Revision: 10/19/05

INITIAL APPROVAL REQUEST
for Social and Behavioral Studies Involving Human Subjects

For UCHS Use Only
UCHS ID#____-____-_____

CORNELL UNIVERSITY
University Committee on Human Subjects

Click in shaded fields to enter information

SECTION I

Name of Investigator: [redacted]
Email address [redacted]
Campus address [redacted]
School & Department [redacted]
Administrative Mgr. [redacted]

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

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

Title of Project: **Chef's experiences and opinions about healthy menu items in restaurants**

Other Study Investigators: Name	Affiliation	Location
[redacted]	[redacted]	[redacted]

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): **5/23/2006** **Estimated End Date of Project**: **5/29/2007**

1. 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.

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

   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.

   The purpose of the study it to obtain information from chefs about their experiences with and opinions about healthy menu items in restaurants. This information will help better understand food industry professional's standing on important issues regarding the American diet.

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.)

   Approximately 200 surveys (see attached) will be distributed to the [redacted] has a booth (via [redacted] and [redacted]) that will be used as the home base of survey distribution.

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] or [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.
   Participants do not experience anything that they would not otherwise experience in daily life.

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:

    a. Can the names or identities of subjects in the dataset be deduced from the data fields? _____

    b. 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.

    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? ☐ Yes ☐ No
    If yes, 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 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.

1. How many subjects do you plan to recruit for the entire study? **200**

2. What is the expected age range of subjects? **18** to **99** years **[Note: this must match all attached documents submitted.]**

3. Will your subject sample include [redacted] students? ☐ Yes ☒ No

   If Yes, answer a. c. below:

   a. 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.

   b. will subjects be obtained from the Psychology Dept. [redacted] website? ☐ Yes ☐ No

   c. will subjects be obtained from the University Registrar? ☐ Yes ☐ No

4. Please estimate: Proportion of female subjects 50% Proportion of minority subjects (U.S. only) 20%

5. 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 SUSAN.** (Please also indicate the specific locations where subjects will be recruited.)

   Participants will chefs attending the [redacted] at [redacted]. They will be approached by researchers either from [redacted]. Chefs will be asked to complete a survey of their experiences and opinions about healthy menu items in restaurants that will take 15 minutes to complete. They will be given a consent form (see attached) created and approved by [redacted].

6. Will subjects be compensated for their time? ☐ Yes ☒ No
   If Yes, please describe the compensation.

   ____

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.

   ____

   ☐ 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.**

The time taken to read the consent form and complete the survey should be approximately 15 minutes.

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.)? **no names recorded**

c. For what purpose(s) will names be recorded? _____

d. If confidentiality is promised, what additional steps are you taking to keep their data secure? _____

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.)

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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.

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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.

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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).

Consent form is in "exempt" format. Reading the consent form and continuing with study is consent.

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.

We do not.

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.

In the consent form (see attached).

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

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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] Medical)?

☒ 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.

[redacted] and [redacted] ***received approval from their respective IRBs. We are awaiting transmission of documentation of approvals to give to [redacted]...should be here 5/10***

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.