and/or human biological specimens?	☐	☐
b) Will data collection include educational tests, surveys, questionnaires or psychometric testing?	☐	☐
c) Will data collection include interviews or focus groups? *(provide interview/focus group question with protocol application)*	☐	☐
d) Will research include deception or less than full disclosure?	☐	☐
e) Will research include accessing Student Educational Records?	☐	☐
f) Will the research be conducted in commonly accepted educational settings and focus on regular educational practices?	☐	☐

g) Will data collection include:	*Audio Recording?	☐	☐
	*Video Recording?	☐	☐
	*Photography?	☐	☐
*If you answered "Yes" to any of the recording options in *Question g*, this information must be disclosed in the consent document AND/OR a separate release consent form.			

7. Full description of the study design, methods and procedures including:

- the type of experimental design;
- describe study procedures;
- provide a sequential description (explained in steps, phases etc.) of what will be asked of/done to subjects;
- clarify if subjects will be assigned to various groups/arms of the study (if applicable);
- explain what kinds of data will be collected;
- provide details on the primary outcome measurements including any scripts to be used; and
- explain any follow-up procedures (if applicable).

If you answered "YES" to any of the items in Q #6, please provide explanation/description in this section.
Attach 2 copies of the questionnaire(s); inventories, or scales that will be completed by participants.

8. Duration of entire study and duration of an individual subject's participation, including follow-up evaluation if applicable, including:

- Provide information on the number of required visits, tests, surveys to be completed, interventions.
- Provide information on the approximate duration of each intervention (i.e., how much time should the subject expect to spend).

9. Where will the subjects be studied?

If off MSU campus, list locations.

Attach a letter(s) of permission to conduct the research project from elementary, junior high, or high school(s) principal (s).

10. Confidentiality

Explain how you will protect the confidentiality of the data collected. Describe procedures for protecting against or minimizing any potential risks from breach of confidentiality or invasion of privacy. How will you protect the data with respect to privacy and confidentiality? For example:

- Where will the data be stored?
- What security measures will be applied?
- Who will have access to the data? Provide explanation of why they need access.
- If applicable, specify your plans for de-identifying or making the material anonymous if audio/video recordings or photographs will be used.
- If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator.
- If applicable, describe procedures for sharing data with entities not affiliated with MSU.
- Provide a timetable for destroying the data and identify how they will be destroyed or provide explanation for perpetual maintenance.

Please note: The IRB expects researchers to access the minimal amount of data to conduct the study and to comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements.

11. Data security for storage and transmission.

Check all that apply.

For electronic data:	
Secure network	☐
Password access	☐
Encryption	☐
Other (describe in question #14 above)	☐
Portable storage (e.g., laptop computer, flash drive) Describe in question #14 above how data will be protected for any portable device	☐

For hardcopy data (including human biological specimens, CDs, tapes, etc.):	
Data de-identified by research team	☐
Locked suite or office	☐
Locked cabinet	☐
Data coded by research team with a master list secured and kept separately	☐

Other (describe in question #14 above)	☐

Mandated Reporting Responsibility: Is there a possibility that certain information will be obtained in the course of the research that you will be legally obligated to disclose to the proper authorities (e.g., child abuse, neglect, or threats of harm)?

No	☐
Yes – describe	☐

Note: Mandated reporting must be disclosed to participants in the consent document.

12. Full description of risks and measures to minimize risks:

Give full descriptions and measures risk factors.

For example:

- psychosocial harm (e.g. emotional distress, embarrassment, breach of confidentiality, etc.)
- economic harm (e.g. loss of insurability), and
- legal jeopardy (e.g. disclosure of illegal activity) as well as
- risk of pain and physical injury.

13. Benefits to subjects and/or society:

The possibility of benefits to society should be clearly distinguished from the possibility of benefit to the individual subject, if any. If there is no direct benefit to the individual subject, say so. Do not list monetary payment as a benefit.

14. Inducements for participation:

If monetary, specify the amount and how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completion. If the inducement is extra credit specify the amount of extra credit and what non-research alternatives (equal in time and effort) are available to the students for earning extra credit.

15. Costs to be borne by subjects:

If there are no costs to subjects, indicate this.

16. Methods of recruiting:

Tell how prospective subjects are contacted. Provide recruitment script (letters, email, flyers and advertising, telephone script, verbal, website, etc.).

17. Dual Relationships: Does the investigator, co-investigator, student investigator, or any member of the research team have an authority relationship with the potential participants (e.g. instructor/student, employer/employee)?

☐ No

☐ Yes- describe the relationship and indicate how the research will be conducted to avoid undue influence

18. How will informed consent be obtained?

Give full descriptions and measures for all of the following applicable risk factors:

- Describe the process.
- It is typical to obtain assent from children ages 7-17.
- When the consent of a legally authorized representative is substituted for consent of the adult subject, explain why this is necessary.
- If non-English-speaking subjects will be enrolled, a consent form should be prepared in their foreign language.
- Someone who is fluent in the subjects' language must be available to interpret**.**

If decisionally impaired participants are to be enrolled, consent form should be written at appropriate comprehension letter

Attach a copy of the informed consent document(s).

19. **Will the Research be conducted at an international site?**

No	☐
Yes- Indicate site and investigator's familiarity with the culture/cultural norms, whether or not the different cultural context presents any problems or risks that need to be addressed, and how those issues will be handled.	☐

Submission Reminders

Submit a signed copy of the entire IRB Approval Application to:
Bryan Schmidt, Ph.D.

Have you included the following items?

- ☐ Informed Consent document (see sample on IRB web site for information that needs to be included in informed consent) on appropriate MSU letterhead (parental and assent if applicable)
- ☐ Surveys
- ☐ Questionnaires
- ☐ Psychometric Testing Instruments
- ☐ Interview and focus group questions
- ☐ Assessments
- ☐ Pre-Test, Post-Test
- ☐ Inventories, or scales that will be completed by participants
- ☐ Recruitment scripts (email, telephone, verbal announcements) & Flyers
- ☐ Letter(s) of permission/cooperation to recruit participants from and/or conduct the research project from school(s), organization(s) or any off- campus location.
- ☐ Grant proposal methodology section, if applicable

Other IRB Reviews:

Has/will this project be submitted to another IRB for review?

- ☐ No
- ☐ Yes – note the IRB(s) and status of the application. If already reviewed submit copy of protocol reviewed and the IRB's determination.