# Randolph-Macon College
# HUMAN RESEARCH PROTECTION PROGRAM
## Faculty or Staff Generated Research Application Form
## IRB #2 (Social/Behavioral)

**Submission Date:**

**Title of Project:**

**Principal Research Investigator Information (must be a faculty or staff member)**

Name

Highest Degree(s) earned and field

Campus Building and Office Number

Office Phone RMC E-Mail

Principal Investigator Academic or Staff Assigned Department:

Have you ever had any research privileges or license suspended or removed? Yes ☐ No ☐

If yes, where, and why?

Are you or any member of your research staff under sanction by any state licensing board, Office of Research Integrity board, or any other research-related investigation? Yes ☐ No ☐

If yes, explain.

Have you been a Principal Investigator in the last 5 years? Yes ☐ No ☐

How many years have you been conducting research in any capacity?

Have any of your studies been suspended or terminated? Yes ☐ No ☐

If yes, an submit explanation as an attachment to your application.

Have you or any member of your research staff been under sanction for unethical behavior in research activities? Yes ☐ No ☐

If yes, submit explanation as an attachment to your application.

**<u>Research Staff</u>:** *(Co-Investigators and other research staff). Please list the name and position of each person on your research staff. For research staff outside of RMC, please list each individual's place of employment with their position.*

Name Position

Name Position

Name Position

Name Position

Name Position

Name Position

Is there an adequate number of qualified staff? Yes ☐ No ☐

**Research Funding**

Is this study sponsored? Yes ☐ No ☐

If yes, what Federal Department, agency, or foundation is sponsoring the research?

If yes, please attach a copy of the grant application or proposal with your submission. *Note: If this is a Federally Funded study the grant application or proposal must be approved by the IRB in accordance with 45CFR46.103(f).*

Sponsor Contact Name (if applicable):

Sponsor phone: Sponsor E-Mail:

**Research Project Information**

What is the purpose of this research?

Please outline the scientific or scholarly rationale for the research

Please give a detailed description, either in paragraphs or bullet points, of the protocol or procedure to be performed. Be specific, including all steps in the process:

If on-site data collection is done:
Will you be on the premises whenever data are collected? Yes ☐ No ☐
If no, what supervision will be provided on site?

Will you be on the premises whenever follow-up is done? Yes ☐ No ☐
If no, who will conduct the follow up data collection? Indicate their name, degree, and position:

Is any special training required to do the data collection required in this study? Yes ☐ No ☐
If yes, explain.

Is this a multi-center study? Yes ☐ No ☐

If yes, list external sites where the research will be conducted (e.g., schools, business, and health care facilities) and subject to the review of the Randolph-Macon College IRB. For each site indicate:

- The name of the site
- Whether the site has an IRB
- Whether the site has granted permission for the research to be conducted (attach approval letters)
- Contact information for the site
- If the site has an IRB, has the IRB approved the research or do they plan to defer to the R-MC IRB?

If yes, describe the management and communication among sites of information obtained in this research that may be relevant to the protection of research participants, such as:

- Unanticipated problems involving risks to participants or others
- Interim results
- Protocol modifications

**Study Subjects and Procedures**

Does the study involve ONLY records review? If so, skip to the next section. Yes ☐ No ☐

Total number of anticipated subjects (minimum number – maximum number)

Minimum age of subjects

Maximum age of subjects

*(**Note**: If subjects are minors, consent must be obtained from both the subject and a legal guardian.)*

Does the research present more than **minimal risk**? Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research 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.

Yes ☐ No ☐

If yes, describe the provisions for monitoring the data collection to ensure the safety of participants.

Will you have the availability of medical or psychological resources that participants might require because of the research? Yes ☐ No ☐

Does your study target a specific population by identity? (for example, gender, race, socioeconomic status, sexual orientation) Yes ☐ No ☐
If yes, please explain the rationale:

Does the study include **protected populations**? Yes ☐ No ☐
If yes, please explain the measures you will include to make sure you are following the appropriate rules to study protected subjects. Protected subjects include mentally and physically disabled persons, children, pregnant persons and neonates, incarcerated individuals, students where the researcher is their instructor, employees where the researcher is their employer, educationally disadvantaged individuals, etc.

How will you recruit subjects? Please note that sending mass emails to any RMC mailing list requires Provost approval.

Are there any finder's fees involved in recruitment? Yes ☐ No ☐
If yes, explain

How will informed consent be obtained?

Will the Principal Investigator obtain consent? Yes ☐ No ☐
If no, state who will conduct consent and describe their informed consent training.

What steps will be taken to minimize the possibility of coercion or undue influence?

How long will the potential subject have to decide to take part in the study?

Describe the provisions included in the protocol to protect the **privacy interests** of participants

| | | |
|---|---|---|
| Will any of the subjects have a primary language other than English? | Yes ☐ | No ☐ |
| If yes, is there an experienced translator available? | Yes ☐ | No ☐ |
| If yes, will the consent form be translated? | Yes ☐ | No ☐ |
| Will subjects be paid or endure charges for participation? | Yes ☐ | No ☐ |

**Records Collection and Storage:** Data (including record of informed consent when applicable) must be safely stored by the Principal Investigator for a period of at least 3 years after the termination of the data collection. Data must be stored separately by the informed consent. Data must be stored either on a password-protected college-issued device or inside a locked cabinet in a locked office.

Who will have access to the research record(s) besides your research staff and the agencies already authorized access such as FDA auditors, other federal auditors, and Study Coordinator?

Where will subjects' records be stored during the study?

Where will the signed consent form(s) be stored?

Where will subjects' records be stored after completion of study?

Are subjects' forms coded to protect privacy? Yes ☐ No ☐

If yes, where will the key to the code be stored?

If yes, who will have access to the code key?

**Please sign the attestation below and submit your IRB application to IRB@rmc.edu with the following supporting documents:**

1. A copy of any recruitment materials that will be utilized, including texts of emails, posters, solicitation letters, etc.
2. A Financial Interest Disclosure Form for the PI and each investigator.
3. A copy of your informed consent form (or text, if consent will be obtained digitally).
4. A current CV for each PI and co-PI

**ATTESTATION**

This certification verifies that I have completed all training required for the submission of this protocol:
1) Read, understand, and will abide the Belmont Report, and
2) completion of the CITI Educational Course Modules.

I am responsible for the conduct of this research protocol, including the co-investigator(s) and other research staff. I have certified that all co-investigator(s) and other research staff have completed the training requirements and signed the Financial Interest Disclosure Form.

I hereby certify that:

- The information contained in this document is accurate and correct.
- I will carefully follow the approved research and submit **ALL** changes to the IRB for consideration **BEFORE** incorporating them into the study.
- I will notify the IRB of:
  - any deviations from the approved research taken in an emergency to protect the subject from harm.
  - any unanticipated problem, or serious, unusual, or unanticipated **adverse event**.

I or my designee will abide by the informed consent process with each subject and document this process on the approved consent form, allowing each subject adequate time before the study to decide voluntarily to participate in this study.

I will protect the rights and welfare of each subject to the best of my ability.

PI Name: Submission Date: