Principal Investigator:	IRB #

Project Title:

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review by a convened IRB in accordance with the non-expedited procedure set forth in 45 CFR 46.108(b) and 21 CFR 56.108(c).

PRELIMINARY QUESTIONS If **yes** to any of these questions, the research is **not** eligible for review using the expedited procedure, **except as noted**. Review by the convened IRB will be required.	**Yes**	**No**
1. Does the research involve . . .		
○ an investigational drug or medical device?	☐	☐
○ more than minimal risk* to human subjects?	☐	☐
○ children, where the procedures differ from standard educational practices?	☐	☐
○ prisoners?	☐	☐
2. Could identification of the subjects and/or their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing? (The answer is No **if** there are reasonable and appropriate protections implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.)	☐	☐

APPLICABLE RESEARCH ACTIVITIES
(REGULATION: FEDERAL REGISTER; 63 FR 60364-60367)

MINIMAL RISK STUDY (FOR INITIAL REVIEW)

Research activity presents no more than minimal risk* to human subjects AND

Involves only procedures included in one or more categories of research (see categories here) that may be reviewed through an expedited review procedure.

Reviewer:	Date:

PROTOCOL CHECKLIST

Performance Sites (#14.1, #14.2, #14.3)

Yes No N/A

◯ ◯ ◯ Is research taking place at MSUB? Research taking place at other location, please name:

◯ ◯ ◯ Letter of approval for site is attached.

◯ ◯ ◯ As appropriate, approval from the MSUB Registrar is included.

Comments:

Project Description & Procedures (#12, #13, #14)

Yes	No	N/A	
○	○	○	Is the description provided in non-technical terms?
○	○	○	Is it clear what the project will be doing and what the PI's role is?
○	○	○	Are objectives clearly stated?
○	○	○	Are the sources of the data and/or specimens adequately identified?
○	○	○	Are all relevant materials submitted for review (data collection tools, surveys, educational materials, etc.)?

Comments:

Subject Selection (#15)

Yes	No	N/A	
○	○	○	Subject selection is reasonable and equitable.
○	○	○	If any specific social/ethnic groups, such as minorities and women, are not included, is there adequate justification for their exclusion?
○	○	○	Is the research targeting any Native American population?

Comments:

Vulnerable Subjects/Special Population Requirements (#15.3, 15.4)

Check if the application targets or includes any of the following:

TARGET	INCLUDE	
☐	☐	Pregnant Women/Fetuses
☐	☐	Fetal or Embryonic Tissue
☐	☐	Children
☐	☐	Prisoners
☐	☐	Adults who cannot consent for themselves
☐	☐	Genetic testing with identifiers:
☐	☐	Growth of perpetual cell lines
☐	☐	Classified research involving human subjects
☐	☐	Major Deception
☐	☐	Other (describe):

Comments:

Recruitment (#15.6)

Yes	No	N/A	
○	○	○	Do you have any concerns with recruitment methods/plan described in the protocol?

Concerns

Yes No N/A

- Is the proper authority/individual contacting the potential subjects?
- If the PI is directly contacting potential subjects, do they have an appropriate relationship to do so?
- Is the number of attempted direct contacts (per subject) excessive?
- Do advertisements reference PI and the MSUB IRB?

Advertisements must NOT (check boxes if not present in ads):

- ☐ Imply a certainty of favorable outcome
- ☐ Imply the study provides treatment (must state "research" not just "study")
- ☐ Promise free medical care
- ☐ Overemphasize payments

- Are subjects pre-screened in recruitment?
- Are waivers of consent or documentation of consent needed?
- Are pre-screening data handled appropriately?
- Is compensation reasonable and not unduly influencing subjects?
- Are payments pro-rated?

Other:

Risks (#16)

Yes No N/A

- Is there a clear and accurate identification of risks?
- Are any risks from deviations from standard care (e.g. standard educational practices with children) clearly described?
- If needed, is there adequate follow-up for subjects following participation?
- Are procedures for mitigating risks described and appropriate?

Comments:

Benefit Assessment (#17)

Yes No N/A

- The risks are reasonable in relation to the benefits, which include:

  - ☐ Generalizable knowledge
  - ☐ Improves treatment or system
  - ☐ Close monitoring
  - ☐ Potential therapeutic intent
  - ☐ Potential early diagnosis
  - ☐ Other

Comments:

Privacy and Confidentiality (#18)

Yes No N/A

- Does the researcher have plans to present/publish their research outside of MSUB?
- Are procedures adequate to protect data confidentiality or anonymity?

Yes No

Does the researcher collect the minimal amount of identifying information necessary to achieve the aims of the study?

Is the investigator collecting any information such that the identification of the subjects or their responses could increase the risks to the subject?

Consider:

- Information about personal use of alcohol drugs or other addictive products
- Information about sexual attitudes, preferences, practices
- Information about illegal activities
- Information that could damage an individual's financial standing, employability, or reputation within the community
- Information in a subject's medical record that could lead to social stigmatization or discrimination or information about psychological well-being/mental health

If YES, are there reasonable and appropriate safeguards to ensure the risks related to the invasion of privacy and breach of confidentiality are no greater than minimal?

Comments:

Data Management and Security (#18)

Yes No N/A

Will computer data be held in a secure manner?

Will audio/visual data be held in a secure manner?

Is there a plan to disguise or destroy unintentional identifying information collected during the recordings?

Will paper records be held in a secure manner?

Will biological samples be stored securely?

Is the data destruction plan acceptable?

Comments:

Consent Process (#19)

Yes No N/A

Are the procedures adequate to inform and negotiate consent?

Is sufficient opportunity given to the prospective participant or representative to read and consider whether or not to participant?

Are there elements of influence/possible coercion to entice consent (e.g., excessive compensation, unequal relationship such as instructor-student)?

Will non-English speaking subjects be enrolled?

YES NO If so, have they included a certified translation?

Is consent appropriately documented and a copy of the signed and dated consent form given to the person signing the form?

Comments:

Consent Form Checklist

If involving individuals under 18, all need to be true for consent AND assent forms.

Yes	No	N/A	
◯	◯	◯	If involving individuals under 18, is an assent form included?
◯	◯		Is the consent form written in language understandable to the participants?
◯	◯		Is the possibility of coercion minimized?
◯	◯		Is information provided enough for subjects to make an informed decision?
◯	◯		Does consent form information (risks, benefits, description) match that described in the application?
◯	◯	◯	If project excludes those under 18, is there clear language stating as much?
◯	◯	◯	If recording participants, is there a separate line/form for subjects to consent to recording?

Are the following required elements of informed consent described/included?

Yes	No	N/A	
◯	◯		Duration of participation
◯	◯		Purpose of the research
◯	◯		Procedures to be followed
◯	◯	◯	Procedures that are experimental (if any)
◯	◯		Risks
◯	◯	◯	Benefits
◯	◯	◯	Disclosure of appropriate alternatives (if applicable)
◯	◯	◯	Extent to which confidentiality of records will be maintained (if applicable)
◯	◯	◯	Contact info for PI, IRB (and faculty mentor if applicable)
◯	◯		Statement that participation is voluntary
◯	◯		Statement that participant can quit at any time without penalty

Comments:

Conflict of Interest

Yes	No	N/A	
◯	◯	◯	Have the PI and all co-PIs checked the proper boxes?
◯	◯	◯	If a conflict of interest is acknowledged, is a description of the conflict included?

Comments:

CITI Training

Yes	No	N/A	
◯	◯	◯	PI and all CO-PIs have completed CITI training.

Comments: