

**RENEWAL APPROVAL REQUEST**  
**for Medical and Clinical Studies Involving Human Participants**

**Please read and follow these directions carefully. Omission of required components of the application will delay review of your application pending receipt of all materials.**

*Because this is a “locked” document, the links unfortunately do not work. All the pages referenced can be accessed from the IRB homepage: <http://www.irb.cornell.edu>*

1. All information must be typed. Handwritten proposals are not accepted by the IRB.
2. Refer to *Required Components of Informed Consent Documents* (follow the *Principles, Guidance & Resource* link), to ensure that the consent form that was previously approved by the IRB continues to fulfill current requirements and standards.
  - a. If the currently-approved consent document conforms to the current requirements and standards, *and you intend to continue using this consent form*, attach to this application a photocopy of a **recently-signed consent form that you have collected from one of your participants**. Feel free to block the signature to maintain confidentiality of this participant’s name. **Please do this for each different consent/assent form that you are currently distributing**.
  - b. If the currently-approved consent document does not conform to the current requirements and standards or if you are modifying your consent form, modify it using *Required Components of Informed Consent Documents* as a guide, and attach to this application a copy of the new form.
3. If you have allowed your approval to lapse, you must submit with your renewal application a **signed letter indicating that you have suspended all human participants-related activity since the termination date (specify the date) and will not resume such activity until IRB has approved your renewal application**.

Refer to the *Application Deadlines and Schedule of IRB Meetings* page (follow the *IRB Submission Requirements* link) for a brief overview of projects that require **full** committee review, and those that qualify for **expedited** review.

4. If **full committee review** is required:
  - c. *Turn-around time*: Applications must be received **at least** three weeks prior to the next scheduled IRB meeting. There are no exceptions to the deadline. Turn-around can therefore be between three weeks and six weeks.
  - d. Submit one copy of the Renewal Approval Request (one copy signed), recruitment materials (if still recruiting), consent form(s), and debriefing scripts to IRB, 35 Thornwood Drive, Suite 500.
  - e. Submit one copy of the funding proposal (minus appendices; you may block out salary figures) *if submitted to funding source since the last IRB review* **as well as the funding review comments that pertain to the use of human participants in your study** (if available). Also submit one copy of all measurement instruments (surveys, questionnaires, etc.) for which you need continuing approval.
5. If this study qualifies for **expedited review**.
  - f. *Turn-around time*: Allow three weeks for review and notification. (If the University is closed for holidays, please allow additional advance time equivalent to the time Cornell is closed.)
  - g. Submit 1 copy of the Renewal Approval Request (signed) and consent form(s) to IRB ORIA, 395 Pine Tree Road, Suite 320, Ithaca, NY 14850.
  - h. Also submit 1 copy of funding proposal (minus appendices; you may block out salary figures) *if submitted to funding source since the last IRB review* **as well as the funding review comments that pertain to the use of human participants in your study** (if available).

**RENEWAL APPROVAL REQUEST  
Medical and Clinical Studies**

**CORNELL UNIVERSITY  
Institutional Review Board – Human Participants**

*Click in shaded fields to enter information*

**Name of Investigator:** \_\_\_\_\_

Email address \_\_\_\_\_

Campus address \_\_\_\_\_

School & Department \_\_\_\_\_ & \_\_\_\_\_

Administrative Mgr. \_\_\_\_\_

Status:

Faculty

Research Associate

Post-doc

Ph.D. Candidate

Grad Student

Staff

Undergrad

Other

Faculty member supervising project (if applicable) \_\_\_\_\_

Email address \_\_\_\_\_

Campus address \_\_\_\_\_

**Title of Project:** \_\_\_\_\_

*Please be sure to use the same title as that used when this project was previously approved.*

**Anticipated End Date of Project:** \_\_\_\_\_

**Other Study Investigators:** Name(s) / Affiliation / Location

**Other Members of Research**

**Teams (include students):**

**Have all investigators and other researchers working on this project successfully passed the IRB, the NIH, or another university’s human participant’s training online?**  Yes  No If not, you need to inform them that Cornell must have written documentation of training in human participant’s protection.

1. Is this research funded by an outside (non-Cornell) sponsor?  Yes  No  Pending approval

If Yes, what is the name of the sponsor(s)? \_\_\_\_\_

If you know the project’s SPS #(s), please provide: \_\_\_\_\_

2. Is this research being conducted for a course?  Yes  No

If Yes, name of course: \_\_\_\_\_

Name of instructor: \_\_\_\_\_

3. Is this research being conducted for your thesis or dissertation?  Yes  No

4. Study Description and Study Progress Report. Clearly report progress on your study to date, including an approximate percentage of the data you have collected. Also provide clear details on your current and future research activities for this protocol. Be sure to include the specific location(s) at which any interaction with human participants will take place.

- \_\_\_\_\_
5. Will you ship any biological or diagnostic samples/specimens as part of this research?  Yes  No  
 If Yes, please contact the Biological Safety Officer at Environmental Health & Safety (4-4888 or fac2@cornell.edu) for specific shipping requirements.
6. Have there been any changes to your study since last year's approval?  Yes  No  
 If Yes, please describe:  
 \_\_\_\_\_
7. Has the IRB approved any revisions to study protocols, procedures, questions, or forms since its initial approval or last renewal?  Yes  No  
 If Yes, please describe. Also, attach all revised protocols, procedures, or forms, highlighting the changes made.  
 \_\_\_\_\_
8. Do you wish to request approval for any revisions (in recruitment, the consent form or process, study design, co-investigators, questions) at this time?  Yes  No  
 If Yes, please describe the changes requested. Also, attach the revised documents, highlighting changes from the originals.  
 \_\_\_\_\_
9. Please describe:
- any adverse events or unanticipated problems involving risks to participants or other this year:  
 \_\_\_\_\_
  - any withdrawal of participants from the research:  
 \_\_\_\_\_
  - any complaints about the research  
 \_\_\_\_\_
10. Have any potential benefits or risks to individual participants, social group, or society emerged that you have not listed in previous application(s)?  Yes  No  
 If yes, have you revised your consent form accordingly?  Yes  No  
**If yes, please provide a copy of the revised consent form.**
11. Have you published any papers pertaining to this research?  Yes  No  
 If Yes, please indicate:  
 \_\_\_\_\_
12. How many participants have taken part this since the project was last reviewed? \_\_\_\_\_  
 Approximate percent female:       %       Approximate percent minority:       %
13. What is the age range of participants to date? \_\_\_\_\_ to \_\_\_\_\_ years [**Note: this must match all attached documents submitted.**]
14. Actual duration of participant's participation, through each component of the study, and in total. **Please provide full information for each component of the study.**  
 \_\_\_\_\_
15. How many additional participants do you intend to recruit? \_\_\_\_\_  
 a. If additional participants will be recruited, how will they be recruited? Please be very specific. \_\_\_\_\_

- b. If **no** additional participants will be recruited, have you completed all your data collection?  Yes  No  
If yes, have you separated out *ALL* identifiers from your data?  Yes  No

16. Are participants compensated for their time?  Yes  No  
If Yes, please describe the compensation. \_\_\_\_\_

17. Which health/disease categories do participants represent? Please be explicit (i.e., healthy participants, patients with arthritis, recovering cancer patients, etc.)  
\_\_\_\_\_

18. Does your participant sample include Cornell University students?  Yes  No

If Yes:

- a. do you recruit participants from classes that you personally teach?  Yes  No

**Federal regulations discourage investigators from collecting data from their own students.** Explain why it is necessary for you to collect data from your own students. Please be very specific in your explanation.  
\_\_\_\_\_

- b. are participants obtained from the Psychology Dept. SUSAN website?  Yes  No

- c. are participants obtained from the University Registrar?  Yes  No

19. Are **prisoners or juveniles in detention centers or on probation** participants?  Yes  No

20. Does this study involve **secondary data analysis or analyses of limited (HIPAA) data**?  Yes  No

If Yes, provide a brief description in the field below of each dataset and indicate from which databank(s) or sources the data will be (has been) obtained. For each dataset, please include the following information:

- a. Can the names or identities of participants in the dataset be deduced from the data fields? \_\_\_\_\_

- b. Is the dataset public-use (no restrictions on use) **OR** is the dataset restricted/limited access? (If restricted/limited access, attach a copy of the licensing agreement you signed with the distributor, as well as a copy of your data security plan.) \_\_\_\_\_

- c. Are you planning to merge geographic, company, census, community or other potentially identifying data into an individual-level dataset during the course of this project? (If so, attach a description of how you plan to protect the data from unauthorized use.) \_\_\_\_\_

- d. Will anyone other than you have access to any restricted/limited access dataset(s)? (If so, provide their names, and ensure that they have completed the required education in the use of human participants. Submit copies of affidavits or similar documents they were required to sign with the distributor.) \_\_\_\_\_

21. Will any data be gathered through photographic, video or sound-recording devices?  Yes  No

If yes, answer a.-d. below, and be sure to include all this information on your consent form(s) as well as **provide a separate signature line for the subjects to agree to be video/audio taped and/or photographed.**

- a. What types of recording devices will be used and what will be recorded? \_\_\_\_\_

- b. Please provide scientific justification for gathering data using the device(s) enumerated above. \_\_\_\_\_

- c. What will be done with the still photos, video or audio recordings after the study has concluded? (I.e., used in publications, presentations, etc.) \_\_\_\_\_

- d. When, if ever, do you plan to destroy these records (specify when for each type)? \_\_\_\_\_

- e. How will you protect the confidentiality of the materials produced by such devices (if so promised)? (Remember that faces alone reveal identity, even if captions with names are not provided.)  
\_\_\_\_\_

22. Will you or your study staff know the names of any participants? This includes collecting signed consent forms.  
 Yes  No

If Yes, answer questions *a – d* below.

a. Where will the names be recorded (e.g., on test protocols, on a separate list with code numbers, in a computer file, etc.)?  
\_\_\_\_\_

b. For what purpose(s) will names be recorded?  
\_\_\_\_\_

c. Will access to names be under your exclusive control?  Yes  No  
If No, what will be done to protect the confidentiality of the participants?  
\_\_\_\_\_

d. Will names of participants be included in any publication based on this study?  Yes  No  
If Yes, for what reason(s)?  
\_\_\_\_\_

e. If confidentiality is promised to participants, how will you keep their identities private?  
\_\_\_\_\_

f. Sometimes research findings are presented in a manner that permits knowledgeable readers to infer the identity of a person used as a subject, even if names are omitted. Do you expect to present findings that may possibly provide such clues?  Yes  No  Confidentiality not promised

If Yes, explain how you will protect the identity of participants, or alternatively how you will explain to them that their confidentiality cannot be absolutely protected. This information should also be conveyed to participants on the study consent form.  
\_\_\_\_\_

23. Are you currently using a written consent/assent procedure?  Yes  No

If **yes**, please attach a photocopy of each version of consent/assent form you are distributing.

If **no**, please provide explanation and/or script of oral consent process:  
\_\_\_\_\_

24. Has this study been reviewed (or will it be reviewed) by another institution's Institutional Review Board (IRB)?

Yes  No

If already reviewed, attach a copy of the approval/deferral notification you received from that IRB. If this study **will be** submitted to another IRB, please indicate below the name of the institution.  
\_\_\_\_\_

If individuals from other institutions are collaborating on this research, please attach the current, unexpired human participants approval notification from their institutions.

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### Financial Conflict of Interest Disclosure

In order to fulfill the requirements of federal regulations, investigators conducting clinical or medical research at Cornell must disclose known *significant financial interests* that would reasonably appear to be affected by the research project. Significant financial interests include:

- An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children exceeds \$10,000 in value, or represents more than 5% ownership interest in a single entity
- Salary, royalties, or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months are expected to exceed \$10,000

1. Have you and all key *faculty* personnel on this project completed the Annual Disclosure Statement?  Yes  No
2. Have you and all key personnel disclosed all significant financial interests (including those of spouses and

- dependent children) that would reasonably appear to be affected by this research project?  Yes  No
3. Do any of the investigators, their spouses or dependent children, have any significant financial interests that would reasonably appear to be affected by this research?  Yes  No
4. Do any of the investigators, their spouses or dependent children, have any financial interest or other relationship with any company or entity that sponsors or supports this research?  Yes  No

**If you answered Yes to either #3 or #4**, the Chair of the IRB must receive a letter from your dean or director stating in summary form how any potential financial conflict of interest involving this research project has been reduced, managed or eliminated. *The IRB is not able to review this project until receipt of the dean's/director's letter.* Please address the letter to: IRB Chair, ORIA, 395 Pine Tree Road, Suite 320, Ithaca, New York 14850.

Approximate date the IRB Chair can expect to receive the letter: \_\_\_\_\_

**Review of your application will be delayed  
if you do not submit the correct number of copies or the requested study instruments.**

## Signature Page

This page is to be signed by the investigator(s). If the investigator is an undergraduate, graduate student, or doctoral student, the faculty supervisor must also sign in the lower box.

### Investigator(s)

I certify that the information I provide in this application is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Cornell University's Institutional Review Board.

\_\_\_\_\_  
Signature of Investigator (1)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator (2)

\_\_\_\_\_  
Date

### Faculty Supervisor:

NOTE: A research proposal by a graduate or undergraduate student **must** have the following statement signed by a faculty supervisor.

"I have examined this completed form and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects. I will take responsibility for informing the student of the need for the safekeeping of all raw data (e.g., test protocols, tapes, questionnaires, interview notes, etc.) in a University office or computer file."

\_\_\_\_\_  
Print Name and Title of Faculty Supervisor

\_\_\_\_\_  
Signature of Faculty Supervisor

\_\_\_\_\_  
Date

\_\_\_\_\_  
Office Phone

**Please also attach a letter describing how you will provide continuing supervision over the student. Review of the proposal will begin after receipt of your letter.**