# APPLICATION FOR EXEMPTION FROM IRB REVIEW


Mailing Address:
26455 Rockwell Canyon Road
Santa Clarita, CA 91355

Physical Address:
26455 Rockwell Canyon Road
Santa Clarita, CA 91355

Phone: (661) 362-5329
Fax: (661) 362-5600
E-mail: IRB@canyons.edu


## EXEMPTION APPLICATION SUBMISSION CHECKLIST

- ☐ Exemption Application
- ☐ Appropriate Appendices
- ☐ Consent form and/or statement indicating that the study meets the requirements to obtain a waiver of consent
- ☐ Documentation of human subject protection training for all key research personnel
- ☐ Recruitment materials/advertisements (If Applicable)

College of the Canyons

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Submission Instructions:
Submit the original plus 2 copies of the application and any other supporting documentation to the IRB Office. This application must be typed. No handwritten applications will be accepted.

1. IRB Protocol ID: - -
2. Title of Study:
3. Describe the objective(s) of the proposed project including hypothesis, purpose, research questions, methodologies, and background information. **Please see attached IRB proposal approved by Stanford University's IRB for project description.**
4. Principal Investigator (PI):

| | |
|---|---|
| Name: | Highest Degree Earned: |
| Mailing Address:<br>City:<br>State: Zip: | Phone Number: |
| | Pager / Cell Phone: ( ) - |
| | Fax: |
| | Email: |
| Completion Date of Human Subject Protection Training: (MM/DD/YYYY) | |
| Contact Person / Study Coordinator Name: | Highest Degree Earned: |
| Mailing address (if different from PI):<br><br>City:<br>State: Zip: | Phone Number: |
| | Fax Number: |
| | E-mail: |

## Principal Investigator's Assurance

I understand that as Principal Investigator, I have the ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulation imposed by the College of the Canyons' Review Board. I am responsible for the actions of co-investigators and must notify the IRB in writing of any addition or deletion of a co-investigator to/from the protocol.

I agree to comply with all IRB policies, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including but not limited to, the following:

- Performing the protocol by qualified personnel according to the approved protocol,
- Implementing NO changes in the approved protocol or consent form without prior IRB approval, (except in an emergency, if necessary to safeguard the well-being of human subjects),
- Obtaining the legally effective consent from human subjects or their legally responsible representative, and using ONLY the currently approved, stamped consent form,
- Assuring that each executed consent form includes the name of the person who explained the protocol, the subject's signature, the signature of a witness and the signature of the investigator,
- Reporting in writing all **fatal or life-threatening adverse events** to the **IRB within 72 hours (3 days) after discovery**,

| **Principal Investigator's Assurance** |
|---|
| • Promptly reporting in writing all **serious and/or unexpected adverse events** to the IRB within 7 calendar days after discovery,<br>• Reporting **all adverse events at continuing review** (including all deaths, regardless of cause). |

| Signature of PI: | Date: : / / (MM/DD/YYYY) |
|---|---|

## APPLICATION FOR EXEMPTION FROM IRB REVIEW

## Co-Investigators:

| Name: | Highest Degree Earned: |
|---|---|
| Mailing Address:<br>City:<br>State: Zip: | Phone Number: |
| | Pager / Cell Phone: ( ) - |
| | Fax: ( ) - |
| | Email: |
| Completion Date of Human Subject Protection Training: (MM/DD/YYYY) | |

| **Co-Investigator's Assurance** |
|---|
| I agree to comply with all IRB policies, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including but not limited to, the following:<br><br>• Performing the protocol according to the IRB-approved protocol,<br>• Implementing NO changes in the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects),<br>• Obtaining the legally effective consent from human subjects or their legally responsible representative, and using ONLY the currently approved, stamped consent form,<br>• Assuring that each executed consent form includes the name of the person who explained the protocol, the subject's signature, the signature of a witness and the signature of the investigator,<br>• Reporting in writing all fatal or life-threatening adverse events to the IRB within 72 hours (3 days) after discovery,<br>• Promptly reporting in writing all serious and/or unexpected adverse events to the IRB within 7 calendar days after discovery. |

| Signature of Investigator: | Date: / / |
|---|---|

# APPLICATION FOR EXEMPTION FROM IRB REVIEW

## Research Staff:

| | |
|---|---|
| Name: | Highest Degree Earned: |
| Mailing Address<br>Office: | Phone Number: (  )  - |
| | Pager / Cell Phone: (  )  - |
| | Fax: (  )  - |
| City: | Email: |
| State:  Zip: | Completion Date of Human Subject Protection Training:  /  /<br>(MM/DD/YYYY) |

5. Exemption Category Claimed (*categories of exemption at the end of this form*): **[Choose]**

6. Estimated period of project or of human subject involvement: Start Date: / / End Date: / /

Funding Source (if applicable): **Check appropriate box and include funding source.**

☐ Industry Sponsored ☐ Investigator Sponsored ☐ Privately Sponsored ☐ Grant ☐ Other Source:

10. Conflict of interest: Do any of the investigators listed on this study have a potential conflict of interest? Yes☐ No ☐ Please explain:

11. Has the potential conflict of interest been disclosed and managed? Yes☐ No ☐ Please explain:

12. Source of Subject Population:
Number of Subjects/projected records/data files/or specimens:

**IF YOU ARE REQUESTING EXEMPTION UNDER CATEGORY # 4, COMPLETE THE FOLLOWING QUESTIONS:**

13. Will data, documents, records, biological specimens be used? Yes ☐ No ☐

a. What are the types of specimens?

b. Were the data/biological specimens to be used for your project originally collected solely for research purposes? Yes ☐ No ☐
(If yes, please include a copy of the IRB approved consent form used for the original collection of data/biological specimens.)

c. Is the source of data/biological specimens publicly available (i.e. available to the general public)? Yes ☐ No ☐

d. Will the data/biological specimens you receive contain any identifiers? Yes ☐ No ☐ If yes, please describe:

e. Who will have access to the data/specimens?

f. Describe provisions that will be taken to maintain confidentiality of data/specimens. Describe the security plan for the data/specimens including how and where stored and duration of storage (i.e. encrypted data, password protected etc.)

**IF YOU ARE REQUESTING EXEMPTION UNDER CATEGORIES # 1-3 OR # 5-6, COMPLETE THE FOLLOWING QUESTIONS:**

14. Describe the recruitment procedures (include any flyers, advertisements, informed consent forms etc).

15. Describe the procedures in which subjects will participate. If data collection instruments will be used indicate the time necessary to complete them, the frequency of administration, and the setting in which they will be administered, such as telephone, mail, or in person interview. (Please submit a copy of all instruments for this study, including all questionnaires, surveys, protocols for interviews, etc. **Please note that exploration of sensitive or private topics is not an exempt activity.).**

16. Will data be recorded by audiotape or videotape? Yes ☐ No ☐ Please clarify how subjects will be identified in study records / taped responses.

17. Will the study subjects be identifiable either by name of through demographic data? Yes ☐ No ☐ (If "Yes" is checked, please answer questions 17a and 17b. If "No" is checked, please go to questions #18.) (Note: Aggregate grouping of demographic data will prevent subject identification through that data.)

    A. Please describe how the confidentiality of subject's identity will be maintained.

    B. Please describe how subject identifiers will be maintained or destroyed after the study is completed.

18. Do you intend to collect protected health information (PHI) from subjects in the course of providing treatment / experimental care? Yes ☐ No ☐

19. Will you have access to PHI in the subject's records? Yes ☐ No ☐

**If you answered yes to either of questions #18 or #19 you must do one of the following:**

A. obtain the authorization of the patient, or
B. obtain from the IRB a waiver of HIPAA authorization [see HIPPA Waiver form] and a waiver of research informed consent, or
C. obtain from the IRB permission for the use of a limited data set (LDS)] and a waiver of research informed consent, or
D. obtain from the IRB permission for the use of a de-identified data set and a waiver of research informed consent, or

20. **Informed Consent:** (Please attach an appropriate informed consent document to this application. If subject participation is anonymous, an Information Sheet is recommended. If subject participation is not anonymous, please attach a consent form to this application or provide a justification for a waiver of informed consent. Waiver or alteration of the requirements for informed consent should be justified by addressing the items listed below. Please refer to the Santa Clarita Community College District's IRB Investigator's Manual.
    A. Explain why the proposed study presents no more than minimal risk to the subjects.

    B. Describe why the proposed research could not practicably be performed without the waiver of informed consent.

    C. Explain why a waiver of informed consent will not adversely affect the rights and welfare of the subjects.

**FOR SANTA CLARITA COMMUNITY COLLEGE DISTRICT'S IRB OFFICE USE ONLY**

I have reviewed the above information and recommend this study for exemption.

| **Signature of IRB Committee Co-Chair** | | | **Date:__/__/__** |
|---|---|---|---|
| **IRB Co-Chair: Check 1 box:** | ☐ **Approved** | ☐ **Approved with Conditions** | ☐ **Refer to Full Committee Review** |

## APPLICATION FOR EXEMPTION FROM IRB REVIEW

**Federal Regulations stipulate that a study can be exempt if the study meets one or more of the following conditions:**

### Categories (1-6)

**(1)** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**(2)** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

**(3)** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**(4)** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

**(5)** Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

**(6)** Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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**Federal regulations Stipulate that a study cannot be exempt if:**

**1) The study targets one or more of the following populations:**

- Prisoners
- Fetuses and/or
- Pregnant Women

**2) The Study involves the following types of research:**

a. Human in-vitro fertilization (i.e. and fertilization of human ova which occurs outside the body of the human);

b. Review of records if the information gathered from these records is identified in such a way that is can be linked back to the individual (either directly or through the use of a code);

c. Surveys or interviews given to minors;

d. Any procedure that may cause a subject either physical of psychological discomfort or is perceived as harassment above and beyond what the person would experience in every day life;

e. Deception;

f. Observation of minors if the investigator participates in the activities being observed unless there is a federal statute covering the activity;

g. If the sponsoring agency requires that the proposed research received full or expedited review even when the activities would otherwise qualify for exemption; or

h. The study involves genetic research (College of the Canyons' IRB policy)

Studies granted exemption by the IRB are exempted for the life of the research unless changes are made to the study procedures. Changes to exempted research must be reviewed by the IRB to ensure that the research continues to qualify for exemption. Even minor changes to research may necessitate IRB review under current regulations. Investigators are encouraged to contact the IRB office if changes to exempted research occur and there are questions regarding the need to submit research for continuing exemption determination.