Impact of Osteopathic Clinical Skills (OCS) tutor content on RVU-MCOM first-year medical students' academic performance?

Admin	
Protocol ID	2024-036
Panel	No Panel Assigned
Student Investigator	Isaac Hartman Signed 02/09/2024 2:23 PM MST **No COI Reported**
PI Type	Student
Faculty/Preceptor	Karma McKelvey 02/07/2024 Signed 02/09/2024 3:07 PM MST
Campus	MT
Faculty/Preceptor Acceptance Status	Accepted 02/09/2024 3:07 PM MST
Department	Research & Scholarly Activity
PI Institution	
External co-PIs	
Exempt Reviewer	Calli Cahill / Completed / 02/21/2024 5:00 PM MST
Exempt Reviewer	Calli Cahill / Completed / 02/19/2024 5:00 PM MST
Review Type	Exempt Review
Approval Status	Exemption Approved
	(2) Tests, Surveys, Interviews
Submitted By	Isaac Hartman
Date Received	02/09/2024
Date of Completion	02/15/2024
Date Approved	02/15/2024
Approval Expires	*Approved Without Project Report*
Proposed Start Date	02/07/2024
Proposed End Date	04/19/2024
Date Closed	
Type of Research	Student Research
Funding Source	
Sponsor	
Sponsor Contact	
Sponsor Address	
Sponsor Email	
Sponsor Phone	
Consent Waived	Yes - Request Alteration of Informed Consent
Waiver of Documentation of Informed Consent	Requested
Regulatory Agency	None
Subjects	• RVU Students
Other Subjects Type	
Total Number of Subjects	80
Searchable Keywords	

(2) Tests, Surveys, Interviews Questions **Date Last Updated: 02/07/2024 11:32 AM MST**

What type(s) of instruments/activities will be used (Check all that apply.)

- ☐ Educational tests (cognitive, diagnostic, aptitude, achievement)
- ✔ Questionnaire/survey
- ☐ Interviews
- ☐ Observation of public behavior in which the research *does not participate* in the activities observed (may include audio or video recording)
- ☐ Observation of public behavior in which the research *does participate* in the activities observed (may include audio or video recording)

Will information be recorded in a manner that participants can be identified (e.g., name, social security number, license number, phone number, email address, photograph)?

Answer: Yes
✔No

Will subject responses be recorded?

Answer:
Audio
Video
Digital Recording
✔No Recording

Would disclosure of information obtained put participants at risk for civil or criminal liability or damage to their financial standing, employability or reputation (e.g., drug or alcohol use; criminal or other illegal activity)?

Answer:
Yes
✔No

Is the information recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects AND disclosure of the information could place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing employability, educational advancement or reputation.

Answer:
Yes
✔No

Will your participants include anyone under the age of 18 years old?

Answer:
Yes
✔No

Describe the source of the subject population:

Answer:
RVU-MCOM first-year medical students.

Where/How will the survey/interview occur? (describe the location and/or survey tool):

Answer:
Paper survey will be taken within the first 5 minutes of an integrated case on 2/22/24 on the MCOM campus taught by Dr. Dennis Kinder. Dr. Kinder has approved giving the survey at this time and this will not affect his ability to effectively present his content.
02/09/2024 2:22 PM MST

Pre-Protocol Questionnaire	02/07/2024 Pre-Protocol Questionnaire.pdf
Reviewer Notes	02/15/2024 Exempt Reviewer Review Notes.pdf 02/15/2024 Exempt Reviewer Review Notes.pdf
Student Research Approval Form	02/09/2024 iNet Student Research Approval Form - Hartman, Isa...
Consent Form	02/08/2024 Confidential Survey Consent Form.doc
Survey Instruments	02/07/2024 Fellowship Research Student Survey.pdf 02/15/2024 Fellowship Research Student Survey (edited).pdf
Additional Documentation	02/09/2024 Biohazards and Safety Cert (CITI).pdf 02/09/2024 FERPA Cert.pdf 02/09/2024 Introduction to Research Cert (CITI).pdf
Notifications	02/15/2024 Revisions Required: IRB #2024-036.pdf 02/15/2024 Exemption Approval: IRB #2024-036.pdf
Approved Application Sections	02/15/2024 Approved Application Sections Start Here.pdf

Personnel

PI

Isaac Hartman (02/07/2024)

Responsibilities

1. What is the Campus Location for the Principal Investigator?

Answer:
MCOM

Faculty/Preceptor

Karma McKelvey

Responsibilities

1. What is the Campus Location for the Principal Investigator?

Answer:
MCOM

Project Description

Please upload your signed Student Research Approval Form. It can be found on the RVU iNet at: https://inet.rvu.edu/home/forms-2/student-research-approval-form/

Answer:

iNet Student Research Approval Form - Hartman, Isa... 02/09/2024 (Student Research Approval Form)

Briefly state the objective(s) and procedures associated with this project in the space provided.

NOTE: Incomplete or unclear information will delay IRB review and approval.

Answer:

Students will be surveyed to assess the impact of OCS tutor created content on student academic performance and satisfaction. Students will be surveyed in the first 5 minutes of Dr. Dennis Kinder's integrated case taught on 2/22/24. Dr. Kinder has approved the survey be given at this time and that 5 minutes at the beginning of the class will not affect his ability to effectively deliver his content. The survey has been piloted tested and it takes roughly 3 minutes to complete. No identifying information will be collected. We are not proposing to use RVU institutional data, rather we asking students to self-report their test scores. Data will not be cross referenced with official records.

Objective: Assess usage rates, perceived impact on OMS I students' test scores, and usefulness of fellow-created OCS tutor materials.

02/15/2024 2:25 PM MST

DATA COLLECTION METHODS

Will audio taping or videotaping of subjects occur?

Answer:

Yes

✔No

Will any of the following instruments/methods be used?

Answer:

Interview

✔Anonymous Surveys/Questionnaires

Identifiable Surveys/Questionnaires

Focus Groups

Standardized (published) Tests/Assessments

Not Applicable

Are you planning on using RVU institutional data (e.g. student information, grades, test scores, evaluations, assessment data) for your research?

Answer:

Yes

✔No

Will the records or specimens be collected from RVU?

Answer:

RVU only

RVU and other institutions

Other institutions only

✔Study does not involve records or specimen collection

Upload survey(s)/questionnaire(s):

Answer:

Fellowship Research Student Survey.pdf 02/07/2024 (Survey Instruments)

Fellowship Research Student Survey (edited).pdf 02/15/2024 (Survey Instruments)

02/15/2024 2:30 PM MST

Project Details

***Specific Aims* – State the specific scientific objectives of the research:**

Answer:

Evaluate impact of Osteopathic Clinical Skills (OCS) tutor created content on self-reported academic performance and satisfaction by the MCOM OMS I class.

02/08/2024 11:44 AM MST

Background and Significance **- Briefly sketch the background leading to the present proposal. Describe the contributions that the study will make to the health of human beings and/or to the scientific data base, using documentation from the literature where appropriate. Although it is helpful for the Board to have a decent understanding of the basis for conducting a research project, it is not necessary to have a full-blown literature review or extensive background and rationale for the proposed research plan or activity.**

Answer:

- As the inaugural Osteopathic Teaching Fellow for the first class of medical students at MCOM, I created the Osteopathic Clinical Skills (OCS) I and II course tutor content for exams and assessments.
- As this is the first year MCOM is teaching medical students and the first year of the MCOM Fellowship, there was no previously created tutor content for the OCS courses.
- OCS is a new curriculum course not taught on the other RVU campuses, so there were no tutors assigned to this course from the other campuses.
- Therefore, I created all the OCS I/II tutor content, which included exam reviews, OMM summaries, and OCS competency reviews.
- This research project attempts to assess the usability, acceptability, and effectiveness of the OCS I/II tutor content by comparing the first-year medical students' academic success in the OCS courses.

Preliminary Studies **- Summarize preliminary studies conducted by the investigator pertinent to this proposal. State "none" if applicable.**

Answer:

None

Investigator Experience **- Provide a brief synopsis of the Principal Investigator's (and/or faculty mentor's) expertise, experience, and capability to perform this research. Please DO NOT PASTE CV in this answer section. You may attach a copy of the curriculum vitae or research background of the principal investigator on the protocol page by uploading under "Files" at the bottom of the page.**

Answer:

Faculty, mentor, Karma McKelvey, PhD, MPH has decades of experience conducting human subjects research and is in close contact with me (PI).

Experimental Design and Methods **- Detailed protocol for this project / subject-related studies.**

Methods and Procedures - Describe the procedure (s) in sequential detail. Clearly identify any experimental element of the study. Include a thorough description of any investigational drugs, therapeutic procedures, monitoring techniques, test procedures or medical devices.

[The description of investigational medical devices should include information on each important component, ingredient, principle of operation, and anticipated developmental changes in the device. On a separate page describe and address issues associated with the device presenting "Significant Risk" or "Non-Significant Risk"]

Answer:

Anonymous, paper and pencil/pen survey completed during first 5 minutes of the integrated case taught by Dr. Kinder. Karma McKelvey, PhD, MPH will distribute and collect the surveys. Then Karma McKelvey, PhD, MPH and PI will collectively digitize them into an excel spreadsheet or appropriate statistical program. Paper surveys will be securely shredded after digitization.

02/09/2024 2:01 PM MST

Data Analysis and Data Monitoring **- Describe plans for statistical analysis of data when appropriate. If a data safety monitoring committee is appropriate to protect the safety and/or welfare of subjects, describe its operation (e.g., membership, stopping rules and frequency of review).**

Answer:

Descriptive statistics will be reported. Including, but not limited to, main differences, and differences of proportion as appropriate (I. E., Continuous versus categorical data).

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Data Storage and Confidentiality **– Describe where the research data will be stored during the study and how it will be secured. The investigator must take necessary steps to maintain confidentiality of data. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to data. State who will have access to the data. If data with subject identifiers will be released, specify the person (s) or agency to whom the information will be released and the purpose of the release.**

Answer:

No identifying information/data will be collected. Once paper surveys are collected, PI will transfer data into excel spreadsheet or appropriate statistical program. Paper surveys will be securely shredded after digitization.

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Setting **- Describe briefly where the study will be conducted, e.g., private outpatient clinics, physicians offices.**

NOTE: If other institutional review committees (IRBs) or approvals are required, note them by name, affiliation and contact person. Also, be aware that the approval of other involved institutions' IRBs must be obtained before initiation of the project (but are not essential for RVU IRB review to begin).

Answer:

The survey will take place in the first 5 minutes of an integrated case taught on 2/22/24 by Dr. Kinder on the MCOM campus. Dr. Kinder has approved the survey be given at this time and that 5 minutes at the beginning of the class will not affect his ability to effectively deliver his content. The survey has been piloted tested and it takes roughly 3 minutes to complete.

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Are other IRBs involved in the approval of this project?

Answer: Yes

✔No

***Laboratory Methods and Facilities* - Indicate where specific laboratory tests will be performed; e.g., hospital chemistry laboratory, investigators' laboratory, radiology clinic, etc. If None, state N/A**

Answer:

N/A

***Estimated Period of Time to Complete the Study* – Describe the stages and total time of subject participation as well as overall time for the entire study (start to completion). Also, if study involves more than one visit, describe time range estimates for each visit (e.g., 20-30 minutes; 2 – 3 hrs, etc.). Where possible use a table or "bullet-point" format to clearly illustrate the flow of activities and procedures.**

Answer:

The survey takes roughly 2-3 minutes to complete, but students will have 5 minutes.

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***Human Subjects* - Describe the characteristics of the research population**

***Description of subjects* is to include the projected sample size, plans for the selection of subjects, and inclusion and exclusion criteria.**

Answer:

RVU-MCOM first year medical student (n = 80).

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***Sample Size:* Number of subjects to be enrolled in this study at this site. Approximately ____ subjects at ____ sites in the U.S. will be enrolled in the study overall. For Clinical Trial studies, indicate number of subjects to be randomized.**

Answer:

Approximately 80 subjects at 1 site in the U.S. will be enrolled in the study overall.

Describe both *Inclusion / Exclusion Criteria*. BE SPECIFIC! Also, if children (persons under age 18) are excluded from this study provide scientific justification for such exclusion. Include physical, mental, cognitive, medical, and other relevant Inclusion and Exclusion criteria.

Answer:

Inclusion: all MCOM OMS I students
Exlusion: none

Describe intended gender or sex, age range, intended racial and ethnic distribution. If any vulnerable subjects are involved in this study (e.g., those with limited autonomy or decision-making capabilities) are included, justification must be provided.

Answer:

Entire class of MCOM OMS I students. (n = 80)

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Identify the source(s) from which you will obtain your study population.

Answer:

RVU-MCOM first-year medical students.

Describe plans for *recruitment of subjects*. All materials (e.g., flyers, ads, emails, letters, postings, handouts, etc.) to be used for recruiting subjects must be submitted to the IRB for review. Please upload recruitment materials under the "Files" tab at the bottom of your protocol page.

Answer:

Plan to give the survey to the MCOM students at the beginning of an integrated case taught by Dr. Kinder on 2/22/24. Dr. Kinder has approved the survey be given at this time and that 5 minutes at the beginning of the class will not affect his ability to effectively deliver his content.

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Risk/Benefit Assessment and Informed Consent:

Describe the level of risk, and if more than minimal, describe how this research holds the prospect of a direct benefit for the subjects. If there is NO direct benefit to subjects, state such in protocol and in the consent documents.

Answer:

Minimal risk and this research may improve the OCS tutor content in the future. There is the risk of emotional upset if students are unhappy with their grades and reporting them could cause discomfort. Students will be informed the survey is voluntary and that they may stop at any time.

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Describe how the anticipated benefit justifies the risk.

Answer:

Improving the OCS tutor content will positively impact future MCOM medical students' academic success. Minimal risk.

Describe how the anticipated benefit of this research is at least as favorable to the subjects as that to be received by available alternative approaches for the subjects.

Answer:

N/A

Describe any potential *RISKS OR DISCOMFORTS* in detail. Use evidence from clinical and/or animal studies to evaluate the level of potential hazards associated with participation in the research protocol. Indicate the methods for detecting adverse reactions. Describe the procedures for protecting against or minimizing potential risks (e.g., confidentiality, reputational injury, direct injury or harm to subject, etc.) and assess their effectiveness. Discuss why the risks to the subjects are reasonable in relation to proposed benefits to mankind. Be sure to describe any anticipated adverse events that might occur during the course of the study.

Answer:

As mentioned above, potential risk includes emotional upset if students are unhappy with their OCS grades. Risk is minimized by presenting anonymous data.

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***Payment/Compensation* - Describe any financial payments for subject participation (e.g. compensation for time and travel). Indicate any partial payment schedule for less than complete study participation. Recall that payments cannot be perceived as coercive (overpayment for time and effort). Remember: payments are NOT benefits.**

Answer:

None.

***Subject Costs* - Describe any anticipated costs to research subject. If none, state such.**

Answer:

None.

***Literature Cited* – If any, the references should be limited to relevant and current literature pertinent to the proposed research.**

Answer:

None.

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Do you ever intend to publish or present (oral, poster, or written) the results of this project?

Answer: ✔Yes. *Please remember to fill out the Attestation form on iNET if you present or publish any of your work.

No

Funding

Indicate the category of the sponsor:

Local Government

State Government

Federal Government

Industry or Pharmaceutical Company

Non-Profit Foundation/Institution

RVU Intramural Grant

Informed Consent

Is a signed Informed Consent document being used?

Answer: Yes

✔No

You have indicated that this is an anonymous survey. Please download the "Anonymous Survey Consent Form.doc" file listed above, enter your consent script information into that file and then upload that file here:

Answer:

Confidential Survey Consent Form.doc 02/08/2024 (Consent Form)

Will a Certificate of Confidentiality be requested from NIH?

Answer: Yes

✔No

Waiver/Alteration of Informed Consent

Is this research regulated by the US Food and Drug Administration?

Answer: Yes

✔No

Is this research regulated by the US Department of Defense?

Answer: Yes

✔No

Explain why and how the research involves no more than minimal risk to the subjects:

Answer:

We are conducting an anonymous survey that will be collected during the first 5 minutes of a regularly scheduled class. No identifying information will be collected.

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Explain why the waiver will not adversely affect the rights and welfare of the subjects:

Answer:

No identifying information will be collected.

Is the research team collecting identifiable private information and/or identifiable biospecimens?

Answer: Yes

✔No

Explain why the research could not be practicably be carried out without the waiver of informed consent:

Answer:

Informed consent would be collecting identifying information.

If an alteration of informed consent is approved by the IRB, will subjects be provided with additional pertinent information after participation?

Answer: ✔Yes

No

Explain/describe why or why not:

Aggregated results will be presented during Research Day at the MCOM campus on May 16, 2024.

02/09/2024 2:14 PM MST

Correspondences

Publicationss

Project Reports

Modifications

Adverse Events

Event / Date	Status / Comments / Files	Submitted By
No Adverse Events Found.		

Deviations

Status	Deviations File/Comments	Submitted By
No Deviations Found		

Reviewer Comments

Exempt Reviewer: Calli Cahill, Review Completed, Due date 02/21/2024 5:00 PM MST

- no review text -

Exempt Reviewer: Calli Cahill, Review Completed, Due date 02/19/2024 5:00 PM MST

- no review text -