**NOTE: This is a protected document!**

*Please do not delete, modify or change the format of this application. Any applications submitted with changes to set questions or formatting will be returned.*

[**Institutional Review Board**](https://www.vcom.edu/institutional-review-board)



**IRB Study Application Instructions**

*Please answer all questions appropriately, providing enough detail in the narrative sections for an approval determination to be made by the VCOM IRB. Responses should be written for both the “expert” and a “non-expert”. For questions that do not apply to your study, please respond with N/A.* ***Please provide responses to the questions in this application using Times New Roman, black font.***

This application is for use by researchers proposing to conduct human subjects research at Edward Via College of Osteopathic Medicine, and its hospital partners utilizing the VCOM IRB as their IRB of record. The application is for use by the VCOM Institutional Review Board, a committee charged with protecting the rights and welfare of human subjects research.

Research protocols may be reviewed at a convened meeting of the IRB or through a single reviewer process involving the IRB Chair and/or one or more experienced reviewers designated from among the members of the IRB. The type of review is determined by the nature of the project, the level of potential risk to research subjects and the characteristics of the subject population. The final determination is made by the IRB.

* **Full Board Reviews:** Research that would require review at a convened meeting of the IRB would include but is not limited to research that involves: 1) more than minimal risk, 2) vulnerable populations, 3) experimental drugs or devices, 4) invasive procedures, or 5) deception (e.g., in behavioral research). The IRB will meet on the second Tuesday of every month throughout the calendar year. IRB applications must be submitted at least 14 business days prior to the second Tuesday of the month if they are to be included in the agenda for the next IRB meeting.
* **Expedited or Exempt Reviews:** Some studies may not require review by the convened IRB, but may be eligible for “Expedited review” or “Exempt status”. Expedited studies involve no more than minimal risk to subjects. Federal regulations define minimal risk as the probability that the 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. Some research may be Exempt from

further review once this initial determination is made. The VCOM IRB must determine whether proposed studies meet the criteria for Expedited or Exempt review.

**Submission Instructions**

All Full Board, Expedited, and Exempt study submissions to the VCOM IRB should be submitted using this application. Investigators should submit this completed application via IRBNet.

Instructions for How to Create a New Protocol in IRBNet can be found in the Forms and Templates library of IRBNet.

NOTE: Consent Forms and Recruitment Materials should be uploaded in IRBNet with this completed application and should be submitted in Word, not in PDF, because IRB staff may need to make minor revisions and edits to these documents. Please refrain from adding a footer to these documents, as all approved Consent Forms and Recruitment Materials will be returned with a footer “stamp” which includes the local reference number assigned the study, as well as the date of approval. After approval, is granted please use the stamped version of Consent Forms and Recruitment Materials when initiating the research study.

**Section 1: General Information**

* 1. **Date Completing Form** *(Must change with each revision):* Click or tap here to enter text.

## Project Title: Click or tap here to enter text.

* 1. **Principal Investigator (PI) Name:** Click or tap here to enter text.

*(Note- VCOM students are not eligible to be designated the Principal Investigator.)*

**PI Email:** Click or tap here to enter text.

**Phone:** Click or tap here to enter text.

**Department:** Click or tap here to enter text.

* 1. **Has the PI ever had any research suspended or terminated by an IRB?**

Yes No

* **If yes, please explain:** Click or tap here to enter text.
  1. **Research Personnel – Investigators**

*List the names of all individuals who are “investigators” on this study under* [*OHRP’s definition*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html)*.* (*ALL individuals listed in this section should also be found in the project team member tracking of IRBNet. To list research personnel in the project team member tracking of IRBNet, the individual must have registered for a user account in IRBNet and the study package must be “shared” with them.) Please contact the IRB office if additional space is needed.*

|  |  |  |
| --- | --- | --- |
| **Name** | **Affiliation** | **Role and Responsibilities** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

All investigators/participating students of this project are qualified through completion of human subjects research training programs (e.g. CITI) provided by the VCOM Research Division. (*Note-completion certificates for required training should be uploaded to the user’s IRBNet profile or sent to the IRB office. Please* ***do not*** *upload these certificates as supporting documents for your study).*

## Research Personnel – Administrative Access

*List any non-investigator individuals who need access to the online protocol and will receive all IRB-related emails [****Administrative Access****].* ***NOTE-*** *these individuals should NOT meet* [*OHRP’s*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html)[*definition*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html) *of an investigator and should have NO access to identifiable data or interaction with research participants. You may skip this question if it does not apply to your study.*

|  |  |  |
| --- | --- | --- |
| **Name** | **Affiliation** | **Role and Responsibilities** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

## Investigator Experience:

All investigators/participating students of this project have uploaded a CV, NIH- Style Bio-Sketch, Resume or experience statement to their IRBNet User Profile.

* 1. **Location of the Research:**

**VCOM-Campus,** *Specify***:** Click or tap here to enter text.

**Hospital Site,** *Specify***:** Click or tap here to enter text.

**Other:** Click or tap here to enter text.

* 1. **Will this research involve collaboration with another institution?**

Yes No

* **If yes, please name the institution(s):** Click or tap here to enter text.

**Source of Funding:** None VCOM Funding Program Extramural Federal

## Funding/Sponsor: Click or tap here to enter text.

*Note- If extramurally funded, a copy of the proposal must be uploaded to IRBNet as a supporting document and Conflicts of Interest training is required of all researchers on the project.*

## Is there any conflict of interest for the PI or other study personnel?

**No Yes**

**If yes, please explain:** Click or tap here to enter text.

* 1. **Estimated Time Needed to Complete Study:** Click or tap here to enter text.
  2. **Is this a Drug, Device or Biologic Study? Yes No**

**Section 2: Project Information**

* 1. **Study Abstract:**

*Provide a brief, non-technical summary of the study, including study purpose and methods. Evaluate prior research for relevance to the research question under study.*

Click or tap here to enter text.

## Background:

*Summarize background information about the research question(s). Tell why the research is needed and include the relevance of this research to the contribution of this field of study.*

*Evaluate prior research for relevance to the research question under study. When the proposed research is the first of its type to involve human participants, the results of relevant animal studies can be included.*

Click or tap here to enter text.

## Specific Objectives/Hypothesis*:*

*State the research hypothesis or the question that the research will answer. List the research objectives and expected outcomes. A primary outcome or objective must be clearly and succinctly identified and stated. After the statement of the primary objective, secondary objectives may be listed. Objectives should be simple and specific. In experimental designs, objectives will be stated as hypotheses to be tested.*

Click or tap here to enter text.

## Research Design:

*The research design should be identified and should be appropriate to answer the research question(s) under study. Describe the type of research proposed (e.g. experimental, correlational, survey, qualitative) and specific study design that will be used (e.g. pre-test/post-test control group design, cross-sectional design; prospective longitudinal cohort design; phase III double-blind randomized control group design, etc.)*

Click or tap here to enter text.

## Measurement/Instrumentation:

*Identify the variables of interest and study endpoints (where applicable). Justify measurement techniques selected. Provide validity and reliability data for selected measures (threats to internal/external validity should be considered). Describe measures that have been taken to avoid study bias.*

Click or tap here to enter text.

## Data Analysis:

*Specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytical approaches.*

Click or tap here to enter text.

* 1. **Explain what the research team plans to do with the study results** (*e.g. publication, presentation, or use for dissertation)*.

Click or tap here to enter text.

## The results will be:

## Given to subjects. Explain how: Click or tap here to enter text.

## Added to their medical record.

Neither

**Section 3: Recruitment**

* 1. **Subject Population:**

*Please provide background information such as gender, age, clinical condition, and other relevant characteristics. Include inclusion and exclusion criteria.*

Click or tap here to enter text.

* 1. **Does the subject population include participants currently residing outside of the United States?** *Note- if responding with “yes”, the VP of International Missions should review this project prior to submission to the IRB. Please include as a supporting document, a letter or email of support from the VP of International Missions.*

Yes No

**3.3 Has an ethics review and permission to conduct research at the international site been obtained?** *For more information regarding additional regulatory reviews that may be required for research conducted outside the United States, please contact the IRB office.*

Yes No N/A-study does not involve international research

## 3.4 Number of Subjects/Enrollment Goal:

*The enrollment goal must match the number of subjects needed to meet the primary outcome. If this is a retrospective record review, this figure is the number of records that will be used for analysis.* ***Note: Once research begins and it is anticipated the enrollment goal will be exceeded, the IRB must be notified. In most cases, prior IRB approval must be given to exceed the anticipated enrollment goal.***

Click or tap here to enter text.

## 3.5 Describe the sampling approach/randomization.

*For experimental designs, include justification for sample size determination. Include how the number of subjects was estimated/selected. Was a biostatistician consulted? Will studying this number result in definitive answers to major research questions?*

Click or tap here to enter text.

**3.6 Will recruitment materials be used?** *Note-all recruitment materials should be submitted for IRB review and approval. Recruitment flyers will be date stamped with the protocol number and approval period.*

Yes

If yes, check all that apply and include with this submission:

Brochure Email Recruitment Letter Flyer/Poster

Radio/Television Script Newspaper Ad Telephone/In Person Script

Website Ad (including Facebook, Craigslist, etc.) Other:

No

* If no, please explain how potential participants will be identified and/or recruited:

Click or tap here to enter text.

**3.7 How will potential subjects be contacted?** *(Please check all that apply)*

N/A

Direct in-person contact Telephone Call Letter Email

Potential subjects will not be contacted. Potential subject will contact the researchers by responding to a flyer, brochure, email, etc.

**3.8 Who will contact the potential subjects?** *(Please check all that apply)*

N/A

Principal Investigator

Other Investigator (specify names):

**3.9 Alternatives to Joining Study:**

*Explain any appropriate alternatives to participation that subjects should consider. If there is no treatment alternative, or the only alternative is not to participate, say so.*

Click or tap here to enter text.

# Section 4: Consent

*For guidance on required elements for a VCOM informed consent document, please see the Informed Consent Checklist or Informed Consent Template located in the forms and templates library of IRBNet.*

**4.1 Are you planning to obtain written (signed) informed consent from subjects for this research?** *(Note- if your study will be reviewed as non-exempt you must request a waiver of signed consent if signed consent will not**be obtained).*

Yes, I am planning to obtain consent and signature using a consent form. (*Note-this document must be submitted for IRB review. The approved document will be date stamped with the protocol number and the approval date).*

No, I am planning to obtain verbal consent. *(Note- if obtaining verbal consent,* ***please complete and upload Form F Waiver/Alteration of Signed Consent AND upload a copy of the verbal script to be used****).*

No, Consent will be implied by the return of the questionnaire. *(Note- the IRB recommends providing consent information at the beginning of the questionnaire. Please see Consent Statement for Online Survey template in the forms and templates library of IRBNet for further guidance).* ***If consent will be implied by the return of a questionnaire/survey, please complete and upload Form F Waiver/Alteration of Signed consent.***

No, I am requesting a Waiver of Signed Consent. ***Please complete and upload Form F Waiver/Alteration of Signed Consent***  *(Note- for further guidance on whether your study is eligible for a waiver of signed consent, please see the guide titled “Can Informed Consent Be Waived?” located in the forms and templates library of IRBNet).*

## 4.2 Provide a general description of the process the research team will use to obtain and maintain informed consent, including where the consent process will take place.

Click or tap here to enter text.

**4.3 Who will conduct the consent discussion with subjects and obtain consent?**

Principal Investigator

Other Investigator (specify):

Research Coordinator (specify):

For Survey Studies only: Information sheet will be mailed and no discussion will take place

N/A- Waiver of Signed Consent Requested via Form F.

**4.4 During what point in the study process will consenting occur? How will researchers give ample time for participants to review consent document before signing?***(Note- participants should be given a copy of the signed consent document.)*

Click or tap here to enter text.

**4.5 How will you assure the consent form or information sheet is written at a level that can be understood by research subjects?** *Note- consent forms should be written using common, non-technical language that can be clearly understood by participants. The IRB recommends writing at an 8th grade reading level. Use of the VCOM IRB “Informed Consent Template” located in the forms and templates library of IRBNet is strongly encouraged.*

Determine grade level and reading ease by using spelling and grammar function in Microsoft Word. Provide Scores Here:

*For instructions on how to use the feature described above:*

* + - [*PC Users*](https://support.office.com/en-us/article/test-your-document-s-readability-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2)
    - [*Mac Users*](https://support.office.com/en-us/article/determine-the-reading-level-of-a-document-in-word-for-mac-acec642a-f4e5-44ee-bb08-d47fb381bb94)

Use another readability formula or index (specify type used and results here):

**Note: Consent Forms with difficult reading scores may be returned for editing and may delay IRB review.**

**Section 5: Procedures**

* 1. **Detailed Study Procedures and/or Methodologies.**

*List all activities or procedures that will be performed (e.g. pre-treatment tests and medications, tests and medications used during therapy, diagnostic tests, x-rays, lab tests, questionnaires and*

*other forms, interviews, focus groups, chart reviews, etc.). Describe how, when and where the research activities will be administered and analyzed.* ***Distinguish any standard processes from those that are research.*** *Please describe activities/procedures in a step-by-step chronological order. State the length of time subjects will be in the study and the expected amount of time required for each study visit or activity.*

Click or tap here to enter text.

## Describe how data will be collected and recorded.

*Submit for IRB review a copy of your data collection tool or spreadsheet listing exactly what data is to be gathered during this research study. Describe below the data collection methods and how data can be compiled for assessment.*

Click or tap here to enter text.

## Is any deception used in the study or any aspect of the study kept secret from the subjects, such as the full purpose of the study?

Yes No

* If yes, describe the deception involved and the debriefing process: Click or tap here to enter text.

## Describe the process for dealing with adverse events and/or unanticipated problems:

Click or tap here to enter text.

* 1. **Will any media be used to record subjects’ voice or image?**

Yes No

* + - If yes, describe what media will be used, how the media will be used, and justify why it is necessary to use the media to collect data: Click or tap here to enter text.

## Will the subject’s voice or image be recorded without their knowledge?

Yes No

* + - If yes, describe the deception and the debrief procedures: Click or tap here to enter text.

# Section 6: Risk and Benefits

* 1. **What are the direct or indirect anticipated benefits to study participants and/or to society based on scientific knowledge gained? Explain how the potential benefits offered by this research outweigh the risks.** O*utline the possible direct and indirect benefits or advantages the proposed study may provide to an individual subject, group of subjects, or society. If there are no direct individuals, clearly state this up front. Note- payments, gifts, or other free services given as a token of participation are not benefits, but instead are classified as compensation.*

Click or tap here to enter text.

## What are the potential risks to study participants?

*For studies initiated after August 20, 2021 and involving face-to-face interactions or intervention, investigators should be mindful of current COVID threat levels. Participants should be reminded that while things are improving since 2020, the pandemic is not completely over. Exposure to COVID remains a potential risk for in-person activites and should be identified as a potential risk.*

*Include risk of psychosocial harm (e.g. emotional distress, embarrassment, breach of confidentiality), economic harm (e.g. loss of employment or insurability, loss of professional standing or reputation, loss of standing with the community) and legal jeopardy (e.g. disclosure of illegal activity or negligence), as well as known side effects of study medication, if applicable, and risk of pain and physical injury. Include potential discomforts and/or inconveniences. Define the level of risk (minimal risk, risk but with potential benefit to patient, risk but no benefit to patient).*

Click or tap here to enter text.

* 1. **Describe any procedures or measures that will be used to prevent or minimize risks or discomforts, *including COVID prevention measures to be implemented for participants and study personnel*.** *Note- Most studies create at least a small risk of breach of confidentiality or privacy.*

Click or tap here to enter text.

* 1. **Describe who is responsible for expenses incurred as a result of a study related injury. Describe how subjects will be compensated for injury incurred as a result of being in the study.** *Note- this information should also be clearly defined in the informed consent document.*

Click or tap here to enter text.

# Section 7: Compensation

## 7.1 Will subjects be compensated for their participation?

No

Yes – **Describe Compensation Below. Will it be pro-rated (partial compensation awarded if withdrawing from the study prior to completion)?** *Note-if compensation will be pro-rated this should be explained to participants in the informed consent document.*

Click or tap here to enter text.

# Section 8: Risk Assessment

* 1. **Does the research involve intervention or interaction with individuals?** *(Examples include physical procedures, written or verbal communication with individuals, or surveys.)*

Yes No

## Does the research involve chart review?

Yes No

## Which vulnerable populations may be included in this study? Check all that apply:

N/A- Does not involve vulnerable subjects.

Children/Minors (less than 18 years old

Wards of the State

Pregnant Women

Fetuses

Neonates of uncertain viability OR non-viable neonates

Prisoners (please contact the IRB prior to submission of application)

Mentally Disabled Persons

Cognitively Impaired Persons

Limited or non-readers

Non-English Speakers (You must use a certified translated consent form. Contact the IRB office.)

Economically Disadvantaged Persons

Educationally Disadvantaged Persons

Employees under the investigator’s supervision or authority

Students under the investigator’s supervision or authority

Patients in Emergency Situations

Terminally ill patients

Others that may be vulnerable to coercion: Click or tap here to enter text.

## If persons in any of the vulnerable groups checked above will be enrolled in this study, please explain the additional safeguards that will be used to protect the rights and welfare of those subjects. Check all that apply:

N/A- Study does not involve vulnerable subjects.

For economically disadvantaged subjects, there will be no financial screening for potential subjects and any eligible subject will be allowed to enroll regardless of financial standing or insurance status.

For educationally disadvantaged subjects, additional time will be spent with them to ensure their understanding of the research participation by answering questions and clarifying any issues. The consent will be read to them if necessary.

For limited or non-readers, the consent will be read to them and additional time will be spent with them to ensure their understanding of the research participation by answering questions and clarifying any issues. This process and the subject’s signature will be witnessed by someone who is not part of the research team.

For students, medical residents, or employees under investigator’s authority, an investigator, research coordinator, or other member of the research team that does not have direct authority over the students or employees will obtain informed consent.

Other (specify): Click or tap here to enter text.

Explain additional safeguards not listed above: Click or tap here to enter text.

## If this research does not exclude children please assess the level of risk involved (check only one):

N/A - Study excludes children.

Minimal Risk (no greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations)

Greater than minimal risk but has potential benefit

Greater than minimal risk but has no foreseen benefit

* 1. **For research involving children, will an assent form be used?** *Note-If minors are involved in a research project, parent permission is needed. If a child is at least 11 years of age, but below the age of majority, his or her “assent” (agreement to participate) should also be obtained. Templates for both a “Child Assent Form” and an “Adolescent Assent Form” can be found in the forms and templates library of IRBNet and should be submitted with the study application for IRB review.*

N/A - Study does not involve children.

Yes

No; If no, please provide justification: Click or tap here to enter text.

## For research involving children, are you requesting a waiver of assent?

N/A - Study does not involve children.

Yes; If yes, please check all that apply:

The capability of some or all of the children is so limited that they cannot reasonably be consulted.

The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is only available in the context of the research.

The research meets the same conditions as those for a waiver or alteration of informed consent in research involving adults, as specified in the regulations at either [45 CFR](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116(c)) [46.116(c)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116(c)) or [45 CFR 46.116(d).](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116(d))

Other; Specify: Click or tap here to enter text.

No. Assent will be obtained. (*Note- assent document must be submitted for review).*

**Section 9: Privacy and Confidentiality**

**9.1 Do you or anyone on the research team plan to access healthcare records for this study?**

Yes If yes, from where? (Specify): Click or tap here to enter text.

No If no, you may skip to question 9.3.

**9.2 Please check all of the following items that will be collected or recorded for this study:**

Name

A geographic subdivision smaller than state except for the first three digits of the zip code

An element of a date, except year, for dates related to an individual, including birth date, admission date, discharge date and date of death; and all ages over 89 and all elements of such ages may be aggregated into a category of age 90 or older

Telephone numbers

Fax numbers

Electronic email address

Social security number

Medical record number

Health plan beneficiary number

Account numbers

Certificate/license numbers

Vehicle identifiers, including license plate numbers

Device identifiers and serial numbers

Web Universal Resource Locators (URLs)

Internet Protocol (IP) address numbers

Biometric identifiers, including finger and voice prints

Full face photographic images and any comparable image

Any other unique identifying number, characteristic, code

**9.3 Will the individually identifiable data be related to or linked to the past, present or future physical or mental health condition of an individual; the provision of health to an individual; or the past, present or future payment for the provision of health care to an individual?**

Yes

No

N/A, we are not collecting or recording any identifiers listed above.

**9.4 Will the individually identifiable data be created or received by any person or entity that is a healthcare provider or an employee of a VCOM affiliate hospital?**

Yes

No

N/A, we are not collecting or recording any identifiers listed above.

**9.5 Is the private information being requested the minimum necessary to meet the research goals?**

Yes

No

N/A, we are not collecting or recording any identifiers listed above.

**9.6 What records or data will you be using or collecting? Check all that apply:**

New data for this study

Data already collected for another research study. Specify the study: Click or tap here to enter text.

Data already collected for administrative purposes

Medical records; If so, state the approximate number of records: Click or tap here to enter text.

Electronic information from a clinical database; If so specify the database (include URL): Click or tap here to enter text.

Data collected solely for non-research purposes

Other: Click or tap here to enter text.

**9.7 Will any sensitive information be collected, such as information regarding sexual behavior, HIV status, recreational drug use, illegal behaviors, physical abuse, mental health disorders, etc.?**

Yes If yes, please explain: Click or tap here to enter text.

No

**9.8 Will personally identifying study results or data be released to anyone outside of the research team?**

No

Yes If yes, to whom will the data be released and why? Click or tap here to enter text.

**9.9 Will the study involve video or audio recording of participants?**

No

Yes If yes, specify: Click or tap here to enter text.

**9.10 Describe if/how the study will utilize study codes. At what stage will identifiers be removed from the study? If identifiers must be retained, explain why.**

Click or tap here to enter text.

**9.11 If applicable, where will study code key be stored and who will have access?**

*Note- study key code should be kept in a separate, secure location from the research data.*

Click or tap here to enter text.

**9.12 How will data be stored to ensure security (e.g. password protected computers, encryption, etc.) and limited access?**

Click or tap here to enter text.

**9.13 Who will have access to study data?**

Click or tap here to enter text.

**9.14 When will the research data be destroyed?**

Click or tap here to enter text.

**9.15 If data will not be destroyed until the end of the study, describe where, in what format and for how long it will be stored.**

Click or tap here to enter text.

**9.16 How might you use stored human material in the future, and how would you obtain the subject’s permission for future use of their data? How and when will the human material be destroyed?**

Click or tap here to enter text.

**9.17 Are any of your data sources covered entities under HIPAA? If so, please identify the institution and explain what arrangements have been made to comply with the HIPAA privacy rule in order to access subject’s protected health information.** (Please see <http://privacyruleandresearch.nih.gov/pr_08.asp>for information on protected health information.)

Click or tap here to enter text.

**Section 10: Bibliographies**

**10.1 Include a reference list of literature cited to support the protocol statement.**

Click or tap here to enter text.