The Institutional Review Board (IRB) is a seven to ten member committee whose task is to review all research conducted by VWC students, faculty, and staff that involves the use of human subjects. The purpose of the IRB is to make sure that this research is being done in compliance with Federal and Virginia State and University statutes for the protection of human subjects in research.

**FUNDAMENTAL IRB RULES**

Investigators conducting research in accordance with VWC policy must:

1. Obtain IRB approval prior to soliciting subjects or collecting data.
2. Provide potential subjects with information necessary to make an informed decision regarding participation in the study.
3. Protect the confidentiality of all subjects participating in research and all data that may be collected from the subjects, unless the researcher has provided thorough documentation indicating to participants that they will be identified in publication or dissemination.
4. Provide special safety procedures, as needed, to avoid any harm to subjects. Harm includes psychological trauma, physical injury, and the release of potentially damaging personal information.
5. Provide additional protection for “at risk” subjects, such as children, pregnant woman, the elderly, the infirm, and any person receiving treatment for a serious psychological or physical problem.
6. Provide immediate and follow-up care in case of research-related injury, and report any research-related injuries to the IRB Coordinator immediately.

Federal and Virginia State statutes and University policy require that investigators are knowledgeable about and comply with regulations for the protection of human subjects in research.

**CONTACT PERSON:**

Dr. Taryn Myers
tmyers@vwc.edu
Roop 3
IRB Co-Chair
Does Your Research Require IRB Review?

1. Yes, you need IRB review if the activities are considered research. Research means a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.

   The IRB considers generalizable knowledge to include the dissemination of research findings beyond the boundaries of the institution (e.g., publication or presentation or use outside the specific instructional setting).

2. Yes, you need IRB review if the activities involve human subjects. Research is considered to involve human subjects if it involves living individuals about whom an investigator obtains data through intervention or interaction with the individual(s) or obtains identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

   **There is human subjects involvement when:**

   1. Human beings are asked to participate physically in an activity or to donate their tissue, organs, fluids and other bodily material.

   2. People are asked to participate through interaction that solicits personal information (surveys, interviews, observation).

   3. Information concerning specific, individually identifiable human beings is asked for from third parties - whether through access to files, data banks, or other means - or through direct inquiry of third parties concerning the individuals in question.

Who Needs to Submit an IRB Application?

1. VWC faculty, students, or staff planning to conduct human subjects research.

2. Outside investigators must register their protocol with the VWC IRB prior to collecting data at VWC by filling out an IRB application and submitting a copy of the protocol that was reviewed by their home institution as well as a copy of the IRB approval letter.

Types of IRB Review

**There are three types of IRB review:**

1. Level 1 or Exempt Review (protocol approval is determined by the IRB co-chair).*

2. Level 2 or Expedited Review (protocol approval is determined by a single reviewer).

3. Level 3 or Full Review (protocol approval is determined by every member of the IRB).

*Please see below to determine if your research is exempt from IRB review.
Timeline for Submissions

Protocols must be submitted and approved prior to data collection or recruitment of human subjects.

The stated timelines and dates in the protocol must allow enough time for IRB approval. The IRB cannot retroactively approve data collection and protocols with unrealistic timelines and these proposals will be withdrawn from consideration.

Data collected without IRB approval cannot be disseminated or published.

The Submission Process

1. The investigator submits an electronic copy of a complete IRB application to the IRB Coordinator. Please note that the IRB may request a hard copy if needed. Any subsequent documents or revisions that are submitted must contain the researcher’s name and a clear indication that an IRB revision is attached.

SUBMIT TO: tmyers@vwc.edu

2. If the protocol qualifies for Level 1 (exempt) review, the IRB co-chair will email the investigator to indicate that the protocol has been approved (3-5 business days).

3. If the protocol does not qualify for Level 1 (exempt) review, the IRB co-chair pre-screens all protocols, enters the protocol in a tracking database, identifies any necessary preliminary revisions or missing documents, and sends the protocol to an IRB reviewer (time varies, but typically 2-4 days).

4. The IRB Reviewer examines the protocol, identifies any required revisions, and returns the protocol to the IRB coordinator (7-14 days).

5. The IRB co-chair will convert the review into a letter either approving the protocol or requiring revisions prior to approval. The IRB co-chair will then send this letter as an email attachment to the researcher (time varies, but typically 1-3 days).

6. The researcher then has as much time as is needed to revise the protocol and return the revisions via email the IRB co-chair. These revisions should be done in track changes and should also be highlighted in an answering letter to the co-chair’s revision letter. The IRB co-chair will then review the revisions and either approve the protocol or require additional revisions (time varies, but typically 1-3 days).

7. If the IRB co-chair determines that full board review is needed (e.g., a protected/vulnerable group, risky protocols, or sensitive questions such as questions about suicidality are used), then all of the IRB members will review the protocol and form a consensus opinion, which will be communicated to the researcher as in steps 5 & 6 above.
Does your research need to undergo review?

Your research does not need to undergo IRB review if it falls into one of the following categories:

A) Research is conducted in a commonly accepted educational setting (e.g., classroom, conference facility as opposed to a laboratory) and involves commonly accepted educational instructional strategies (e.g., exams) as opposed to psychological manipulations or non-instructional interventions. Research on the effectiveness of instructional techniques for the sole purpose of improved instruction within that class (not to be presented at a conference) would fall under this category. However, if such research is to be presented at a conference or published, you need to undergo at least Level 1 review.

B) Research (educational tests, surveys, interviews, observations of public behavior) is conducted completely anonymously such that the investigator never collects or records names and/or identifying information and the research involves the collection of benign information that could not be damaging to a person’s financial status, employability or reputation if disclosed. “Public behavior” is defined as behavior in places that any person can visit without special permission (e.g., street corners, parks, restaurants, theaters) or Internet communications in public forums. Observations of the public behavior of children do not qualify for exemption if the investigator interacts with them.

C) Research (educational tests, surveys, interviews, or observations) is conducted among elected/appointed public officials or candidates for office.

D) Research involves the collection and use of already existing data (e.g. archival documents, records, diagnostic specimens) that are publicly available or that are recorded in a manner such that the original participants cannot be identified (e.g. through an existing master list and identification number)

E) Research is conducted with the goal of studying or evaluating (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; (iv) possible changes in methods or levels of payment for benefits or services under those programs. This research must be approved by federal departments or agency heads and determined to be exempt by those departments and agencies.

F) Research is conducted with regard to a specific individual or group of individuals with no intent to generalize the information to a larger population. Biographies and oral history projects would be examples of research that would fall into this category.

If you believe that your research falls into the one of the above categories, then you do not need to contact the IRB regarding your intention to collect data. However, please remember that exempted studies are still considered human subjects research and investigators are expected to maintain high ethical standards for the conduct of the research. You should take all necessary steps to minimize risks to your participants and maximize research benefits.

In all other instances, you must submit an IRB application. Please see below.
Once under review, the IRB reviewer can either:

1. Approve the protocol.

2. Provisionally approve the protocol, pending the submission of revisions, additional documents, or information. The revisions are submitted to and reviewed by the IRB coordinator.

3. Request a Full IRB Review. Cases when this may occur:
   * The research involves greater than minimal risk to participants.
   * The subjects are a protected/vulnerable group (e.g., prisoners).

The IRB meets once a term or as needed. Full Reviews are scheduled as needed for the next available meeting. Investigators are notified by the IRB coordinator regarding the date, time, and location of the Full Review.

Please note: To avoid complications and problems, student projects should be designed such that they will not require a Full Review. The majority of students will not be qualified to work with these special populations; and the extended time frame of a Full Review is unlikely to meet the more immediate time frame of their projects.

4. Ask investigator to submit a new protocol. Cases when this may occur:
   * protocol is poorly written or lacks sufficient information for approval
   * investigator is a student who has submitted a proposal that requires Full Review (see note above)

5. Once the protocol is approved by the reviewer, and the investigator has submitted any requested revisions, the IRB coordinator notifies the researcher of IRB approval via email (1-7 days).

Does IRB Approval on My Project Ever Expire?

IRB approval is valid for one year. During that period, investigators may submit a description of any significant changes to their project to the IRB coordinator along with any documents that may have changed. Investigators must submit an Extension Request Form to continue with data collection beyond the one year approval period prior to the expiration date indicated on their IRB approval letter.
DOCUMENTS NEEDED FOR A COMPLETE VWC IRB APPLICATION

To ensure compliance the IRB requires that all investigators submit a standard set of documents designed to procure all of the essential information about a particular study prior to initiation of the research. All of the documents and materials that are submitted to the IRB are what constitute the IRB Application.

I. Training Verification

It is required that the investigator or sponsoring professor (if applicant is a student) has completed a mandatory online IRB training available at:
http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp

If the sponsoring professor has previously submitted a certificate of completion from the IRB training to the IRB coordinator, it is not necessary to include the certificate with every student application.

II. Application

The IRB application is composed of the following sections. It includes a request to use human subjects in research as well as a request to determine eligibility for exemption.

Please place an X on the appropriate line to request an exempt, expedited, or full board review. If the investigator is a student, a sponsoring professor must read and approve the student’s IRB protocol and electronically sign the application where indicated.

NOTE THAT ALL APPLICATIONS MUST BE SUBMITTED IN MICROSOFT WORD (.docx)

SECTION A: Summary of Research

Title of Research: Give the research a descriptive, distinctive title

Submitted by: The name and contact information of the primary research should be entered here. If the primary researcher is a student, the name and contact information of the sponsoring faculty member should be included.

Indicate if the research is funded by federal dollars.

Indicate if this is a resubmission the IRB. This section will be helpful when submitting requested revisions following the first round of IRB review.

Brief Abstract: Give a 150-word-or-less summary of your research project, including the major research question(s) and methodologies.

SECTION B: Summary of Research

a. Research Question: This section should outline the major research questions and/or hypotheses for the proposed research study, linking these questions to the existing literature if possible.
b. Methods: This section requires a full description of how you will carry out the proposed research. For Level 1 (Exempt) applications, this section need only specify which data will be used. For all other applications, this includes a description of any and all methods, instruments, and procedures utilized in this research. Provide details about any written materials that will be used (e.g., questionnaires, surveys, vignettes, interviews). If conducting an experimental manipulation, specific information is needed as to what phenomenon will be induced and/or how participant will be manipulated. If information is recorded by the investigator, be specific about how this will occur (e.g., written notes, photographs, audio/video recording, transcription). If participants will be recorded or photographed, the investigator should describe how these materials will be used and note this in the consent form.

This section also requires a description of the exact procedure that will be used. Be specific about what participants will be instructed to do and what they will encounter during each step of the study. Identify at what point in the process both the informed consent and debriefing will occur.

Include as an appendix to the application (in the same Word document) all data instruments, and other materials to be distributed to participants (e.g., surveys, questionnaires, interview questions, description of physical interventions or tests, data intake sheets).

SECTION C: Confidentiality
This section requires a description of how participants will remain anonymous and/or their responses remain confidential. Specify how you will insure that responses will not be linked to participant’s identity (e.g., how materials will be kept safe, who has access to the data, use of pseudonyms, or coding systems). Also indicate where any data will be stored when the research is completed.

SECTION D: Characteristics of Participants
This section requires a full description of the sample you intend to investigate. Please specify who the participants will be with respect to gender, age, ethnicity, and recruitment environment. Please specify here how the investigator will recruit participants (e.g., recruitment flyers/advertisements) and how the research will be advertised. Please note any inclusion/exclusion criteria for your sample here. Also note any compensation provided to participants for their involvement.

SECTION E: Consent
This section should clarify how informed consent will be obtained for adults and how assent will be obtained if participants are minors (see Informed Consent Materials below for more information). Informed consent forms must be included with the application.

SECTION F: Risks and Benefits to Participants
This section requires a summary of the benefits to participants and the risks to participants that may result from participating in this research. Potential benefits should outweigh potential risks. It is helpful to note how participants’ experiences in this study (e.g., what they are exposed to, what they are asked to discuss or think about) might compare to participants’ experiences outside this study (e.g., their day-today environment, media exposure). Any irregular or novel types of exposure should be explained.
SECTION G: Debriefing
In this section, specify what participants will be told about the study, what contact information is provided, and how potential distress will be handled. State how any deception will be explained to participants. Include a debriefing statement with your application.

Informed Consent Materials
Attach to the application the appropriate consent form, letter, or script containing all of the elements of informed consent. A sample informed consent form can be found on the IRB Blackboard page. The purpose of informed consent procedures is to:
1. Inform participants of the research and what it will entail, including the risks and benefits of the research.
2. Inform participants of their rights (e.g., participation is voluntary).
3. Provide participants with information on who to contact if they have any questions.

What kind of informed consent materials should be submitted to the IRB?

a. If the protocol qualifies for exemption and data is being sought directly from participants, the investigator may obtain informed consent either in writing or verbally. Documentation of informed consent is not required; however, the IRB recommends providing participants with information that addresses the above three items in writing whenever applicable. For anonymous and/or online surveys, for example, signature lines on the standard consent form are replaced with a statement such as “Your completion of the survey indicates your willingness to participate. Please keep this information for your records and do not write any information that could identify you on the survey.”

b. If the protocol does not qualify for exemption, the investigator must submit a document that solicits the informed consent of participants (e.g., consent form, script). Written consent may be waived under certain circumstances. For example, when participants come from a culture that has an oral rather than written tradition, investigators may submit an informed consent script, outlining the manner in which informed consent will be obtained verbally. Investigators must explicitly request that written consent be waived in their protocol narrative, and must document alternative procedures for obtaining informed consent. Requests to waive the need for written consent will be considered on a case by case basis.

c. If the research involves minors, the investigator must always submit a consent form that solicits the permission of a parent or guardian, as well as information on how assent will be obtained from the minor (either verbally or in writing depending on the age group).

d. If the research involves minors who are wards of the state, the investigator must submit written permission from the judge assigned to the youth for their participation.

e. If the research involves the evaluation of student records in which the investigator has access to individually identifying student information, the investigator must submit a consent form that solicits the permission of the student, or a parent/guardian if the student is a minor, to access the records. Permission from a participating institution is also required when applicable (see Permissions from Participating Institutions section for more information).

f. If the research involves evaluation of employee records in which the investigator has access to individually identifying employee information, the investigator must submit a consent form that solicits the permission of the employee to access the records. Permission from a participating
g. If the research involves evaluation of medical records in which the investigator has access to individually identifying patient information, the investigator may be required to submit a consent form that solicits the permission of the patient to access the records. Permission from a participating institution is also required (see Permissions from Participating Institutions section for more information).

**Permissions from Participating Institutions**

If applicable, you must obtain permission from outside institutions or agencies that either serve as a source of subjects, a source of records and information, or on whose facilities your project will be conducted. Participating institutions may include: schools, hospitals, government agencies, community organizations

Be aware that other institutions may have their own IRBs; if so, you must make your project known to them and go through the proper channels to get permission.

Permission from participating institutions must be on their letterhead and must include: the title of the study, the inclusive dates for which the permission is granted, and the title and type written name of the individual with the authority to grant such permission, in addition to their signature.

**Translations**

If applicable, provide translations of both the consent documents and all data instruments to be distributed to participants AND provide a Verification of Translation Accuracy Form signed by someone other than yourself who is adept in the language. Investigators may translate documents, but may not verify the accuracy of the translation. The IRB does not require that a certified translator perform the document translation. The verification may, for example, be provided by a member of the Department of Foreign Languages or an individual who has a bachelor's degree in that language.