

VICTOR VALLEY COLLEGE INSTITUTIONAL REVIEW BOARD**APPLICATION TO INSTITUTIONAL REVIEW BOARD
for REVIEW and APPROVAL of
RESEARCH WITH HUMAN PARTICIPANTS**

Guidelines:

- (1) Submit form in typed format only.
- (2) This form must be completed in full. Please do not use abbreviations. If an item on the form does not pertain to the submission, then “not applicable” should be entered.
- (3) Provide as accurate a project duration as possible. In accordance with federal guidelines, projects must be reviewed each year of their duration. For projects greater than one year duration, the investigator must submit to the VVCIRB chair a written progress report and request for renewal. This must occur no later than 11 months after the previous approval date, to avoid interruption of the project.
- (4) Submit completed applications to the chair of the VVCIRB. If necessary, a copy of support information (funding source information; articulation agreements with other institutions; etc.) is required with project submission. Support information will not be returned unless explicitly requested by the investigator (See application form).
- (5) **Submission MUST include a Written Informed Consent(s). (See example attached)**

VICTOR VALLEY COLLEGE INSTITUTIONAL REVIEW BOARD

**APPLICATION TO INSTITUTIONAL REVIEW BOARD
for REVIEW and APPROVAL of
RESEARCH WITH HUMAN PARTICIPANTS**

TITLE OF PROJECT: _____
(Do not abbreviate) _____

DATE OF SUBMISSION: ____/____/_____
(MM/DD/YYYY)

PROJECT TYPE: New [] Continuation [] VVCIRB # _____ Other [] _____

PROJECT DURATION: _____
(If project lasts more than 1 year, an annual progress report and renewal is required)

PRINCIPAL INVESTIGATOR(S):

Name	Position	Academic Unit
E-mail Address		Phone #

CO-INVESTIGATOR(S):

Name	Position	Academic Unit
E-mail Address		Phone #

FUNDED: [] No [] Yes _____
Funding agency(ies) ; type of funding; grant number

Filing for Expedited Review of Survey/Questionnaire Research

[Insert your name(s) here]

[Insert title(s) here]

[Insert date here]

1. Indicate by a [X] whether the following are involved:

- Patients as subjects
- Non-patient volunteers
- Students as subjects
- Trainees as subjects
- Minor subjects (less than 18 years)
- Subjects whose major language is not English
- Mentally disabled subjects
- Mentally retarded subjects
- Prisoners, parolees, or incarcerated subjects
- Subjects studied at non-Victor Valley College locations
- Subjects studied at Victor Valley College-affiliated hospitals
- Subjects in the Armed Services (active duty)
- Filming, video-, or voice-recording of subjects
- Department subject pool
- Pregnant women
- Data banks, data archives and/or registration records
- Subjects to be paid

2. To qualify for expedited review, the following conditions should be met

(Check each of the following to confirm):

- _____ The protocol consists only of the administration of a written survey or questionnaire.
- _____ Participants will NOT be audio- or videotaped.
- _____ No members of at-risk populations (e.g. minors, pregnant women and prisoners) will be enrolled in the study.
- _____ The survey instrument will include the appropriate statement of voluntary participation provided in the consent form.
- _____ There are no foreseeable risks or discomforts (physical, emotional or psychological) associated with participation in the study.
- _____ Participants will not receive monetary compensation.
- _____ The survey instrument will ensure participant privacy by being distributed in such a way as to leave no public record of participation.
- _____ No personally identifiable information will be reported in any published or unpublished work.
- _____ Access to the data generated by this survey will be restricted to the investigators listed in this proposal.

IF ANY OF THE ABOVE DOES NOT APPLY, THEN THIS STUDY MAY NOT QUALIFY FOR EXPEDITED REVIEW. See item #4 for checklist and page 6 for amendments. From this information, the VVCIRB will determine if expedited review is allowable.

3. Project Description

Attach separate page(s) if necessary. A prepared study proposal (e.g., thesis; course project; IRB application from granting institution) may be attached in lieu of a description. The description must be sufficient to allow the VVCIRB to achieve a clear understanding of the project objectives, methods, and significance.

4. Checklist for expedited review of survey or questionnaire research protocols:

Confirm those of the following that apply to the proposed protocol. To ensure expedited approval, at least one option must be confirmed in each of the sections 4a – 4d below. If the protocol does not include at least one option in one or more of these sections, provide an explanation and alternative protocols under “Amendments to Approved Protocols”.

4 a. Participant Selection (Confirm at least one of the following)

Participants will be recruited only from my classes at Victor Valley College.

Participants will be recruited from classes other than my own, or in my own classes by a party other than myself, at Victor Valley College.

Participants will be recruited with a web-based system in which students volunteer to participate through a website. The recruiting system and website will leave no public record of participation.

Other (Please explain)

4 b. Data Collection (Confirm at least one of the following)

Paper and pencil

Electronic Interface (online survey, web-based application, clickers)

Other (e.g. Archival data)

4 c. Data Storage (Confirm at least one of the following)

Data files will be stored using an *encryption method on a password-protected and access-restricted computer.

Data will be stored confidentially in hard copy in a locked file cabinet, combination locked safe, or comparable physically secure device.

*Encryption = process of transferring information using an algorithm to make it unreadable to anyone except those possessing special knowledge, usually referred to as a key.

4 d. Privacy Considerations (Confirm at least one of the following)

_____ The data will be collected anonymously.

_____ The data will be collected confidentially. However, participant data will be identified by a private ID code.

5. Description of instrument:

5a. Please provide a brief description of the instrument(s) (1 – 3 Sentences):

5b. How long does it take to administer?

5c. Is/are the proposed instruments published? Yes No
(If yes, then please provide reference/s):

***Attach a copy of all instruments to the application.

Amendments to Approved Protocols

Expedited approval can only be assured if at least one approved protocol in each of sections 4a. – 4d. is confirmed. However, expedited approval may still be granted if a satisfactory alternative protocol is provided and explained below.

(Note that under 4b. Data Collection, no amendments that would result in a deviation from the use of written surveys/questionnaires will be accepted.)

Section 4a. Participant Selection

Alternative Protocol(s):

Explanation for Amendment:

Section 4b. Data Collection

Alternative Protocol(s):

Explanation for Amendment:

Section 4c. Data Storage

Alternative Protocol(s):

Explanation for Amendment:

Section 4d. Privacy Considerations

Alternative Protocol(s):

Explanation for Amendment:

THE PRINCIPAL INVESTIGATOR MUST ASSURE THE INSTITUTIONAL REVIEW BOARD THAT ALL PROCEDURES PERFORMED UNDER THE PROJECT WILL BE CONDUCTED BY INDIVIDUALS LEGALLY AND RESPONSIBLY ENTITLED TO DO SO, AND THAT ANY DEVIATION FROM THE PROJECT (E.G., CHANGE IN PRINCIPAL INVESTIGATORSHIP, RESEARCH METHODOLOGY, SUBJECT RECRUITMENT PROCEDURES) WILL BE SUBMITTED TO THE VVCIRB FOR ITS APPROVAL PRIOR TO ITS IMPLEMENTAION.

NOTE: Applications and any additional material requested by the VVCIRB will not be processed unless legible, properly prepared, and signed personally by the Principal Investigator, Sponsor (if applicable), and the Principal Investigator's supervisor or department/division chair.

I acknowledge that all procedures will meet relevant local, state, and federal regulations regarding the use of human subjects in research (VVCIRB *Institutional Assurance Concerning Human Research*).

I have completed the NIH Certification and included a copy with this proposal.

<http://phrp.nihtraining.com/users/login.php>

Other organizations for certification: _____

I have included documentation of IRB approval by my granting institution.

Signature of Principal Investigator(s)

Date

Signature of Co-Investigator(s)

Date

FOR OFFICE USE ONLY

After expedited review, the following proposal has been approved.

VVCIRB Member _____ Date _____

VVCIRB Member _____ Date _____

VVCIRB Member _____ Date _____

VVCIRB Member _____ Date _____

VVCIRB Chair _____ Date _____ VVCIRB# _____

See addendum for informational item(s) to division dean and CIO.

VVCIRB# _____

Informed Consent for Participation

[Insert Project Title Here]

[Insert Granting Institution Here]

[Insert Granting Institution's Address Here]

PRIMARY INVESTIGATOR(S): _____

CO-INVESTIGATOR(S): _____

I have been asked to participate in a research study that investigates _____. Results from this study will aid in understanding _____.

I understand that the [survey/interview] is completely confidential, that I will retain absolute anonymity, and that completion is voluntary. I also understand that I may stop participating in this study at any time for any reason. I understand that data collected for this study may be published, but that confidentiality concerning my identity will be maintained. If the study design or use of the data is to be changed, I will be so informed and my consent re-obtained.

I understand that:

- A. There are no foreseeable risks associated with completing the following survey.
- B. There is no direct benefit to participating in this study and I will not be compensated for my time.
- C. Any questions I have concerning my participating in this study will be answered by **[Include phone number and/or e-mail address]**
- D. I may refuse to participate or may withdraw from this study at any time without negative consequences. Also, the investigator may stop the study at any time.
- E. No information that identifies me will be released without my separate consent and that all identifiable information will be protected to the limits allowed by law. If the study design or the use of the data is to be changed, I will be so informed and my consent re-obtained.
- F. If I have any questions, comments or concerns about the study or the informed consent process, I may write or call **[Include phone number and/or e-mail address]**
- G. I acknowledge that I have received a copy of this form.

I will be less than 18 years of age during the duration of this study.

I have read the above and understand it and hereby consent to the procedure(s) set forth.

Name (please print)

Date

Signature

WITHDRAWAL LETTER

Research Study Title:

Dear {place researcher here} _____

I would like to withdraw my participation and previous authorization to use my information for the current study. I am aware that there is no risk in withdrawing my participation.

Participant phone:

Participant email:

Printed name of participant _____

Signature of participant _____

Date _____