University of La Verne

View xForm - Initial La Verne IRB Application V5 New Regs

Please use this form for all new initial applications for the Institutional Review Board.

Initial Application Data Entry

Instructions

Most applications at La Verne fall under exempt review. Please review our exempt decision charts website and exempt application policy before starting your application to ascertain if you have an exempt study.

Human Subjects Research

Are you a researcher who is NOT affiliated with University of La Verne?

No

Are you currently staying in the European Economic Area (EEA; for list of countries, see guide on the right)?

No

The EEA is comprised of: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the UK, Iceland, Leichtenstein, and Norway

Is this human subjects research?

Yes

Select "No" if this is a secondary data study or other type of research that does not use human subjects (e.g., analysis of policy).

Review Type Determination

The worksheet below will help you determine if you should apply for an exemption (exempt review) or if your application is better suited for an expedited or standard review.

Does your study completely fall into any of the exemption categories listed below?

None of these categories apply

You must have reviewed the federal regulations at §__.104 prior to making a selection as the categories are summarized from the regulations and are not comprehensive.

Application Header and Instructions

Under which of the following expedited categories does your application qualify for an expedited review?

Collection of data through noninvasive procedures...

*Please refer to the **nonexempt policy** for more information on each category.*

Is your study more than minimal risk?

No

Does your study specifically target vulnerable populations or individuals who are experiencing situational vulnerability?

No

Your study appears to qualify for an expedited review. Please mark expedited below.

Please mark the review type populated in the box above this question.

Expedited

Review the nonexempt policy to determine your review type.

Submitter

Guerrero, Amanda

Email: aguerrero@laverne.edu **Phone:**

Title of proposed research study:

The Freshmen 15 Intervention

Principal Investigator (PI) email address: the name will populate once you move to the next question.

Putter, Natasha

Email: nputter@laverne.edu **Phone:**

Please enter the email address of the principal investigator. If you are the principal investigator please enter your own email address.

Choose the most appropriate research category for this application

Faculty or Staff Professional/Academic Research

*If you are an **external researcher wishing to conduct research at La Verne,** select "Outside Research by Non-Affiliated Researcher"*

Principal Investigator (PI) Position:

Professor

Enter the appropriate position for the principal investigator.

Did you verify you have a human subjects training certificate (NIH or CITI) on file with the La Verne IRB? Please read and follow the instructions to the right of the drop down list. If you fail to follow these instructions, your application will be returned unread.

Yes

If an expiration date for your human subjects training certification is listed in your settings (Click on Settings in the top right hand corner, and then My Expirations), select Yes. Otherwise, select "No."

Do you have a funding agency associated with this proposed research study?

No

Choose the most appropriate La Verne on-campus department/program.

Kinesiology

In which college is your program/department housed?

College of Arts and Sciences

Have you reviewed the La Verne IRB policies and procedures located on the on the IRB website?

Yes

If you have not reviewed the website, please make sure to review it (http://sites.laverne.edu/institutional-review-board/policies-and-procedures/) prior to submission of your application.

Do you have additional proposed research personnel associated with this study?

Yes

Additional proposed research personnel may include; advisor, students, mentor, other investigators, research coordinators, etc...

This field automatically populates the date of your first submission. No action is required by you.

5/16/2017

Additional Proposed Study Personnel

Click the link provided below if your contact is not found in IRBManager. You will know this is the case if the email address cannot be found in the table where you are adding the researchers.

Click Here - Add a New Contact into IRB Manager

Enter details for any proposed Co-Investigator(s) below. You are *required* to attach a human subjects training certificate if the new personnel does not have one on file with the IRB. You must click "Save" after inputting each Co-Investigator's information.

Additional Proposed Research Personnel Contact Email	Attach your current human subjects training certificate (NIH, CITI, etc...)	Choose the most appropriate position for the Co-Investigator(s)/Additional research personnel.	If other, describe title/position.
Holmes, Sherlock **Email:** sherlock.holmes@university.edu **Business:** 987-654-3214	*No answer provided.*	Master's Student	*No answer provided.*

Enter details for any proposed Non Co-Investigator(s) below. You must click "Save" after inputting each Non Co-Investigator's information.

Additional Proposed Research Personnel Contact Email	Attach your required "current" human subjects training certificate (NIH, CITI, etc...)	Additional Proposed Research Personnel Position	If other, describe title/position.

Is any investigator or non-investigator named above currently staying in the European Economic Area (EEA; for list of countries, see guide on the right)?

No

The EEA is comprised of: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the UK, Iceland, Leichtenstein, and Norway

Study Details

Briefly describe the purpose(s) of the study:

Young adults exhibit an increasing prevalence of obesity, linked to metabolic disturbances that may contribute to increased risk of type II diabetes, cardiovascular heart disease, and other conditions later in life. Obesity rates have been shown to increase within the first year on a college campus in both males and females at both a state and private University in the US. Recently lower BMI levels were seen following 6 weeks of feedback incorporating an internet intervention in college age first year students.

Therefore, the focus of this study is to observe the impact of the academic semester in addition to an intervention group obtaining four 1-hour health (once a month) and wellness seminars based on certain variables (described below).

*Give as many details as possible for study purpose. If this is a **Senior Thesis** or **Graduate Capstone** that you plan on publishing/presenting, you are **required** to state this in your application, here.*

What are your research questions, hypotheses, and key variables?

Research Question: What impact, if any, does an intervention group have on first year college students in an academic semester?

Variables: dietary intake and behaviors, physical activity habits, body composition measurements, and medical history and lifestyle (caloric education, socioeconomic status, physical activity, etc.) behaviors in young male and female first year college students within the first academic semester (Fall 2015 – December 2015) on the University main campus. It is hypothesized that first year resident students who attend the monthly seminars (Group 1) will result in a positive impact on their health in regards to their body composition values (Group 2).

It is also hypothesized that for group 2 an intervention of lecture health based seminars (see attached summaries of activities for young first year college students (18-20 years) who are residents on the main campus will result in possible weight loss or maintenance ultimately reducing their potential risk for disease later in life in order to lead a possible healthy life.

*If your study does **NOT** have research questions, hypotheses, and/or variables as a result of experimental design, please state this for auditing purposes (e.g. state, "A XX (study type) study does not require the use of variables").*

Will all participants be age 18 or older?

Yes

Describe the characteristics of the expected sample of human participants (i.e., inclusion and exclusion criteria):

Group1: 650 first year college students (male and female) are expected to complete the electronic survey portion of this study. Participants will be asked for their University Student ID number.

Group 2: 300 young (18-20 years) first year college student residents in Baker and Conan dormitories (male and female) will be recruited for this 1 semester intervention study following initial screening procedures including exclusion criteria, see below.

Total number of expected participants: 650 first year University students
Exclusion Criteria:
Participants will be unable to participate if they are found to have any of the following at the time of study participation: under the age of 18 years or over the age of 20 years, sophomore, junior, or senior status, previously enrolled in classes on the University campus, pregnant or planning on becoming pregnant, non-resident at University Baker and Conan dormitories (Group 2). Research staff will review this list of exclusion criteria with each participant at the time of consent in order to identify eligibility

Please make sure to include all characteristics associated with the population (e.g., American or International resident, age range, total number of participants, gender, inclusion or exclusion criteria, how you plan to gain access to the potential participants, etc...)

What is your expected (maximum) sample size?

650

Number of total (or maximum) participants expected to recruit for this study.

Select any of the following vulnerable populations/populations that require special considerations included in your proposed sample.

No Vulnerable Populations

Proposing to study any of these populations may require full (standard) La Verne IRB review.

Recruitment

Will you be recruiting participants (asking people to take part in your study)?

Yes

Participant Recruitment Description

University, Main Campus, first year students
University, Main Campus, first year student residents at Baker and Conan Dormitories

The PI (Dr. Arthur Doyle) and research assistants (Sherlock Holmes and John Watson) will be responsible for recruitment, retention and coordination of subjects.

Recruitment strategies include:
Group 1: Mass email survey to all incoming first year University students. The email will include an active Qualtrics survey link (Active survey link here) sent by the University Housing and Residential Life office of Baker and Conan dormitories. (See Attached Proposed Email)
Group 2: Baker and Conan dormitory group information session (5-10 minutes), on site freshmen orientation recruiting. Group presentations will include a brief overview of the study (similar to the description provided in the Informed Consent), and will provide interested individuals with information to contact the researchers if they wish to participate or receive more information regarding the study.

Permission has been obtained from the Housing and Residential Life and is provided as an attachment.

All data collection will occur on the University main campus either in the Baker and Conan dormitories and/or in main campus lecture halls. The Housing and Residential Life will be responsible for setting the location for the monthly health and wellness seminars.

Describe how participants will be recruited or selected. This should include describing how flyers will be posted, how participant emails will be obtained for emails to be sent, etc.

Recruitment Sources

dorms at University, online at University

From what source(s) will you be recruiting, e.g., hospital, institution, school, class, shopping mall, etc.?

Attach your recruitment materials.

TBD Recruitment Materials

Attach any recruitment materials, e.g., letters, postcards, flyers, for IRB review and approval. Generally, any advertisement to recruit subjects should include: 1. ***The title of the study,*** *2.* ***The purpose of the research and, in summary form, the eligibility criteria that will be used to admit participants into the study,*** *3. A straightforward and truthful* ***description of the benefits (e.g., to society, to the participant)*** *to the participant from participation in the study, 4. Any incentives, 5.* ***The location of the research and the person (the researcher/investigator) to contact for further information,*** *6. The following statement: "****Approved by the Institutional Review Board, #.....****" [Include IRB Approval Number].*

All materials are required to be attached to the application during submission if you plan to email, post flyers, or use any other written materials for recruiting participants.

Please refer to the Advertising Procedures for information regarding this policy.

Will you need permission to recruit from institutions/agencies from where you are recruiting participants and/or to name the organization in presentation/publication/dissemination of the findings?

No

All permissions to recruit participants or name the institutions/agencies during dissemination are required to be submitted with your application.

Please refer to the IRB Policies and Procedures for more information.

Proposed Protocol

Data Collection Method (check all that apply)

Experimental Procedure Direct Measure/Self Report
Intervention - Behavioral
Observation
Questionnaire Administered In Person
Questionnaire Administered Via Qualtrics/Online

*Please review the **Data Protection Policy** concerning which online platforms are allowable for electronic questionnaires.*

Provide a link to your electronic survey.

university.edu

Provide your online survey as a PDF here. This should reflect both the informed consent/information sheet and the final questions as loaded into the electronic questionnaire program of your choice.

tbd Online Survey Attachment

Please attach the final version of the survey, interview script, focus group materials, physiological or behavioral protocol, etc. you propose to administer.

tbd Survey/Interview Script

What will you do with the human participants?

1) There will be three parts/groups to the study: Group 1: Mass Email- Electronic survey through Qualtrics (University Student IDs will be collected) to all University first year students (650 students). Group 2: A small group (approximately 300 students) of first year students who will consent to a series of body composition and dietary intake data collection pre and post-16 weeks. Group 2 participants will be asked to provide their University student ID number in order to link their Qualtrics survey responses (from Group 1).

All study participants (Groups 1-2) will be blinded from their results (surveys, body composition, physical activity, etc. throughout the study). The following steps will occur:

After IRB approval, a recruitment email that will contain study information and a link to an electronic survey will be emailed to all first year students from the Housing and Residential Life office. If this study does not receive ULV IRB approval in time to meet the Housing and Residential Life office's freshmen orientation schedule, the recruitment email will be sent out as a mass email from the researchers, with permission from University IT, once IRB approval is granted. The research team will not have access to these email addresses. Group 2 participants will be selected from the data in order to be able to link and analyze Group 2 participant's answers with body composition, physical activity, and dietary behavior. The survey will contain a consent form where they will choose to agree or disagree to take the study.

On August 24th, the first official floor meeting of both dormitories, the research group will be providing a 5-minute recruitment presentation at each dormitory. The residents will be informed about the Group 2 study where they will be asked to consent for pre and post 16-weeks body composition data collection and lecture seminar attendance. An "I am interested and would like more information" sheet will be available for the group to sign up (name and email address) once the researchers leave the dormitories. Researcher's contact information will also be available to the residents. Once residents reach out to the researchers and vice versa, the researchers will set up a time for interested students to meet on a specific day of their orientation weekend to conduct the consenting and surveying process. Any students not wishing to participate in the research study will still be eligible for all housing activities.

Between August 25 and September 25, the researchers will be set up at a table for recruitment for Group 2 purposes at dorm related events or within the dorm itself. Consenting (paper) and surveying (electronic through iPADs) can be completed at this time. All Group 2 participants will be asked to read and sign a consent form before collecting any data. For consenting or data collection purposes, privacy areas will be set up.

Data collection for Group 2 will occur at set times and days that work for the consenting participants. Data collection will occur in either Baker or Conan. This will be the same process for pre and post 16-week data collection. Data collection specifics are below.

*Describe in detail all the methods and procedures that involve human participants. This section should help the La Verne IRB Committee understand from initial contact to completion of the research protocol what will happen to participants and is the **most important part of your application**. State the following in chronological order and number your answer: 1) what the participants will be asked to do, 2) where the research will occur, 3) what measures will be used (e.g. test), what data and information will be collected, and how, and 4) how long it will take to complete the instrument and/or task (if multiple items, break down by item).*

Body composition scales will be locked in the dormitories (for the entire semester) and each Group 2 participant will be assigned a specific profile to a scale. For pre and post 16-week data collection, Group 2 participants will be using their assigned scale each time they self-weigh in. Group 2 participants will have the ability to step on the scale any time they want in between pre and post data collection but participants will not be able to see any data collected including body composition until the study is complete.

Data for all participants linked to a scale will be electronically sent to the researchers. The scales are linked to a health tracking app provided by Withings. An account will be made for each scale and Group 2 participants will not have the ability to view results, only the designated research team. All group 2 participants will be assigned a study ID number and the scale results will be linked to that study ID separate from any other demographic details.

Group 2 participants will be asked to attend four 1.5-hour seminars throughout the semester (more details below) if they wish, however, since the seminars are a part of the dormitory program and they have the option to attend other seminars (not related to this study) it is not guaranteed that all of Group 2 participants will attend this study's seminars. Therefore, attendance (University student ID number) will be taken (by the dormitory assigned Resident Advisor) at each seminar and the researchers will be able to track how many of the study's seminars each Group 2 participant attends.

3) Survey will ask about basic demographics, medical and lifestyle history and will include questions in regards to psychological, social, and environmental information. University Student ID numbers will be collected.
4) The survey will have 163 questions and should take about 45 minutes to complete. The seminars are 1.5 hours long and there will be 4 of them. Using the scale will be 30 seconds per time used (only 2 required).

Will you be using audio/visual recording?

No

State when (approximate dates) and where the activities involving human participants will take place. The beginning date must be after IRB approval. If location(s) require permission(s), please attach authorization letters. For on campus research use "La Verne," otherwise state location.

Location	Start Date	End Date
University	8/22/2016	6/30/2017

Type in the location, select the appropriate dates, and click "Save."

Are location permissions needed for the proposed research?

No

If the research takes place at a location off-campus (any non-La Verne campus), permission may be required for the research to be conducted there. Examples could include school districts, institutions of higher education, businesses, etc. This is different than recruitment locations.

All permissions are required to be submitted with your application. Please refer to the IRB Policies and Procedures for more information.

Is an off-site location IRB involved with the review of this application?

No

All permissions from the off-site IRB are required to be submitted with your application. Please refer to the IRB Policies and Procedures for more information.

Copyright Permissions Signature

By signing below you are agreeing to the following: 1) you have reviewed the University policies prohibiting misappropriation of research and agree to conduct your proposed research in accordance with such policies; 2) you understand that it is your responsibility for determining and obtaining appropriate and correct permission(s) to use instruments, measurements, scales, etc. as dictated by each individual item created by someone other than you that you use in your study, 3) you are following the La Verne policy on Copyright, which can be reviewed by clicking here, 4) that you have already determined and obtained the appropriate permissions for the materials you have attached as a part of this IRB application, 5) you understand that the IRB does not provide approval for or take any responsibility for the acquisition of necessary permissions for using work by someone other than yourself, and 6) you agree to indemnify and hold harmless the University, the IRB and individual members of the IRB for any claims and liabilities resulting from your failure to obtain the necessary and correct permissions for the study as submitted in this application.

Signed Thursday, August 9, 2018 7:52:13 PM ET by Guerrero, Amanda

Inducements

Are incentives being offered to participants?

Yes

Will you offer money or other incentives for participants' time?

What type of incentive are you proposing?

Opportunity Drawing

Please review California law as it relates to each type of incentive to ensure you are following California law. A quick search of the internet will provide you with the law as it pertains to each of the items listed below. You will be asked to provide tax forms, proof of registration, etc. for the items that require these documents under California law.

Please provide more details for the incentive(s).

The students will be entered into an opportunity drawing for the chance of winning 1 of 5 $10 gift cards to the University's bookstore. To be compliant with California law, all interested individuals may enter the drawing, regardless of participation.

Please provide the following information: 1) how much, 2) how often and when will you provide incentives (e.g. every 10 participants), 3) who will be eligible (check state laws to ensure compliance), 4) how you will handle drop-outs and or those that don't continue participation following consent (again, check state laws), 5) how you will confirm receipt of the incentives, and 6) how long you will provide for claiming incentives after the study is completed.

Consider the information on our website as it pertains to incentive amount.

Tax forms are required to be filed for all incentive increments over $24.99. This means the participants will have to complete a tax form for you to turn in that lists their social security number, address, etc. and the incentive will be reported to the IRS as taxable income. Have you accounted for this in your description of the incentive above?

Yes

Please refer to the Finance Department at La Verne for more information on this institutional and IRS policy. Forms are available from them.

California law requires that opportunity drawings have "general and indiscriminate distributing of tickets." For the La Verne IRB, we interpret this to mean the drawing is open to all who want to join and not just people who participate in your study. Have you updated your informed consent/information sheet and the answer above to account for this portion of the law?

Yes

Proposed Risk

What level of risk does this research present to the dignity, rights, health, welfare, or privacy of the participants?

Minimal Risk to Participants

Minimal Risk to Participants *may require an Expedited IRB review*

More than Minimal Risk to Participants *may require a Standard IRB review*

If unsure what you should select, please visit the La Verne IRB policy webpage for more detailed explanations.

What type of risk is present in the proposed study?

Identifiable
Psychological
Social Group Status

Consider: 1) identifiable (the participants' identities can be traced, which can happen in ***confidential*** *studies), 2) physical (more than the participant may encounter on a daily basis), 3) psychological (more than the participant may encounter on a daily basis), and 4) social or group risk (when a* ***participant belongs to a group, is employed, or is a student*** *and their status may be in jeopardy or impacted by participating or not in the research).*

Select options that describe the identifiable risk in your study.

Data are confidential, but protected

Only describe identifiable risk

Select options that describe the psychological risk in your study.

Discomfort may result from sensitive questions

Select options that describe the social group risk in your study.

Students may experience discomfort answering questions about their institution/teacher/or other school official

Will you be adding the following safeguard (altered to match your study) to your study and specifically state it in the informed consent? Safeguard: The participants' positions with their [write either employer, institution, school, etc. that is specific to your study] will not be jeopardized by participating or not, nor by the content of their answers.

Yes

Is the risk more than everyday life in your study?

No

Please select the appropriate answer for your study. If it is more than everyday life, referrals are required by the IRB.

If, as part of your management of risk, you are referring participants to an agency that is not a part of the University of La Verne, please list the name of the agency here and if applicable attach a letter from that agency stating its qualifications and granting you permission to use its name.

Referral agency for participants.	Referral Agency Attachment

*The La Verne IRB requires a minimum of **three** referrals if you are referring participants to a non-La Verne agency.*

Please select what you will implement in your study from the following safeguards (check all that apply):

Using strong confidentiality procedures (see Confidentiality Procedures below for more information)
Referral to CAPS

Describe any benefits to the participant(s) and/or society that may reasonably be expected from the research.

Upon completion of the study, participants can be provided with their health information that was collected as part of the study (percent body fat, body weight, weight gain, dietary intake etc.) in order to review their personal information on their own time with a medical professional (or university student health services, university counseling center). Findings from this study could be used to develop future college health and wellness programs nationwide. Participants will be prompted to request the information from a research study investigator.

Provide a summary of research findings where appropriate, benefits to organizations, professionals, the discipline, or others.

Please select the appropriate description of your study.

Confidential - identifiers are present in the data, but you will not be sharing this information in a manner that can be traced back to a specific individual, thus protecting the participant

*Most studies are **EITHER** confidential **OR** anonymous. If you have designed a study that is **only** confidential **or** anonymous, please be consistent throughout the application and only use the appropriate term (i.e., don't use the terms interchangeably)*

Check all confidentiality/anonymity procedures you have put in place. Per the La Verne IRB Policies and Procedures, signed informed consent forms must be stored for 3 years.

Use of protocol numbers that do not link participants to answers
Data will be reported in aggregate/summary
Signed consents will be stored separate from data so they cannot be re-associated

Do you need to request permission from La Verne to use their name in your research as the institution at which you conducted the research?

No

Please mark the box below to add the safeguard that you will not be naming the institution in your research.

Institution at which research is conducted will not be named

Faculty, staff, and administration are able to apply to store data beyond the standard 3 years for archiving purposes. Are you applying to do so?

No

Per the La Verne IRB Policies and Procedures: If the data are approved to be kept more than 3 years, the corresponding informed consents must also be retained. If the data are anonymous and an informed consent was not used to collect the data, informed consents are not required to be retained with the data if approved for retention beyond 3 years.

Please sign here to 1) agree to storing the signed consent forms (if applicable) and data for 3 years upon which time they will be destroyed, and 2) agree to put this information in the confidentiality section of your information sheet/informed consent.

Signed Thursday, August 9, 2018 7:53:58 PM ET by Guerrero, Amanda

Survey Confidentiality Procedures

The consent form will contain an agree/disagree statement and no names will be collected

Please select from the storage options for data and consents approved by the IRB. These are the only options allowable under IRB policy and procedure as they are compliant with federal and international law.

Paper forms: locked in a University of La Verne filing cabinet, also locked in a University of La Verne office
A password-protected computer stored in a locked University of La Verne office

For more information, refer to the Data Protection Policy.

Do these data fall under HIPAA protections (e.g., medical data)?

No

Who all will have access to the data and/or consents/assents?

Myself and co-investigators

Please name all people and their association to this study with access to the data and/or consents/assents.

Will a form of debriefing be needed for this study protocol or for this population?

No

If sensitive issues are raised in the research protocol, or if deception or incomplete disclosure is used, mark "Yes."

Informed Consent

Choose your informed consent option.

Informed Consent and/or Informed Assent required

An informed consent is the standard (typical) format (paper, oral, electronic, etc.) for informing future participant(s) of all procedures, risks, benefits, etc. Confirm you have met the required categories for informed consent by visiting the IRB website for more information.

*A **waiver of informed consent** is proposed in situations that may require an altered consent form (studies involving deception, situational vulnerable populations, etc.).*

***Please note, if you **choose the waiver or alteration** in the usual informed consent process option, you will need to state any risk(s) to participants caused by their participation in this research and justify that the requested waiver or alteration to the usual informed consent procedures will not adversely affect the rights or welfare of the participants.*

Please mark all conditions that are contained in your study for obtaining informed consent.

If collecting surveys, interviews, focus groups, etc. in person/signature will be obtained: the consents and completed instruments will be collected and stored separately so they cannot be re-associated
If collecting surveys online/no signatures obtained: the participants will click to agree or disagree to the consent/information sheet prior to taking the online survey

Briefly describe when and how you will get informed consent (or an altered informed consent) from the participants. If using an information sheet in an exempt study, describe when and how you will provide it.

Group 1: Participants of the electronic Qualtrics survey will be asked to read and agree/disagree to consent before beginning the survey. They will be prompted that by participating or not in the study, their student or housing status will not be in jeopardy.
Group 2: Participants will be asked to read and sign their agreement to consent in the body composition/dietary intake/health and wellness seminars study before any data is collected. A PI, co-PI, or research assistant will go over the informed consent form with each participant.

See the La Verne IRB Forms and Examples webpage for template and examples.

The federal regulations state that adequate time must be given to participants to review and accept the informed consent. Please describe the amount of time given in your study and indicate how it is proportional to your research design.

Potential participants will be given 10 days to review and respond to the Informed Consent form.

For example, an informed consent is provided to the participants and they are told that your study is accepting participants until a particular date, at which time they will turn in an informed consent. That time frame is 10 days from the date they are provided the informed consent. 10 days is provided as it is a clinical trial testing the effectiveness of a medical device.

Will you be providing a copy of the informed consent to the applicants?

Yes

Please detail how applicants will receive a copy of the informed consent.

A copy will be scanned and sent to participants via email.

Will you go over the informed consent/information sheet?

Yes

Will the potential participants have an opportunity to ask questions?

Yes

Will participants be in a confidential location?

Yes, if they choose to be (typical of surveys administered in Qualtrics)

Informed Consent Attachment. Please *CHANGE* the document type to match the type of document you are uploading (e.g. consent, assent, information sheet, etc.).

tbd Consent Form (Informed) - Participant

If you have multiple consent forms *in your study, please upload all consent forms prior to application submission. All consent forms are required to be submitted prior to review.*

Please only upload Word versions of the consent/information sheet.

Optional Informed Consent Oral Explanation/Script.

No answer provided.