Grodno State Medical University

IRB Application for Human Participant Research

v.1.0

INSTRUCTIONS: Download this form to your computer. Then open, edit, and save the file using XODO reader. Using any other platform or program, such as the Apple PDF viewer, *will corrupt this form*. Please download the most recent version of free application XODO *before* using this form. Fields marked * are required.

IRB use only:

Date Received: | Sent to Review: | Date Approved/Exempted:

CR Required? ◉ YES ○ NO | Next CR date: | Most recent revision date:

1. PROTOCOL TITLE

Title of Project*:

IRB Log No. (*Assigned by IRB*):

2. PROJECT DATES

NOTE: Project work may **not begin** prior to approval or exemption from the IRB.

a. Anticipated starting and completion dates*: to

b. Will this project be conducted on an annual basis*? ○ Yes ○ No

3. PRINCIPAL INVESTIGATOR INFORMATION

a. Contact Information

Principal Investigator*:

Department or Affiliation*:

Email*: Phone*:

b. PI Status*: Select One

c. GRSMU Teacher / Staff as a Supervisor / Mentor

Name :

Department or Affiliation :

d. Student / external investigator information (Projects involving GRSMU Faculty / staff / students exclusively may SKIP the section below)

Name:

Affiliation :

Email :

Phone :

4. FUNDING

Is this project being funded by a source external to GRSMU*? ○ Yes ○ No

If YES, list the funding source and/or sponsor name below:

5. **RESEARCH STATEMENT*:** Provide a brief summary or abstract of your project. Include information about the motivation, research hypothesis, and goal(s) of the study. Cite previous research where applicable. Specific or technical jargon should be avoided or explicitly explained.

6. **RESEARCH RESULTS*:** What will you do with the results of the study? (e.g. publish, present publicly, upload results onto an online or cloud-based platform, archive the data for a future project, etc.)

7. **PARTICIPANT POPULATION***

a. Indicate which of the following groups will be research participants (check **ALL** that apply):

- ☐ Adults
- ☐ Minors (under 18)
- ☐ Students
- ☐ Psych Pool
- ☐ Employees in a work setting
- ☐ Single Subject Populations (e.g. by Gender, Race, Ethnicity, or Religion)
- ☐ Other groups, please specify:
- ☐ Senior Citizens (over 65)
- ☐ Institutional Residents
- ☐ Mentally/Physically Disabled
- ☐ Cognitively Impaired
- ☐ Terminally Ill
- ☑ Prisoners or parolees
- ☐ LGBTQ+
- ☐ Homeless Persons
- ☐ Addicts

Please describe the study population characteristics, including inclusion/exclusion criteria, if applicable:

b. Research Involving Students of GRSMU as subjects

Will you include students from GRSMU as subjects*? ◯ Yes ◯ No

If "Yes", explain how you will ensure you will know which of your students have or have not consented to participate. Please consult IRB Members and authorities before you begin your work.

c. Population Size

What is the approximate number of participants to be recruited*?

If applicable, please describe the targeted number or percentage for each arm of the study:

d. Recruitment*

How will participants be recruited*? direct patient interaction, database access, others. (describe below)

8. INFORMED CONSENT*

See the IRB Guidelines on Informed Consent for more information and for helpful templates. Attach ALL applicable consent and assent materials with this form. Check ALL that apply below.

a. Type of Informed Consent Obtained:

- ☐ Adult Consent
- ☐ Consent from an adult's Legally Authorized Representative (LAR), if applicable

Use of Minors (under 18 years of age)

- ☐ Parental/Guardian consent
- ☐ Child/Minor Assent for non-readers (not able to read or not proficient at reading)
- ☐ Child/Minor Assent for proficient readers (can read and understand a simple assent form)

b. Waiver of Informed Consent:

Indicate if participants will not be informed and consent will not be obtained prior to the study. See the IRB Administrator for the *very specific circumstances* in which informed consent may be completely waived. If consent will not be obtained, please offer justification in the box below.

- ☐ Adult informed consent will not be obtained
- ☐ Parental/Guardian consent will not be obtained
- ☐ Child/Minor assent will not be obtained

If any of the items in **8.b** are checked, please justify why informed consent will not be obtained. Please see the IRB Administrator for guidance on this specific situation.

c. Method to Document Informed Consent: Please check (i) or (ii)*

(i) ◯ Written Consent/Assent with signature(s) will be obtained from participants

(ii) ◯ No signed Consent/Assent will be obtained (Documentation of Consent is waived)

If **(ii) is checked**, a *waiver of signature* is requested. Indicate below how participants will be informed and will grant consent:

☐ A paper **Information Sheet** will be presented to participants. Explain rationale below.

☐ **Oral Consent** will obtained from participants. Explain rationale below.

☐ **Electronic Consent** will be obtained. (for online surveys, or other on-screen experiments) Study information will be presented electronically.

If **8.c.ii.** is checked, please explain the rationale for NOT collecting a signed informed consent form:

9. DATA COLLECTION & CONFIDENTIALITY ISSUES

a. Data collection methods, check **ALL** that apply*:

☐ Questionnaire or Survey
☐ Web or Internet
☐ Interview
☐ Observation
☐ Video or Audio Taping
☐ Computer Collected Task Data
☐ Collecting archived data or databases
☐ Intervention
☐ Focus Groups
☐ Testing / Evaluation
☐ Instruction / Educational Curriculum
☐ Physical Tasks

☐ Other:

b. Will the data be collected **anonymously** so that no one, *not even the researchers*, can determine who participated?*

◯ Yes ◯ No

c. If you answered **NO** to **9.b.**, describe procedures for keeping data confidential and secure. Be sure to explain how the data will be stored both during the data collection process and after the study is conducted since this will affect the confidentiality of the data.

10. METHODOLOGY*

Describe in clear detail *how* the research will be conducted, step by step. Be sure to address: how participants will be identified, contacted, and recruited; how informed consent will be handled; the location where the study will take place; how all the data will be collected; how participants will be debriefed, if applicable, and how the data will be analyzed. If you are using an electronic survey (Qualtrics, Google Forms, etc.), provide the link to the survey. Reference all attachments when applicable.

11. RISK FACTORS*

Does your study involve any of the following elements*?

a. Coercion or undue influence, or the potential for coercion ◯ Yes ◯ No

b. Procedures that might cause mental discomfort ◯ Yes ◯ No

c. Procedures that might cause physical discomfort ◯ Yes ◯ No

d. Collection of information that, if disclosed, could be embarrassing or harmful to participant's reputation, employability, financial standing, or insurability, or place the participant at risk for criminal/civil liability ◯ Yes ◯ No

e. Procedures that might cause physical harm to participants ◯ Yes ◯ No

f. Biomedical procedures, including the use of drugs or EEG recorder ◯ Yes ◯ No

g. Participants will be audio or video recorded, or photographed ◯ Yes ◯ No

(i.) Describe any other potential risks to participants besides those above. You should consider potential physical, psychological, social, legal, or other risks*.

(ii.) For ALL potential risks, assess both the likelihood of their occurring and their seriousness, even if you think these risks will be avoided*.

(iii.) Describe the procedures you will use to mitigate these risks as well as any provisions for ensuring necessary professional intervention in the event of a distressed participant or other adverse event*.

14. SUPPORTING MATERIALS*

All supporting documents must be submitted with this application. The IRB will review all materials that are presented to or seen by any participants during the study. Indicate below what materials will be attached to this application. Check **ALL** that apply:

- ☐ Recruitment materials (flyer, social media post, recruitment email , etc.)
- ☐ Informed Consent documentation (all formats)
- ☐ Data instruments (surveys, interview questions, tests, links to internet surveys, etc.)
- ☐ Debriefing statement
- ☐ Electronic survey link(s):
- ☐ Other (specify):

Provide all supporting documents separately while submitting the the IRB application form.

15. CERTIFICATION STATEMENT*

ALL investigators who are engaged in this research, including the analysis of human subject data, must be listed on this application and must read and agree to the **Certification Statement** as follows:

By providing my name below, I certify that I have read and I understand GRSMU's policies and procedures governing human subject research as described in GRSMU's Institutional Review Board Policy. I will fully comply with those policies and will not conduct any research activities without IRB approval. I further acknowledge my obligation to:

(1) Submit all significant deviations from the originally approved protocol immediately.

(2) Immediately report all adverse events to the IRB.

Name of Principal Investigator*:

Today's date*:

CO-INVESTIGATORS:

All communication with the IRB Office must include all members of the research team listed on this application, as well as the research sponsor, if applicable. All the co-investigators listed below have read and have agreed to the **Certification Statement** above.
Names must be entered in order of authorship.

1. MENTOR
NAME -
EMAIL -
DEPARTMENT / AFFILIATION -

2. PRINCIPAL INVESTIGATOR
NAME -
EMAIL -
DEPARTMENT / AFFILIATION -

3. NAME -
EMAIL -
DEPARTMENT / AFFILIATION -

4. NAME -
EMAIL -
DEPARTMENT / AFFILIATION -

5. NAME -
EMAIL -
DEPARTMENT / AFFILIATION -

***If more author names need to be listed, please request a customized form from the IRB.**

16. SUBMISSION INFORMATION

For IRB Use Only:

Review Notes:

Revision History:

Continuation History:

Adverse Events or Protocol Deviations:

Project Closed: