COLUMBIA COLLEGE CHICAGO
IRB REVIEWER FORM

(Please submit this form to the IRB Administrator)

Protocol #: _____ Date: _____

Principal Investigator: _____ Reviewer's Name: _____

Protocol Title: _____

Faculty Advisor: _____ Department: _____

Review applicant is requesting: FULL _____ EXPEDITED ____ EXEMPT ____

1. **The research places subjects at no more than minimal risk. ____**
   greater than minimal risk. ____
   Minimal risk is defined as a probability and magnitude of harm or discomfort that is no greater than what might be ordinarily encountered in daily life or during a routine physical or psychological examination or tests.

Comments:

2. **If the research places subjects at greater than minimal risk…**
   Does the merit of the project outweigh the risks? YES ____ NO ____
   Are the benefits maximized and risks minimized? YES ____ NO ____

Comments:

3. **Are there any ethical issues regarding the study's design and conduct?** YES ___ NO ___
   Ethical issues may include but are not limited to the Belmont Report principles: respect for persons (voluntary, fully informed consent); beneficence (obligation to protect subjects from harm and secure their well-being); and, justice (benefits and burdens of research are fairly distributed).

Comments:

4. **Is subject selection equitable?** YES ___ NO ___

   Inclusion and/or exclusion criteria are listed in the protocol. Justification is provided for any proposed exclusion based on membership in a protected class (age, gender, race, color, ethnicity, religion, national

origin, disability, or sexual orientation). Conditions under which participants may be removed from the study (i.e. noncompliance with study rules, study termination, voluntary self-removal, etc.) are described.

Comments:

5. Does the research propose specific recruitment of subjects from a special or vulnerable population? YES ____ NO ____

If special populations are included, the IRB should ensure that subjects can understand the research, give full consent, and voluntarily agree to participate, and they should consider any other possible special problems.

Note all that apply:

- ☐ Pregnant Women/Fetuses/Infants
- ☐ Prisoners/Parolees/Probationers
- ☐ Minors Under Age 18
- ☐ Elderly subjects
- ☐ Minority group(s) and/or non-English speakers
- ☐ Economically and/or Educationally disadvantaged persons
- ☐ Patients
- ☐ Individuals Living with AIDS/HIV
- ☐ Members of the Armed Forces
- ☐ Columbia College Chicago Students
- ☐ Columbia College Chicago Employees
- ☐ Mentally/Emotionally/Developmentally Disabled persons
- ☐ Decisionally Impaired Persons
- ☐ Persons with behavioral abnormalities stemming from a diagnosed condition or disease
- ☐ Other (please specify)

Comments:

6. The recruitment and consent process and materials (including telephone scripts, ads, brochures, letters, compensation) are fully described, appropriate, and non-coercive?

YES ____ NO ____

Comments:

7. The protocol describes procedures for protecting privacy and confidentiality research participants and any data obtained?

YES ____ NO ____

Comments:

8. Is Informed Consent Included in the Application: YES ____ NO ____

Stipulate Missing Elements:

Is the PI identified along with affiliation with Columbia?	☐ YES	☐ NO
Is the faculty advisor identified? (if appropriate)	☐ YES	☐ NO
Does the consent state the study purpose accurately?	☐ YES	☐ NO
Is it clear what the subjects will be asked to do?	☐ YES	☐ NO
Are risks or discomforts clearly and fully stated?	☐ YES	☐ NO
Are benefits clearly and fully stated?	☐ YES	☐ NO
Are alternatives listed? (if appropriate)	☐ YES	☐ NO
Is there a clear statement describing how confidentiality of records identifying subjects will be maintained?	☐ YES	☐ NO
Is it stated that the subjects can withdraw at any time?	☐ YES	☐ NO
Is the consent understandable at an 8th grade reading level?	☐ YES	☐ NO
Are subjects being given a copy of their Informed Consent Form?	☐ YES	☐ NO
Is it stated when and by whom informed consent will be administered?	☐ YES	☐ NO

Alteration to or Waiver of Informed Consent:

Does the protocol request alteration to or waiver of informed consent? ☐ YES ☐ NO

The request is accompanied by information documenting consistency with conditions required by the federal regulations.

Check each condition documented in the protocol:

- ☐ The research is designed to study, examine or evaluate a public benefit or service program
- ☐ The research involves no more than minimal risks to subjects.
- ☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- ☐ The research could not practically be carried out without a waiver or alteration.
- ☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation

Assent Form ☐ Not Required

Is one needed (can the child really refuse to participate)?	☐ YES	☐ NO
Is it one page or less?	☐ YES	☐ NO
Is the language simple and sentences short?	☐ YES	☐ NO

APPROVAL/RECOMMENDATION

(Please add a sheet if additional comment space needed)

Check appropriate Exempt or Expedited Status:

Exempt Protocol Review:

☐	(45 CFR 46102(f)	None intervention with a living individual – Human subject
☐	45 CFR 46 101(1)	Educational settings
☐	45 CFR 46 101(1)&(2)	Educational settings & Educational tests – no identifiers
☐	45 CFR 46 101(1)&(3)	Educational settings & Public official/privacy maintained
☐	45 CFR 46 101(1)&(4)	Educational settings & Study of existing data
☐	45 CFR 46 101(1)&(5)	Educational settings & Public/Service Project
☐	45 CFR 46 101(1)&(6)	Educational settings & Taste/Food quality
☐	45 CFR 46 101(2)	Educational tests – no identifiers
☐	45 CFR 46 101(2)&(3)	Educational – no identifiers & Public official/privacy maintained
☐	45 CFR 46 101(2)&(4)	Educational – no identifiers & Study of existing data
☐	45 CFR 46 101(2)&(5)	Educational – no identifiers & Public/Service Project
☐	45 CFR 46 101(2)&(6)	Educational – no identifiers & Taste/Food quality
☐	45 CFR 46 101(3)	Educational – Public official or privacy maintained
☐	45 CFR 46 101(3)&(4)	Educational – Public official/privacy maintained & Study of existing data
☐	45 CFR 46 101(3)&(5)	Educational – Public official/privacy maintained & Public/Service Project
☐	45 CFR 46 101(3)&(6)	Educational – Public official/privacy maintained & Taste/Food quality
☐	45 CFR 46 101(4)	Study of existing data
☐	45 CFR 46 101(4)&(5)	Study of existing data & Public/Service Projects
☐	45 CFR 46 101(4)&(6)	Study of existing data & Taste/Food quality
☐	45 CFR 46 101(5)	Public benefit or service projects
☐	45 CFR 46 101(5)&(6)	Public benefit or services projects & Taste/Food quality
☐	45 CFR 46 101(6)	Taste and food quality evaluation

Expedited Protocol Review:

☐	21/45 CFR 56/46.110 (a)	Listed in FR.
☐	21/45 CFR 56/46.110 (b)(2)	Minor Change
☐	21/45 CFR 56/46.110 (b)(1)	Minimal Risk

☐	FR Vol. 63, No. 216 (03)	Non-invasive collection of hair, nail clippings & the like
☐	FR Vol. 63, No. 216 (04)	Non-invasive collection of data (e.g. by MRI, EEG, moderate exercise, etc.)
☐	FR Vol. 63, No. 216 (05)	Data/records/specimens collected solely for non-research (treatment/diagnosis)
☐	FR Vol. 63, No. 216 (06)	Voice recordings… for research…
☐	FR Vol. 63, No. 216 (07)	Research on individual or group behavior
☐	FR Vol. 63, No. 216 (08)	Closed to enrollment; only data review analysis remains

Check box next to Reviewer Approved Level of Review:

☐ Full ☐ Expedited ☐ Exempt

Initial on line next to Approval Status:

____ Approved **as is, no changes required**

____ Approved **with Contingencies**

Contingency details/Recommended further action: