

INITIAL APPROVAL REQUEST
for Social and Behavioral Studies Involving Human Subjects

For UCHS Use Only
UCHS ID# _____

University Committee on Human Subjects

Click in shaded fields to enter information

SECTION I

Name of Investigator: _____

Email address: _____

Campus address: _____

School & Department: _____

Administrative Mgr.: _____

Status: Faculty Ph.D. candidate Undergrad
 Research Associate Other Grad. Student Other
 Post-doc Staff

Faculty member supervising project (if applicable) _____
Email address _____
Campus address _____

Title of Project: How does field dependence influence vulnerability to environmental cues of knowing how much wine to pour and how much food to serve to oneself?

Other Study Investigators:	Name	Affiliation	Location
	_____	_____	_____
	_____	_____	_____

Other Members of Research
Teams (include students):

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

Start Date of Project (initial contact with subjects): 3/2/2006 Estimated End Date of Project: 3/1/2007

- Is this research funded by an external (non-Cornell) sponsor(s)? Yes No Pending approval
If Yes (or Pending), what is the name of the sponsor(s)? _____
If you know the project's OSP #(s), please provide: _____
If you are awaiting funding to develop instruments and/or consent forms, etc., please check here:
If this is a new proposal, please submit a copy of the proposal.
- Is this research being conducted for a course? Yes No
If Yes, name of course: _____
Name of instructor: _____
- Is this research being conducted for your thesis or dissertation? Yes No

If Yes, attach a copy of your thesis or dissertation proposal.

4. **REQUIRED:** Provide in layman's terms a brief summary description of the hypotheses or goals (if applicable). Limit to one paragraph.

In this project, we seek to understand how a personality variable (field dependence) could possibly influence vulnerability to external cues that influence both the amount of wine poured and the amount of food served to oneself. Field dependence is a cognitive style that pertains to those who are dependent upon the context of the environment to be able to understand and process information. In contrast, field independence refers to a cognitive style that pertains to those who do not rely on the context of the environment as much to be able to understand and process information. With regards to serving food & drink, it may be that those who are more field dependent (or context dependent) may be more vulnerable to environmental cues, such as the size of glass or plate, that influence how much drink and food we serve to ourselves than those who are field independent. This would suggest that field dependent people are more sensitive to environmental cues. This could lead to overeating.

5. Describe the design of your research and planned use of human subjects. Be sure to include the specific location at which any interaction with human subjects will take place. (Please limit to a maximum of one page.)

Participants will be obtained from adult students and staff at [REDACTED]. Once consent is obtained, participants will be asked first to fill out a brief personality inventory that includes additional demographic information (i.e., age, education, wine experience, body mass index) Next, participants will be asked to pour themselves, from a series of 10 stations that include 10 different wine glasses, a specific amount (i.e., 4 ounces) and specific color of wine. Participants will not drink any wine during the experiment. Also, the 10 stations will be visually isolated from each other so there is no basis for comparison in terms of visually knowing how much wine was poured in a previous wine glass. In addition, participants will also be asked to serve themselves a specific amount (i.e., 8 ounces) and color of food on different plate sizes in 2 different stations.

The following is given as an example of the experimental design for this project: A 10 (glass shape) x 2 (wine color: white or red) x 2 (plate size: large or small) x 2 (food color: light or dark) x 2 (personality: field dependent, field independent) "mixed" subject design will be employed to understand how a personality variable (field dependence) could possibly influence vulnerability to external cues that influence both the amount of wine poured and the amount of food served to oneself. Glass shape and plate size are within subjects factors while wine color and food color are between subjects factors. Personality is a psuedo between subjects factor. Obviously, we are not interested in some possible interactions (i.e., glass shape x food color) that could occur because the standard for measurement for wine (4 ounces) is different than that for food (8 ounces). A post-study questionnaire will also be given to understand how hungry participants feel, how accurate they think they were in estimating, etc.

The main dependent variable in this study is both the weight of each wine glass after wine is poured into it and the weight of the plate after food is served on it. Covariates may include how hungry participants were, how accurate participants thought they were in pouring and dishing out the correct amounts, experience with wine, age, and education.

6. 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 ([REDACTED]) for specific shipping requirements.

7. Outline possible benefits the proposed study may provide to an individual subject, social group, or society. If there are no direct benefits to the subjects as individuals, please state this explicitly here.

There are no known benefits for participating in this study.

8. Please outline possible risks to subjects in your study, including special or select types of subjects.

There are no known risks for participating in this study.

9. Please describe the steps you have taken to minimize risk to subjects.

We keep confidential (and secure) names and associated data pertaining to study.

10. Does this study involve **secondary data analysis or restricted/limited data (includes HIPAA)**? Yes No

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

- Can the names or identities of subjects in the dataset be deduced from the data fields? _____
- Is the dataset public-use (no restrictions on use) **OR** is the dataset restricted or limited access? _____
If restricted or limited access, attach a copy of the licensing agreement you signed with the distributor, as well as a copy of your data security plan.
- 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? Yes No
If yes, attach a description of how you plan to protect the data from unauthorized use.
- Will anyone other than you have access to any restricted or limited access dataset(s)? Yes No
If yes, provide their names, and ensure that they have completed the required education in the use of human subjects. Submit copies of affidavits, non-disclosure agreements, or similar documents they were required to sign with the distributor.

*If your study involves secondary data analyses only, please skip to Section II, question 18.
For all other studies, please fill out the remaining questions.*

SECTION II

Please answer the remaining questions thoroughly and completely.

- How many subjects do you plan to recruit for the entire study? **200+**
- What is the expected age range of subjects? **18 to 70** years [Note: this must match all attached documents submitted.]
- Will your subject sample include **University students**? Yes No
If Yes, answer a. – c. below:
 - do you plan to recruit subjects from classes that you personally teach? Yes No
If Yes, provide a justification for the collection of data from your own students in #8 below.
 - will subjects be obtained from the Psychology Dept. **website**? Yes No
 - will subjects be obtained from the University Registrar? Yes No
- Please estimate: Proportion of female subjects **50%** Proportion of minority subjects (U.S. only) **20%**
- Explain how you plan to recruit your subjects. Specify the exact wording of requests, notices, or advertisements recruiting subjects. **Attach draft advertisements, flyers, letters, or descriptions posted on **University website**** (Please also indicate the specific locations where subjects will be recruited.)

Participants (students and staff) will be obtained from **University website classes and departments in applied economics and management, psychology, and biology. We will recruit both via email, flyers, and presentations to classes. The following is given as an example of recruitment efforts for students and staff:**

Student Email (student email similar, but asked to RSVP researchers via email):

Participate in a fun food study!

Who: **University website**

What: We will ask you to pour specific amounts of wine and dish-out specific amounts of food.

*YOU WILL NEITHER DRINK ANY WINE NOR EAT ANY FOOD, but you may receive extra credit for your participation

When: 4 dates available (sign up on the sheet being passed around)

- March 2nd- 3 p.m to 3:30 p.m.

-March 3rd- 3 p.m. to 3:30 p.m.

-March 7th- 3 p.m. to 3:30 p.m.

-March 8th- 3 p.m. to 3:30 p.m.

Where: [REDACTED]

If you have any questions, please contact [REDACTED]

Thank You!

Staff Recruitment (flyer and email):

Participate in a fun food study!

Who: [REDACTED]

What: We will ask you to pour specific amounts of wine and dish-out specific amounts of food.

*YOU WILL NEITHER DRINK ANY WINE NOR EAT ANY FOOD, but you will receive a \$5 gift certificate at the campus book store. Also, you do NOT have to participate in this study as a condition of current or future employment with [REDACTED]

When: 4 dates available (sign up on the sheet being passed around)

- March 2nd- 3 p.m to 3:30 p.m.

-March 3rd- 3 p.m. to 3:30 p.m.

-March 7th- 3 p.m. to 3:30 p.m.

-March 8th- 3 p.m. to 3:30 p.m.

Where: [REDACTED]

If you have any questions, please contact [REDACTED]

Thank You!

6. Will subjects be compensated for their time? Yes No

If Yes, please describe the compensation.

Students will not be compensated, but Staff will be given a \$5 gift certificate to the campus book store.

7. Do you plan to use email or the Internet to recruit your subjects? Yes No

If Yes, you should be aware that email and Internet transmission are neither private nor secure. Please include a

sentence in your consent document that alerts subjects that there is a chance their answers could be read by a third party.

8. Check which category(ies) of subjects will be included in your study. For all categories other than the first (mentally competent adults), additional safeguards are required to protect these populations from undue influence/coercion in the recruitment process, risk during the study, etc. Explain the additional safeguards to be provided.

- Only mentally competent adults or secondary analyses of existing data
- Children under 18: Active, written parental consent is a federal requirement, unless waived by [REDACTED] after review. It is generally expected that you also obtain the *written assent* of minors 7 years of age and older. **Attach copies of parental consent form (and minor's assent form when applicable).**

- Employees of the investigating group: Please justify the use of this group, and explain how undue coercion in the recruitment process will be avoided.

The recruitment materials mention that current or future employment does not depend on them participating in the study.

- Students enrolled in your own classes: Please justify the use of this group. Federal regulations discourage the use of students enrolled in classes taught by principal investigators.

- Cognitively-impaired persons: How will you screen potentially cognitively-impaired subjects to determine when proxy consent is required? **Attach copy of proxy consent form, and subject assent form (if appropriate).**

- Pregnant or nursing women

- Prisoners or juveniles under detention or on probation

- People in foreign countries: Please describe how you are collaborating with the local communities, government, or other institutions (as relevant to your project), and include documentation as appropriate.

- Other potentially vulnerable subjects: Who, and why?

9. Check additional sources of data that will be used in your study.

- None
- Census/public records
- Discarded human materials
- Medical records
- Registries (e.g. cancer registry) Name of registry: _____
- Blood, urine, or tissue samples
- Other (explain) _____

10. Duration of subject's participation, through each component of the study, and in total. **Please provide full information for each component of the study.**

Once each participant arrives at the lab, they will be seated in one of eight tables. Consent forms will be discussed and then signed by the participant. Any questions that the participant has will be answered at this time (5 minutes). They will be given a brief survey that obtains information about who they are (i.e., personality, age, sex, education, wine experience, etc...). This should take 10 minutes. One-by-one, people

will be led into the portion of the lab where they will notice 12 wine and food stations. They will be told that they are to pour exactly 4 ounces of wine in each glass and dish-out 8 ounces of food on each plate. They will be told to start at the station labeled #1 and continue to the end (#12). Participants will pour wine into 10 different glasses and dish-out food onto two different plates (10 minutes). After this, they will take a short post-experiment questionnaire to understand how hungry participants feel and how accurate they think they were in estimating wine and food amounts (3 minutes). Participants will then be given an opportunity to ask any questions or give comments as they wish (2 minutes). In total, the experiment should take around 25-35 minutes for each person.

11. Check any/all of the following procedures that apply to your study. For *each* procedure checked, 1) explain the procedure in detail, and 2) provide the ethical and scientific justification for employing the procedure.

Deception (When and how will the subjects be debriefed? Generally, the nature of the deception and its necessity should be explained to the subjects. **Attach a copy of your debriefing form/script.**)

Punishment: _____

Use of drugs: _____

Covert observation: _____

Induction of mental and/or physical stress: _____

Procedures that risk physical harm to the subject: _____

Materials commonly regarded as socially unacceptable: _____

Procedures that might be regarded as an invasion of privacy: _____

12. Is confidentiality promised to the subjects? Yes No If No, please explain. _____

a. If confidentiality is promised, will access to names be under your exclusive control? Yes No

If No, who else will have access to the names, and what will be done to protect the confidentiality of the subjects? _____

b. Where will the names be recorded (e.g., on test protocols, on a separate list with code numbers, in a computer file, etc.)? **on consent form and a computer file**

c. For what purpose(s) will names be recorded? **for consent**

d. If confidentiality is promised, what additional steps are you taking to keep their data secure? **data will be locked in a file cabinet and computer, which has security features (passwords to enter computer, which only man investigators know).**

e. Will names of subjects be included in any publication based on this study? Yes No

If Yes, for what reason(s)? _____

13. 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.)

14. 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 subjects, or alternatively how you will explain to them that their confidentiality cannot be absolutely protected. This information should also be conveyed to subjects on the study consent form.

15. Will information be obtained pertaining to persons other than immediate subjects (e.g., their friends)?
 Yes No

If Yes, how will the confidentiality of such persons be protected? If their confidentiality is not promised, please explain here.

16. Do you intend to obtain written consent? Yes No

If Yes, refer to *Required Components of Informed Consent Documents* on the [redacted] website ([redacted]), and attach a copy of the consent form. If collecting data from minors you must address both parental consent and the child's assent.

If No, please answer questions a - c below.

a. Why do you not intend to use such forms? This must be a strong argument (i.e., scientific validity).

b. In what manner and to what extent will you give potential subjects advance information about the study procedures? If using a contact letter, please attach it.

c. In what manner will potential subjects be advised that their participation and continuation in the project is entirely voluntary? Please provide a copy of the text to be used.

17. If proposing to use oral consent (e.g., telephone survey, illiterate subjects), provide a copy (script) of the text that you will use.
- _____

18. Has this study been reviewed (or will it be reviewed) by another institution's Institutional Review Board (IRB) or another ethical review body (including [redacted])?

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 institution and give the approximate date for the review.

Financial Conflict of Interest Disclosure (non-student investigators only)

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 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 [REDACTED] 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 [REDACTED] is not able to review this project until receipt of the dean's/director's letter.* Please address the letter to: [REDACTED]

Approximate date the [REDACTED] Chair can expect to receive the letter: _____

Final Reminder!

When applicable, attach copies of:

- Sponsored funding proposal
- Thesis/dissertation proposal
- Recruitment materials
- Consent/assent documents (including oral consent)
- Surveys/questionnaires/interview scripts
- Debriefing form/script
- Restricted/limited access dataset agreements
- Confirmation of review by other IRBs
- Foreign country collaboration documentation

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 [REDACTED] Committee on Human Subjects.**

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.), as well as signed consent forms, 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.