Randolph-Macon Investigator Guidelines for the Conduct of Research Involving Human Subjects

The purpose of these Investigator Guidelines is to help researchers navigate through policies and procedures related to the conduct of Human Subject Research that are specific to Randolph- Macon College. In these guidelines, we have tried to provide answers to frequently asked questions. While this manual cannot possibly address every situation or question that may arise, it is designed to serve as a reference guide to assist you in your efforts to conduct human subject research and assist in protecting the rights and welfare of human participants in accordance with federal standards in Human Research Protection Programs (HRPP), such as the Federal Wide Assurance (FWA) with the U.S. Department of Health and Human Services Office of Human Research Protections (OHRP).

The complete list of the policies and guidelines for human research can be found in the manual Standard Operation Procedures for the Human Research Protection Programs on the IRB website.

Table of Contents

I. Mission of the Randolph-Macon IRB Board 3

II. What is Human Subject Research? 3

III. How Do I Know if I am Doing Research? 4

IV. How Do I know if My Research Involves Human Participants? 4

V. Do Classroom Projects Require IRB Review? 5

VI. Do Internet/Online Based Projects Require IRB Review? 6

VIII. Who Can be Listed as a Principal Investigator? 7

IX. How Do I Submit My Study to the IRB? 7

X. What are the Components of an IRB Submission? 7

XI. How do I Write an Abstract? 8

XII. How do I Write a Protocol? 9

XIII. Informed Consent. 9

Does My Study Need an Informed Consent? 9

Which Informed Consent Do I Use? 9

XIV. How Long Does It Take to get IRB Approval? 9

XV. How do I Complete the IRB Application? 10

Part I 10

Part II 11

Part III 12

Part IV 13

XVI. How Do I submit a Change in the Protocol of an Approved Application? 13

XVII. How Do I Address Allegations or Issues of Non-Compliance? 14

XVII. How do I Address Unanticipated Problems Involving Risks to Participants or Others? 14

I. Mission of the Randolph-Macon IRB Board

The primary mission of the IRB is to protect the individuals participating in the research process. The Randolph-Macon guidelines for research with human subjects are based on the three principles outlined in the 1979 Belmont Report. Reading and evaluating the Belmont report is mandatory for any principal investigator interested in human research, and as such it is an integral part of the certification offered by the Collaborative Institutional Training Initiative (CITI) program. A link to the CITI program can be found in the IRB website (http://www.rmc.edu/offices/institutional-review-board/education-citi-certification).

The secondary mission of the IRB is to protect principal investigators from potential claims of misconduct. Violating rules established by the Belmont Report is a serious matter that can have long-term adverse consequences for a principal investigator, even if these violations were performed without malicious intent.

II. What is Human Subject Research?

Randolph-Macon follows the regulatory definitions of "Human Subject Research", which are defined as follows:

Under DHHS regulations (45 CFR §46.102(d)) 'Research' is defined as: *A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.*

> Examples: (a) Case studies and individual interviews do not constitute research. You are encouraged to receive an informed consent from the specific individual, but the IRB does not need to review your application. (b) Class projects that do not leave the classroom do not constitute research.

Under DHHS Regulations (45 CFR §46.102(f)) 'Human Subject' is defined as: *Living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.*

> Example: (a) If you are using public marriage records, the IRB does not need to review your application. (b) If you are using data collected by other agencies or individuals and no personal identifier is included in the data, the IRB does not need to review your application.

If you have questions about whether an activity is Human Subject Research, you can speak to IRB Chair or submit an abstract to the IRB Committee and they will make a determination.

III. How Do I Know if I am Doing Research?

Research is defined as a systematic investigation designed to develop knowledge that can be generalized. If you plan to present or publish the work or otherwise share results of the study, it is probably research.

If you are planning on presenting the data of your project on human subjects at an academic conference, publish the data in an academic journal, or use the human subjects research data in a master's thesis or doctoral dissertation? If the research is occurring in a class, will the results be disseminated anywhere outside the classroom (in a poster, presentation, as a SURF presentation, submitted as a writing sample to graduate school, etc.)?

If NO: your project is not considered research and does not require IRB review.

If YES: your project is considered research and requires IRB review. It may however be *EXEMPT* (see pg. 14 of this guide for the definition of the different categories).

Note: If no public dissemination is planned at the time the data is gathered, but the possibility of future dissemination exists, you are advised to submit the project for IRB review and approval before initiating the research project. **IRB approval for Human Subjects data cannot be obtained retroactively.**

IV. How Do I know if My Research Involves Human Participants?

Human participants are defined as: living individual(s) about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information.

Some examples of subjects/participants include:

- Individuals who are asked to complete questionnaires, participate in interviews, or whose behavior is observed in daily activities.
- Oral history interviewees whose subjective perceptions are studied.
- Students and teachers observed in the classroom for the study of various teaching methods or development of curricula.

If NO: you do NOT need IRB approval

If YES: Your project most likely needs IRB review.

V. Do Classroom Projects Require IRB Review?

Certain activities have the characteristics of research but do not meet the regulatory definition of research needing IRB review. Examples of activities that may not need IRB review are:

- Data collection for internal departmental, school, or other College administrative purposes (e.g. teaching evaluations, course evaluations) that are NOT disseminated in public form.
- If research is a class project or term paper and will not be published in any form at any time outside of the class.
- Reviews and searches of existing literature and research involving a living individual, such as a biography, that is not generalizable beyond that individual.

Use the following guidelines to determine if your activities in the classroom are subject to IRB review.

IRB review is NOT required if **ALL** of the following are true:

a. The project is limited to surveys/questionnaires/interviews/observations of public behavior directly related to topics being studied in an official college course.
b. The above surveys/questionnaires/activities, etc. contain no sensitive personal questions (e.g., no questions about drug use, sexual behavior or attitudes, criminal activity, grades, medical history) or other personal information that could stigmatize an individual.
c. No identifying information is recorded to link a person with the data such that it could reasonably harm the individual's reputation, employability, financial standing, or place them at risk for criminal or civil liability.
d. The participants in the project are not from a vulnerable or special population (e.g., pregnant women, prisoners, minors, cognitively impaired individuals).
e. The collected data does not leave the classroom setting in any way.
f. No employee or student is receiving financial compensation for collecting, organizing, analyzing, or reporting the data.

If any of the above are not true, or if your project does not fall into any of these categories, your project will require IRB review and formal IRB approval before you can start with your project.

The following are examples of projects that do require IRB notification but are *exempt* from IRB review. Nonetheless, **formal paperwork needs to be submitted to the IRB prior to the start of the project since the decision on the *exempt* status is the sole responsibility of the IRB committee**.

- The study of or comparison among instructional techniques, curricula, or classroom management methods.
- The collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is

collected in a way that cannot be linked either directly or through identifiers to an individual.

Even in the case where a project is not subject for review, the instructor/faculty member is responsible to uphold all applicable (e.g., American Psychology Association, American Counseling Association, National Institute of Health, etc.) ethical standards and guidelines in course-related research activities when it comes to the treatment of human subjects.

It is the responsibility of the supervising instructor/faculty member to determine whether projects are subject to review. It is always best to err on the safe side and seek consultation from the IRB committee if a question arises regarding human subjects, research and classroom activities.

VI. Does "Existing Data" Analysis Require IRB Review?

Existing data are also called secondary data. Such secondary data analysis involves using existing data from other sources to answer new questions.

IRB review and approval is *NOT needed* if the source of the data is public (e.g., data from public libraries or newspapers) and analysis of the data will not make the data individually identifiable.

IRB review and approval *IS needed* if the source of the data is not public (e.g., government and private data bases) and/or the existing data has not been previously received IRB approval. Please note that is the existing data has already received IRB approval, the IRB *does NOT need* to review your application.

VI. Do Internet/Online Based Projects Require IRB Review?

If the data collected via the Internet and computers involves human subjects and is intended for eventual publication purposes, then it requires IRB review and approval.

All such studies involving internet technologies must ensure compliance with the principles of voluntary participation and informed consent, the anonymity and confidentiality of the participants, and address the potential risks to the human subjects involved.

VII. What is the Difference between Student-Generated and Faculty-Generated Research?

To best serve the needs of Randolph-Macon College, our Institution has elected to follow a dual-path for human subject research. All class projects involving human subjects, including but not limited to capstone, RATS, Research Day and Senior Projects, will follow the application process specified under "Student-Generated Human Subject Research" (http://www.rmc.edu/offices/institutional-review-board/irb-review-where-do-i-begin/what-information-do-i-submit).

All projects pertinent to the faculty, more specifically all projects supported by grants (both intramural and extramural of any kind and from any agencies, including but not limited the National

Science Foundation and the National Institute of Health) will follow the standard IRB procedure specified under "Faculty-Generated Human Subject Research".

VIII. Who Can be Listed as a Principal Investigator?

The principal investigator is the person ultimately responsible for the research and protection of human subjects, and of all communication with the IRB. It is the principal investigator's responsibility to ensure the study is being conducted in the manner approved by the IRB. It is also the principal investigator's responsibility to ensure the safe storage of the data and personal information retrieved from the study. Finally, it is the principal investigator's responsibility to ensure compliance with the auditing processes (both internal audits from Randolph-Macon representatives and external audit from the federal agencies such as the OHRP representatives).

Only a faculty or staff member can be listed as the Principal Investigator (PI) on any submission to the Randolph-Macon IRB. This is true for both student-driven and faculty-driven applications.

The PI is responsible for the entire submission process including any communication with the IRB Committee. Students cannot submit an application directly to the IRB, the PI must do so. The PI is also responsible for the safe storage of the data and the auditing processes.

IX. How Do I Submit My Study to the IRB?

Electronic submission of IRB applications can be submitted via email to the IRB chair. Check the IRB website for updated contact information for the Chair. When submitting the electronic version, be sure that all of the documents requested are included, as a single pdf file if possible. The title of the electronic submission should include the name of the principal investigator and the title of the project (example: *John Smith-Coping strategies in college students*). The IRB chair will then assign a submission number to the application, which will be included on future correspondence.

Incomplete applications, or applications containing incomplete information will be sent back to the principal investigator *without* a review. It is in the best interest of the principal investigator to provide as much information as possible during the process, to reduce the time of the application process.

X. What are the Components of an IRB Submission?

The research protocol, application, abstract and informed consent form are key components of all IRB submissions. Although some exceptions to this rule might exist, generally speaking any new application must provide these four key components. All principal investigators must obtain a certification from the CITI Training service before they can apply for a human research project. Students involved in Student-Generated projects do not need a CITI certification (see below).

For "Student-Generated Human Subject Research" you should submit the following documents:

- Application
- Protocol
- Abstract
- Informed Consent(s)
- Any surveys or other instruments you will used, in their finalized form.

The IRB Chair will confirm CITI completion of the PI upon receipt of the application.

For "Faculty-Generated Human Subject Research" you should submit the following documents:

- Application
- Protocol
- Abstract
- Informed Consent(s)
- Copy of CV/Resume for everyone involved in the study (*PI and research assistants included*)
- Attachment C for all co-investigators / staff
- Recruitment materials (if *applicable*)

The IRB Chair will confirm CITI completion of the entire research team upon receipt of the application.

XI. How do I Write an Abstract?

An abstract should be written in lay terms and provide a brief summary of the study. The abstract must be 1 page minimum and provide the reviewer a complete and accurate description of the procedures to be performed. All of the following information should be addressed in the abstract:

- The Purpose of the Research
- The Scientific or Scholarly Rationale:
- The Procedures to be Performed:
- A Description of What Procedures Were Being Performed Already for Diagnostic or Treatment Purposes *(if applicable)*:
- The Risks and Potential Benefits of the Research:
- Complete Inclusion/Exclusion Criteria

The bullet statements above should be paragraph headers on your abstract. Address each topic individually paying particular attention to the section titled *"The Procedures to be Performed."* In this section it is imperative you provide step-by-step instructions concerning the process of data collection.

XII. How do I Write a Protocol?

In the protocol, the principal investigator should include details about the instruments and methods used in the data collection. If surveys are distributed, the complete survey must be included in the protocol. Any interaction between the researcher(s) and the participants must be detailed in the protocol. All of the following information should be addressed in the protocol:

- All the tools, instruments, materials used in the research.
- An explanation of the rationale for the methods and materials used.
- Any specific risks for the participants related to the methods and materials used.
- The briefing and de-briefing process.

The protocol is needed to review the actual instruments and tools involved in the data collection.

XIII. Informed Consent.

Does My Study Need an Informed Consent?

Yes. In the rare situations in which obtaining an informed consent can put a participant at risk, a waiver can be requested. When requesting a waiver of the informed consent, principal investigators should consider that a Full-Review Board will be necessary to process their submission. Informed consent templates can be found on the IRB website.

Which Informed Consent Do I Use?

It is important that you choose the Informed Consent appropriate for your study. Informed Consent templates are available on the IRB website for your use. These templates incorporate all of the required elements of an informed consent. It is important that you stick to the template as closely as possible.

XIV. How Long Does It Take to get IRB Approval?

For "Student-Generated Human Subject Research" the IRB process usually takes two weeks. Longer times can be expected depending on the number of revisions identified by the IRB members during the review process and the number of applications submitted. For class projects, usually the end of the semester is very busy and dozens of applications can be submitted at once. To ensure a timely review of your application, submit as soon as you can. The review of the revised application can also take a week or longer. Since requests for revisions and/or clarifications are common, **the principal investigator should submit the application at least 3 weeks prior to the planned start of the human subject recruitment**.

For "Faculty-Generated Human Subject Research" the IRB process usually takes a minimum of 2 weeks, and a maximum of one month. More time may be required, however, if the IRB has identified the need for multiple revisions. The review of the revised application can also take several weeks, unless the revisions are minimal and can be reviewed by the Chair of the IRB

committee. The principal investigator should plan ahead keeping these timelines in mind, especially for projects that are usually carried out in a short amount of time.

XV. How do I Complete the IRB Application?

For "Student-Generated Human Subject Research" the IRB application is a simplified form summarizing the information needed by the IRB Committee to review the submission.

For "Faculty-Generated Human Subject Research" the IRB application is a substantially new document, as of 2016, that requires information according to federal rules and regulations. This application is comprised of several parts. It is important you answer each question on the application. Though some of the questions may not apply to your specific research, you must either answer "No" or "N/A" at a minimum.

Part I

This section covers the personal information of the principal investigator.

Research Staff: This is the section where you will list all of the co-investigators and students involved in the study. Everyone listed in this section must complete an Attachment C. The Attachment C provides the personal information for each co-investigator/staff and is similar to the information provided by the principal investigator. Separate Attachment C forms are available on the IRB website or you can just add more pages to the end of the application.

Remember that whenever the word "you" is used in an application question it is referring to the principal investigator. This is important because some questions ask if "you" (meaning the principal investigator) will be on the premises whenever data are collected. If data is being collected by a co-investigator or research staff, then the principal investigator may not be on the premises when data is collected. If you will not be on the premises when data is collected, you should state who will conduct that part of the research.

Be sure to list the external sites where research will be conducted (e.g., schools, business, and health care facilities). You must have written permission from each of these sites. If you are going to use all of the schools in a particular county, permission from the county superintendent will suffice. We do not have a template for permission letters. You just need the person granting permission to state they understand the purpose of the study and grant permission for you to conduct your study at their institution/business. Scan the approval letters and save them as PDFs so you can attach them to your submission.

Part II

Title: In this section you list the title of the project. Make sure the title you insert here matches the title listed on all other documents.

The question concerning minimal risk is very important. If your research is more than minimal risk you will need full board approval for your study. If your research is not more than minimal risk (Exempt/Expedited), it will be reviewed and approved by two IRB Committee members designed by the IRB Chair.

Definition of Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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 [Federal Policy §__.102(i)].
Examples: (a) the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination; *(b) the risk of upsetting a participant asking personal questions for research is no greater than the risk of doing so as a part of a normal conversation*.

Sponsored Studies: Enter the federal department or agency sponsoring the study and, if applicable, include contact information. If not applicable, you can mark this section "N/A."

Study Subjects and Procedures: It is important that you let the IRB know the number of anticipated subjects in your study. For instance, if you are conducting a survey in a Social/Behavioral environment (with detailed demographics), the number of participants is critical in the evaluation of possible identification. A large number of participants would minimize the risk; however, a small number may put the participants at risk of identification.

In the age section you must indicate the age of participants. If the age of the participant is under 18 you will probably need a child assent. If all participants will be 18 or older, and there is no maximum age, you can simply insert "18+" in the age section and "N/A" for the maximum age. If there is a specific age range for your study, insert that information.

Recruitment: In this section you will state the location from which you will draw your subjects (i.e. a certain business, random samples, clinic patients, etc.). If you will use any advertisement you will need to include it with your application.

Informed Consent: You need to let the IRB know what type of consent(s) you will use (i.e. signed consent, survey consent, verbal consent, parental consent, etc.). A copy of the consent/assent must be attached to your IRB submission.

If the principal investigator will not conduct the consent, you must list who will perform this procedure. The person conducting the consent must be listed on the study as part of the research

staff. The consent training can be the CITI course that each principal investigator/co-investigator/staff must complete.

Confidentiality: It is important that you list where the consent forms will be filed. This can be of great concern to the IRB chair if the study is of a sensitive nature. There is also a question concerning copies of the consent. Generally, the consent forms are only copied in the case of a sponsored study where the sponsor requests to receive a copy. Keep in mind that a copy of the consent form is required to be provided to the participant.

List where the subject's records will be kept during the study. Again, if the study is of a sensitive nature the IRB chair will be concerned with safe keeping. You will also be required to state where the records will be kept after completion of the study. Confidential information should be stored in a locked cabinet in a secure location (usually the principal investigator's office), away from the main database including the anonymous measurements for the study. Once the study is complete the records should be stored with the principal investigator and must be kept for a minimum of three years after completion.

If the study records are going to be coded for privacy you must complete that section. Be sure that the code used is not identifiable (i.e. Social Security Numbers, patient identification number, etc.). The key code should be stored separate from the study file to ensure the security of participant identities.

Privacy: Describe how you will protect the privacy of the participants. Confidentiality refers to a person's data and privacy refers to the actual person. For example, if you are going to do an interview, where will you conduct the interview? Will it be in a public area where others can hear? If your study involves a sensitive survey, will the participants be completing the survey where others can see their replies?

Monetary Issues: Answer the questions concerning subject payment/charges.

Part III

Training: All investigators, co-investigators and key personnel must complete the online Collaborative Institutional Training Initiative (CITI) course. This educational training is required as part of our Federal Wide Assurance (FWA) with the U.S. Department of Health and Human Services Office of Human Research Protection (OHRP). An FWA is our contract with the federal government, stating that we will abide by all federal regulations concerning human subject research.

CITI course registration instructions can be found on the IRB website under the Education/Training link. Please note that for faculty-driven submissions, all key members of the research team are required to complete the CITI training, including students and research assistants. **The IRB submission will not be processed until all required personnel have completed the human**

research protections training. The whole process should not require more than a few hours and the certification is valid for three years.

Part IV

Type of Review Requested:

The federal regulations, Title 45 CFR Part 46, describe three levels of IRB Review as detailed below. Note that the IRB will make the final determination whether your application is appropriate for *exempt*, *expedited*, or *full board review*. Therefore, all applications, including *exempt*, must be submitted to the IRB prior of the start of the research.

Exempt: Exempt research at Randolph-Macon College consists mainly of the following types of research: (a) research taken entirely from existing datasets or previously collected and published data that is IRB approved, and (b) Observation of public behavior ***unless*** that behavior could reasonably place the subjects at risks of criminal or civil liability. Only minimal risk research may be classified as *exempt*. Although investigators do not need IRB approval for research that is classified as *exempt*, the IRB needs to make the final determination if the exempt status is granted. Please contact the IRB chair to make a determination of whether your project qualifies as exempt.

Expedited: Certain types of research which pose no more than minimal risk and which do not involve protected populations may be reviewed without convening a full board meeting of the IRB. These applications are reviewed by a subcommittee of two board members.

Full Board: All other research projects, in particular research that poses greater than minimal risk to participants, including any research involving vulnerable populations, must be reviewed at a full convened meeting of the IRB Committee.

XVI. How Do I submit a Change in the Protocol of an Approved Application?

In the event that the Principal Investigator needs to change an already approved research project, all desired or contemplated changes in the research protocol or the consent form must immediately be reported in writing to the IRB. This is done using the "approved project change request form" on the IRB website. These changes may include any changes or new information that may affect the risk/benefit assessment of the study or any significant new findings that may affect, or relate to a subject's willingness to continue their participation in the research, as well as any other changes in research team, protocol, etc. For research projects sponsored by a third-part agency (e.g., NSF, NIH) it is the responsibility of the Principal Investigator to notify the Research Sponsor of all IRB actions.

XVII. How Do I Address Allegations or Issues of Non-Compliance?

Non-Compliance is failure to follow the regulations, the requirements of the Federal Wide Assurance (FWA), or the requirements and determinations of the IRB. Examples of non-compliance may include the following:

- Failure to obtain IRB approval for Exempt studies.
- Inadequate or non-existent procedures for the informed consent process.
- Failure to report protocol changes.
- Inadequate storage of confidential data, missing reports, missing informed consents.
- Failure to provide ongoing progress reports.
- Enrollment of subjects that fail to meet the inclusion or exclusion criteria of the protocol, which in the opinion of the convened IRB and the Provost's Office, increase the risk to the subject.

Serious Non-Compliance is an action or omission in the conduct or oversight of research involving human subjects that affects the rights and welfare of participants, increases risks to participants, decreases potential benefits or compromises the integrity or validity of the research. Examples of serious non-compliance may include the following:

- Conducting non-exempt research without IRB approval.
- Serious protocol deviations that may place subjects at risk from the research.

Continuing Non-Compliance is a pattern of non-compliance that, in the judgment of the Provost's Office, indicates a lack of understanding of the regulations or institutional requirements that may affect the rights and welfare of participants, would have been foreseen as compromising the scientific integrity of a study such that important conclusions could no longer be reached, suggests a likelihood that non-compliance will continue without intervention, or frequent instances of minor noncompliance.

Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance. Detailed instructions on the investigation and resolution of Non-Compliance Issues can be requested of the IRB Chair.

XVII. How do I Address Unanticipated Problems Involving Risks to Participants or Others?

For issues regarding unanticipated problems involving risks to participants or others, an investigator should contact immediately the IRB Chair.