Spatial Accessibility of Pharmacy Care in Vermont

Protocol ID	264
PI	Samuel Roubin Signed 10/06/2023 1:18 PM EDT
PI Type	Student
Faculty Advisor	Joseph Holler 09/26/2023 Signed 10/06/2023 2:36 PM EDT
Faculty Advisor Acceptance Status	Accepted 10/06/2023 2:36 PM EDT
Chair Approval	Completed / 10/25/2023 5:00 PM EDT
Review Type	Exemption
Approval Status	Exemption Verified (2) Tests, Surveys, Interviews
Submitted By	Samuel Roubin
Date Received	10/06/2023
Date of Completion	10/25/2023
Date Approved	10/25/2023
Check-In Deadline	10/24/2024
Proposed Start Date	10/02/2023
Federally Funded	No
Subjects	• None of the above

(2) Tests, Surveys, Interviews Questions **Date Last Updated: 09/26/2023 8:54 PM EDT**

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:
1. Yes
✔2. No

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:
1. Yes
✔2. No

Is the information is 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:
1. Yes
✔2. No

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

Answer:
1. Yes
✔2. No

Reviewer Notes	10/25/2023 Chair Approval Review Notes.pdf
Consent Form	09/27/2023 Depricated consent form 09/27/2023 Valid Consent Form
Survey Instruments	10/06/2023 Survey_IRB.pdf
Recruitment Materials	10/06/2023 IRB_Contact_Email.pdf
Protocol Description	10/06/2023 Incorrect upload spot- Please Disregard
Notifications	10/25/2023 Exemption Notification - IRB ID: 264.pdf
Approved Application Sections	10/25/2023 Approved Application Sections.pdf

Personnel

PI

Samuel Roubin (09/26/2023)
Signed 10/06/2023 1:18 PM EDT

PI Documents **CITI** ✔

- IRB Human Subjects Training Certification

  Curriculum/Group/Stage
  Basic/Refresher Course - Human Subjects Research / Social/Behavioral Research Course / 1 06/05/2025
  File
  – no entries found –

Faculty Advisor

Joseph Holler Signed 10/06/2023 2:36 PM EDT

PI Documents **CITI** ✔

- IRB Human Subjects Training Certification

  Curriculum/Group/Stage
  Basic/Refresher Course - Human Subjects Research / Social/Behavioral Research Course / 1 07/08/2024
  File
  – no entries found –

Proposal Basics

Project summary:
(Briefly summarize your project in non-technical langauge. You will have opportunities later in this application to describe the project in detail, including uploading documents if necessary. This summary is intended to introduce your project to the IRB.)

Answer: *Suggested Word Count Limit: 500, Current Word Count: 229*

Pharmacy care is an essential component of primary medical care and is becoming considered increasingly important in the field. Patient-pharmacist interactions have recently evolved from their traditional focus on medication dispensing towards a more patient-centered medication management role, including vaccinations and chronic disease management. Recent research has underscored the importance of pharmacy access in primary care, as patients visit community pharmacies roughly twice as often as their primary care providers and community pharmacies are particularly successful at reaching rural populations.

Our research aims to measure the spatial variation in access to pharmacy care across the state of Vermont using an established healthcare accessibility model. Other recent studies have measured the geographic variation in pharmacy access on the state and national levels, but no prior study has done so in Vermont. I will collect data on the number of pharmacists and pharmacy technicians working at each pharmacy, as well as the hours of operation of these pharmacies, and use this data to run a temporally-explicit model. Ultimately, this will allow us to gain an understanding of how access to pharmacy care varies across Vermont's populations. It is well established that access to healthcare is correlated with health outcomes, and considering the increasingly important role of pharmacies in primary health care, it is crucial to understand how geographic access to this form of health care is distributed to inform public policy.

10/03/2023 6:33 PM EDT

Study Site:
(Where will the study be conducted?)

Answer:

1. Middlebury College Campus (please specify which campus and, if relevant and known, which building or room)
2. ✔ Online survey platform (please specify which survey tools [e.g., MTurk, Prolific, Qualtrics, SurveyMonkey, etc.]. You will provide more detail later in this application)
3. Another institution (please name and describe - e.g., Duquesne University, or Bristol-Myers Squibb)
4. Another online method (please name and describe - e.g., Facebook, Twitter, a support forum for people with IBS, etc.)
5. Some other location (please describe)

Cooperating institutions:
(Will you need permission from a cooperating institution to perform this study? If you will perform your research at any place other than your home institution, the answer is YES.)

Answer:

Yes
✔ No

Recruitment and Consent

Subjects:
(Describe the target population from which you will recruit your subjects, and specify the inclusion and exclusion criteria you will be using. For example, you may be studying college students at Middlebury who are 18 years or older, or children of recent immigrants to the United States who do not speak English and are between 25 and 35 years old.)

Answer:

The participants of this study are registered retail pharmacies in the state of Vermont, as well as retail pharmacies in adjacent New York, New Hampshire, and Massachussets counties, considering that Vermont residents may cross state boundaries to access a pharmacy near them.

Estimated number of subjects:
(Please provide a range - e.g. 150 - 175 - if you do not have a specific and exact number of subjects you will be recruiting. If you do have a specific number, please provide that here.)

Answer:

There are currently 128 active registered pharmacies across the state of Vermont. There are no more than 115 pharmacies in out-of-state Vermont-adjacent counties. Thus, the maximum number of study subjects would be roughly 250 pharmacies; however, it is estimated that the number of subjects will be closer to 200 pharmacies.

Recruitment
(Briefly, how will you contact individuals and invite them to participate in your research?)

Answer:

We will attempt to recruit all of the pharmacies by phone and email. I will initially attempt to find regional managers of the pharmacy chains in Vermont, such as Walgreens, Kinney, or CVS, to streamline the data collection process. I will attempt to contact them by a phone call or an email. They may be able to provide the hours of operation and staffing levels for the various pharmacy chain locations in the state. If a regional manager cannot be contacted or does not have the necessary data, I will resort to contacting each pharmacy individually. For the pharmacies that have email contact information online, I will email them, attaching the Qualtrics survey link in the email and requesting that the store manager or supervising pharmacist complete the short survey. If there is no email contact online for a pharmacy, I will call the pharmacy, request to speak to the store manager or supervising pharmacist, and ask their preference on taking the survey online via Qualtrics or over the phone. If they prefer to take the survey online, I will request an email address and send the survey link to them promptly. If they prefer to take the survey over the phone, I will administer the survey either during this call or schedule a time to call back. I will follow up with each pharmacy three to four days after initially contacting them if I do not hear back.

Emails will be concise, and are attached to this protocol as IRB_Contact_Email.pdf.

10/03/2023 9:49 PM EDT

Recruitment materials:
(If you will be using recruitment materials such as flyers, posters, or on-line postings, please upload a copy of all such materials to be used here.

*If you are only using on-line recruiting and include the full and complete text of that posting in the **Recruitment** question above, you do not need to upload another copy here.*

To continue without attaching a file, please click SAVE below.)

Answer:

IRB_Contact_Email.pdf 10/06/2023 (Recruitment Materials)

10/06/2023 1:03 PM EDT

Deception:
(Will your research require that you deceive your subjects to get the data you want?)

Answer: Yes, deception is required
✔No, deception is not required

Compensation:
(How are you compensating your participants for their participation? Be as specific as possible. If you are not compensating your participants, please indicate that here as well.)

Answer:

There is no material compensation for participation.

Consent
(Please indicate how you will obtain your subjects' consent. For most studies, that means that consent will be either through a signed paper or electronic form or, for minimal risk online studies, by seeking informed consent at the start of the survey.

If your subjects are unable to give legal consent themselves (i.e., they are younger than 18 or cognitively impaired), you must get both written consent from a guardian and oral assent from the subject.

Some elements of informed consent can, under limited circumstances, be waived. See here for a discussion of the circumstances under which informed consent can be waived, and here for a discussion of when it would be appropriate to waive the documentation of informed consent.

Click here for a sample written consent form
Click here for a sample survey consent document
Click here for a sample oral consent script

You will be asked to attach your consent form or script later in this application.)

Answer:
I will obtain written informed consent.
I will obtain electronic informed consent.
I will obtain both written consent from guardians and oral or written assent from subjects.
✔I will obtain oral consent.
I request a waiver of informed consent.
I request a waiver of documentation of informed consent.
✔My study will be conducted solely online, and participants will consent online by reading a consent statement and indicating their consent without providing their name

Please briefly justify why oral consent is appropriate for your study.

Answer:

This study relies on oral and complied consent in its study design, as a significant portion of the data collected will be over the phone via a survey. It would be far more efficient and simple to obtain oral consent over the phone than requiring respondents on the phone to submit a written or signed consent form before proceeding with the survey.

10/03/2023 5:05 PM EDT

Oral consent:
(Please attach your oral consent script)

Answer:

Depricated consent form 09/27/2023 (Consent Form) (Existing)
Valid Consent Form 09/27/2023 (Consent Form)

Survey Consent:
(Please attach the consent question or statement from your survey)

Answer:

Valid Consent Form 09/27/2023 (Consent Form) (Existing)
Depricated consent form 09/27/2023 (Consent Form)

Methods

Project Goals:
(Please briefly describe your project's goals, including the research question(s) to be addressed. You may attach diagrams, figures, or illustrations below if that would be useful in helping the IRB understand your project.)

Answer:

The ultimate goal of this project is to measure the spatial accessibility of pharmacy care in Vermont, and more specifically, identify areas of the state that have particularly limited access to pharmacies. Importantly, this research is temporally explicit, as it will analyze the variation in accessibility at specific times of the day and week, such as in the early mornings, evenings, and on the weekends. Such temporally granular data have added benefits for the research since it provides information on how spatial accessibility varies at irregular times, improving our understanding of when pharmacy care may be particularly limited for certain populations. Our analysis may also explore the relationship between the social vulnerability of populations and their relative spatial access to pharmacy care to further understand how lack of access to pharmacies may be related to the presence of disadvantaged populations.

Our research does not evaluate a specific hypothesis, but instead presents useful information about spatial equity in the healthcare sector across Vermont. This information is of interest to both service providers and Vermont state public health officials. Our goal is to create a publicly facing product that takes the form of an interactive web map dashboard, as we believe this will maximize the broader impacts of this research.

10/05/2023 5:23 PM EDT

Attach Goals File?
(Do you need to attach a file to provide additional information about your project goals? This is entirely optional, and most projects will not require additional documentation.)

Answer:
Yes, I have one or more files to attach to further explain my project goals
✔No, my project goals were explained sufficiently above

Which methods will you use to collect data from participants?
(check all that apply

Note that this question is asking how you will collect information, not to describe what is done to the subjects. For example, if you are testing the effectiveness of a new heart medication, you may be using survey information [to assess how subjects feel], and physiological data collection [to assess heart function].

If you were asking subjects to rate pictures of butterflies while measuring their heart rate, you would check the same two options - survey [picture ratings] and physiological [heart rate], even though the two studies are very different.

Answer:

Observation: you will watch participants and record data, but not necessarily interact with them directly.

Restricted/secondary dataset: you will use data that is not publicly available and was collected by other researchers.

Structured/semi-structured interviews: you will interact directly with participants to collect their answers to specific or general questions that you formulated beforehand.

✔Survey, questionnaire, or test: you will distribute a paper or electronic survey, questionnaire, or test to participants. Note that if you are tracking their response or completion time, you should also check physiological data collection.

Physiological data collection (through the collection of physical samples, or the use of equipment or devices to measure or assess participants. This includes blood samples, fingernail clippings, EEG, ECG/EKG, weighing participants, etc.)

Other

Survey distribution and collection details:
(How will you distribute and collect the surveys in a way that protects your participants' privacy and ensures that their participation is entirely voluntary? Please describe as specifically as possible how subjects will receive and submit their surveys.)

Answer:

The survey will be distributed electronically using Qualtrics or administered over a phone call. The Qualtrics survey will be provided via a URL link in the email. Participation is optional and participants can skip questions or choose to end the survey at any time. Participant privacy is not at risk in this study, as the surveys ask only about the staffing of pharmacists and pharmacy technicians (in a numerical value) and the hours of operation at each location and do not collect any personal information on the pharmacy personnel themselves. The contact information for all research subjects (pharmacies) is public information. No questions will be asked to the pharmacy employee responding to the survey that identifies them in any capacity. All of the information that is being collected is fundamentally public information, as hours of operation are posted online and the staffing levels of any given pharmacy could be observed by walking into the pharmacy.

10/05/2023 7:24 PM EDT

Survey:
(Please attach a complete copy of the survey that you will use.)

Answer:

Survey_IRB.pdf 10/06/2023 (Survey Instruments)

10/06/2023 1:15 PM EDT

Project method:
(Please describe your research method, being sure to address what the subjects will do, in what sequence, and about how long you anticipate the process will take for the subjects. You may attach diagrams or illustrations in the next question if those would be useful in helping the IRB understand your project methodology)

Answer:

The project method is simple. The research participants— either a supervising pharmacist or the store manager— will complete the survey on behalf of the pharmacy location through the online Qualtrics survey or over the phone. The survey takes the participant through a series of short questions asking about the pharmacy's hours of operation and staffing levels on weekdays, Saturdays, and Sundays. If the survey is completed over the phone, I will read the survey exactly as it is stated on Qualtrics and fill in the answers on behalf of the participant. This survey should take no more than 3 minutes to complete. Only one survey needs to be completed for each pharmacy over the entire study study period.

Pharmacy data will be used to calculate accessibility to pharmacy services for all locations in Vermont using the enhanced two-step floating catchment method (E2SFCA).

10/06/2023 12:59 PM EDT

Additional method file(s):
(Please attach any additional files needed to explain the methodology of your project. If you've changed your mind and don't have additional files to attach, just click SAVE, below)

Answer:

Incorrect upload spot- Please Disregard 10/06/2023 (Protocol Description)

10/06/2023 1:07 PM EDT

Grant funded?

(Is your project funded by a grant? Or are you applying for a grant to fund this project?)

Answer: Yes, this project is funded by a grant, or I am or will be applying for a grant to fund this project

✔No, this project is not and will not be funded by a grant

Grant proposal:
(Please attach your grant proposal here. If you do not yet have a grant proposal available, please leave this blank for now and update the IRB with your grant proposal when it is available.To continue without attaching a document, please click SAVE below.)

Answer:

Other documentation?
(Do you have any other files to upload that the IRB may require to understand your project? Most projects do not require additional documentation.)

Answer: Yes, I have additional documentation to upload

✔No, I do not need to upload any additional documentation

Privacy and Confidentiality

Anonymity and confidentiality:
(Will your data be collected anonymously, confidentially, or neither?

Anonymous data collection means that the data is collected in such a way that it can NEVER be connected to individual persons, and even you won't know which participant provided which data.

Confidential data collection means that you will protect your subjects' identifying information from access by anyone besides yourself, your co-PIs, and/or your faculty advisor.)

Answer: Data will be collected anonymously

Data will be collected confidentially

✔Data will be collected neither anonymously nor confidentially

Will identifiers be removed?
(After you have collected your data, will you remove the information that identifies specific subjects from your dataset, such that no one would be able to trace the study data back to a specific person?)

Answer: ✔1. Yes, identifiers will be removed.

2. No, identifiers will **not** be removed.

Will you take video recordings or photographs of your participants?

Answer: 1. Yes, we will take video recordings or photographs of our subjects.

✔2. No, we will not take video recordings or photographs of our subjects.

Will you make audio recordings of your participants?

Answer: 1. Yes, we will make audio recordings of our subjects.

✔2. No, we will not make audio recordings of our subjects.

Will you use personal (non-public) records as sources of data? Choose as many options as apply.

Answer:
1. Drug & alcohol records
2. Educational records
3. Health care records
4. Psychiatric records
5. Other personal, non-public records

✔6. No personal, non-public records will be used

Plan to protect data:
(Please describe as specifically as possible what measures you will take to ensure that your data are not accessable to anyone besides you [and your advisor, if you are a student]. Please address how the data itself will be stored [e.g. if hard copy, will files be kept in a locked location? If electronic, will files be stored via Middlebury's servers, OneDrive, Google Drive, etc.? Will electronic files be password protected or encrypted?]))

Answer:

We believe that the data does not need to be protected and should be released to the public to maximize broader impacts of the work. The data do not contain any personal or sensitive information. It solely collects the hours of operation of pharmacies, which is public data, and the number of pharmacists and pharmacy technicians working at a given location on a given typical day, which is essentially public information as this can be observed at a given location by any member of the public. These data will ultimately be made public.

10/05/2023 5:21 PM EDT

Risks and Benefits

Civil liability:
(Could participating in your study put a subject at risk of being sued?)

Answer: Yes
✔No

Criminal liability:
(Could participating in your study put your subjects at risk of being accused of or punished for committing a crime?)

Answer: Yes
✔No

Financial or employment risk:
(Could participating in your study negatively affect your subjects' financial or employment status?)

Answer: Yes
✔No

Social risk:
(Could participating in your study negatively affect your subjects' reputation or social standing?)

Answer: Yes
✔No

Physical risk to you or others:
(Could participating in your study post physical risks to you, your subjects, their families, or anyone else?)

Answer: Yes
✔No

Stress:
(How would you describe the possible effects of your data collection on your subjects?)

Answer: A potentially stressful experience
✔Not at all stressful

Risk analysis:
(What immediate or long-term risks might participation in your research entail for your subjects? Think carefully about not only possible physical risks, but also psychological, legal, financial, or social consequences that could result from either participating or from accidental disclosure of such participation.)

Answer:

We do not anticipate any significant immediate or long-term risks associated with this research.

Benefits:
(What benefits, if any, might participants get from your research? Please do not include any direct compensation paid to participants.)

Answer:

There are no major personal benefits for participants. However, the research will put Vermont pharmacies on a map, which may lead to a potential gain in popularity. The research may also be beneficial for business planning purposes.

10/03/2023 5:08 PM EDT

Benefits to discipline or society:
(What benefits, if any, might come of your research for your discipline and/or society at large?)

Answer:

This research is intended to analyze how spatial access to a crucially important sector of healthcare— pharmacies— varies across Vermont's population. Specifically, it will highlight areas of Vermont that have particularly limited access to pharmacy care, which is crucial from a public policy and public health standpoint. Members of the Vermont State Department of Health and the Green Mountain Care Board are interested in the results of this study and its benefits to public health planning in the state. Outside of the context of Vermont, this research is implementing a first of its kind tool to measure spatial accessibility to pharmacy care, and this model may be applied to other geographic regions to find other areas of limited pharmacy access.

10/03/2023 5:08 PM EDT

Physiological Data Collection

Exercise:

(Will you require subjects to perform exercise? If so, at what level of exertion?)

Answer: ✔Subjects will not exercise
Yes, mild exertion
Yes, moderate exertion
Yes, strenuous exercise

Correspondences

Publicationss

Annual Reviews

Year	Status	Due Date	Date Received	Date Approved	Submitted By
1	Due	10/17/2024			

Total # Subjects Enrolled Since Last Annual Review:
Total # Subjects Enrolled in Study to Date:
Total # Subjects Who Have Died: 0
Total # Subjects Who Have Completed Study:
Total # Subjects Still Active:
Continuation Status:
Unforeseen/Adverse Events: None
Describe Unforeseen/Adverse Events:
Additional Comments:

Amendments

Adverse Events

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

Protocol Deviations

Status	Protocol Deviations File/Comments	Submitted By
	No Protocol Deviations Found	

Reviewer Comments

Chair Approval: Review Completed, Due date 10/25/2023 5:00 PM EDT
This proposal has been reviewed and approved.