



**THE UNIVERSITY OF MONTANA-MISSOULA**  
 Institutional Review Board (IRB)  
*for the Use of Human Subjects in Research*  
 CHECKLIST / APPLICATION

IRB Protocol No.:  
152-10

At The University of Montana (UM), the Institutional Review Board (IRB) is the institutional review body responsible for oversight of all research activities involving human subjects outlined in the U.S. Department of Health and Human Services Office of Human Research Protection ([www.hhs.gov/ohrp](http://www.hhs.gov/ohrp)) and the National Institutes of Health, Inclusion of Children Policy Implementation (<http://grants.nih.gov/grants/funding/children/children.htm>).

**Instructions:** A separate registration form must be submitted for each project. IRB proposals are approved for three years and must be continued annually. **Faculty members** may email the completed form as a Word document to [IRB@umontana.edu](mailto:IRB@umontana.edu). **Students** must submit a hardcopy of the completed form to the Office of the Vice President for Research & Development, University Hall 116.

**1. Administrative Information**

Project Title: The Effects of Embodied Cognition on Hunger and Satiety Cue Awareness	
Principal Investigator: Linda Ruiz	Title: Student
Email address: <a href="mailto:ldruiz@stanford.edu">ldruiz@stanford.edu</a>	
Work Phone: Linda is working with Christine Fiore, PHD,x2081	Cell Phone: 406-493-5116
Department: Psychology	Office location: Skaggs 313

**2. Human Subjects Protection Training** *(All researchers, including faculty supervisors for student projects, must have completed a self-study course on protection of human research subjects within the last three years (<http://www.umt.edu/research/complianceinfo/IRB/>) and be able to supply the "Certificate(s) of Completion" upon request. Add rows to table if needed.)*

NAME and DEPT.	PI	CO-PI	Faculty Supervisor	Research Assistant	DATE COMPLETED Human Subjects Protection Course
Linda Ruiz, Psychology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	3/30/2009
Christine Fiore	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1/2010
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**3. Project Funding**

Is grant application currently under review at grant funding agency? <input type="checkbox"/> Yes <i>(If yes, cite sponsor on ICF if applicable)</i> <input type="checkbox"/> No		Has grant proposal received approval and funding? <input checked="" type="checkbox"/> Yes <i>(If yes, cite sponsor on ICF if applicable)</i> <input type="checkbox"/> No		
Agency	Grant No.	Start Date	End Date	PI
Stanford University	18725	6/17/10	5/31/11	Linda Ruiz
Is this part of your thesis or dissertation? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		If yes, date you successfully presented your proposal to your committee: This is a Stanford Honors Project 6/17/10		

For UM-IRB Use Only

**IRB Determination:**

- Approved Exempt from Review, Exemption # \_\_\_\_\_ *(see memo)*
- Approved by Expedited/Administrative Review *(see \*Note to PI)*
- Full IRB Determination
  - Approved *(see \*Note to PI)*
  - Conditional Approval *(see memo)* - IRB Chair Signature/Date: \_\_\_\_\_
  - Conditions Met *(see \*Note to PI)*
  - Resubmit Proposal *(see memo)*
  - Disapproved *(see memo)*

**\* Note to PI:** Study is approved for one year. Use any attached IRB-approved forms (signed/dated) as "masters" when preparing copies. If continuing beyond the expiration date, a continuation report must be submitted. Notify the IRB if any significant changes or unanticipated events occur. Notify the IRB in writing when the study is terminated

Final Approval by IRB Chair: *Linda Ruiz* Date: 7/27/10 Expires: 7/26/2011

<In an effort to be environmentally responsible, please expand/reduce box size as needed.>

**4. Purpose of the Research Project (not to exceed 500 words):** Briefly summarize the overall intent of the study. Your target audience is a non-researcher. Include in your description a statement of the objectives and the potential benefit to the study subjects and/or the advancement of your field. **Generally included are literature related to the problem, hypotheses, and discussion of the problem's importance.** Expand box as needed.

The main objective is to consider the issue of obesity through a preventative lens. While it is understood that the factors that contribute to obesity are complicated and multi faceted, we intend to focus in on one particular, under-studied factor: the tendency to ignore or suppress internal hunger and satiety cues and instead allow external environmental cues to guide eating behavior. We hope to investigate whether it is possible to prevent an overweight population from reaching the point of obesity by educating them about the power of external cues, teaching them mindfulness based eating techniques and making this information salient by associating it with the eating-related motor activation of holding a fork.

**5. IRB Oversight**

Is oversight required by other IRB(s) [e.g., tribal, hospital, other university] for this project?  Yes  No

If yes, please identify IRB(s):

Stanford IRB approval attached

**6. Subject Information:**

a. Human Subjects (*identify, include age/gender*):

Subjects will be members of the community in the Missoula area. Subjects may be between the ages of 18 and 40. There are no gender restrictions and subjects will be from a variety of ethnic backgrounds. Screening will be done for interested participants over the phone. Based on height and weight, participants will have a BMI between 25 and 29.9.

b. How many subjects will be included in the study? 40

c. Are minors included (*under age 18, per Montana law*)?  Yes  No

If yes, specify age range: to

d. Are members of a physically, psychologically, or socially vulnerable population being specifically targeted?

Yes  No

If yes, please explain why the subjects might be physically, psychologically or socially vulnerable:

e. Are there other special considerations regarding this population?  Yes  No

If yes, please explain:

This population will have a BMI between 25 and 29.9, the overweight range. This intervention is targeted at this particular population because they are precariously balanced on the cusp of change, either in the direction of increased weight gain and it's associated health problems or in the direction of healthy weight management. We hope to nudge them in the latter direction by helping them foster mindfulness in their eating practices .

f. Do subjects reside in a foreign country?  Yes *Specify country*  No

If yes, are there human subject regulations listed specifically for this country at

<http://www.hhs.gov/ohrp/international/index.html#NatIPol> under "The International Compilation of Human Subject Research Protections?"

Yes – These regulations **must** be addressed or integrated into your proposal.

No – Explain how you will approach subjects in a culturally-appropriate manner:

While additional information regarding international research is included in the OPRR memo entitled "IRB Knowledge of Local Research Context," provide the IRB with the following information as appropriate:

1. Information about where the research will be conducted (both the geographic location and the performance site, where applicable).

2. A copy of the foreign site's assurance with OHRP, when required.
3. A copy of local IRB or equivalent ethics committee approval, when required.
4. Information about the investigator's knowledge of the local research context, including the current social, economic, and political conditions.
5. Information about whether there are any additional risks subjects might face as a result of the population being studied and/or the local research context.
6. The language(s) in which consent will be sought from subjects and the research will be conducted, as well as whether the investigator is fluent in this language, or whether an interpreter will be used. If an interpreter will be used, it should be clear what risks, if any, this might pose for subjects, as well as how the risks will be minimized.
7. Copies of the translated informed consent documents and instruments, including verification of the accuracy of the translation(s).
8. Information on how the investigator will communicate with the IRB while in the field.

g. How are subjects selected or recruited? What is inclusion/exclusion criteria? (**Attach copies of all flyers, advertisements, etc., that will be used in the recruitment process as these require UM-IRB approval**)

Flyers will be posted around campus and on community information boards around town. The following are the exclusion criteria: a past history of eating disorders, hyper/hypo glycemia or any other sort of metabolic condition, deafness and/or blindness, BMI under 25 or over 29.9 based on height and weight.

h. How will subjects be identified in your personal notes, work papers, or publications: (*may check more than one*)

Identified by name and/or address or other

(*Secure written [e.g., ICF] or verbal permission to identify; if risk exists, create a confidentiality plan.*)

Confidentiality Plan

(*Identity of subjects linked to research, but not specific data [e.g., individuals identified in ICF but not included in publications]; identification key kept separate from data; or, data collected by third party [e.g., Select Survey, SurveyMonkey, etc.] and identifiers not received with data.*)

Never know participant's identity

(*An ICF may be unnecessary [e.g., anonymous survey, paper or online] **unless** project is sensitive or involves a vulnerable population.*)

i. Describe the means by which the human subject's personal privacy is to be protected, and the confidentiality of information maintained. If you are using a Confidentiality Plan (as checked above), include in your description a plan for the destruction of materials that could allow identification of individual subjects.

Participants will be given Linda's e-mail and personal phone contact. They can call into the lab at any point in the study if they have concerns about the way the study is being run or how they are being affected by virtue of participating. Dr. Fiore will be the on campus supervisor and contact for any concerns. Each participant will be assigned a number. Any information that can be tied back to the individual will only be associated with their ID number. The ID number will be kept separate from the participants name. All files will be kept in secure, locked filing cabinets in Dr. Fiore's lab, Skaggs 313. Computers with participant information will be accessible only to those working in the lab. Once the study has been completed and the participant's personal information is no longer needed the documents containing that personal information will be destroyed by paper shredder.

j. Will subject(s) receive an explanation of the research – separate from the informed consent form (if applicable) – before and/or after the project?  Yes (*attach copy and explain when given*)  No

## 7. Information to be Compiled

a. Explain where the study will take place (*physical location not geographic. If permission will be required to use any facilities, indicate those arrangements and attach copies of written permission*):

The study will take place inside the Skaggs building in lab rooms authorized to be used by the supervising party, Christine Fiore, PhD.

b. Subject matter or kind(s) of information to be compiled from/about subjects:

Subjects will be completing daily food journals for the duration of the study. They will be recording how long it took them to eat each of their meals, the state of mind they were in before and after eating, where they consumed their meals, and any particular reason they had to start or stop eating. The participants weight will also be recorded on two separate occasions as well as the weight of food they consumed during two complimentary meals provided by the lab.

c. Activities the subjects will perform and how the subjects will be used. Describe the instrumentation and procedures to be used and kinds of data or information to be gathered. **Provide enough detail** so the IRB will be able to evaluate the intrusion from the subject's perspective (expand box as needed):

**Week 1:**  
 Participants will initially be screened by phone. For all subjects who qualify, the first week will be identical to obtain a baseline of eating behavior, subjects will complete daily food journals online. Subjects will be randomly selected to be in either the control condition or the experimental conditions. They will be brought into the lab individually first thing in the morning to have their weight measurements taken and receive initial instructions for completing the daily food journals which they will complete for the duration of the 2 week study period. They will be instructed not to eat or drink except water prior to their scheduled appointment in order to obtain a baseline measure of their weight, and will be informed ahead of time that we will provide breakfast for them afterwards. After receiving instructions on completing the log, they will be left alone to complete their first entry and to eat breakfast at their leisure. All food will be weighed before and after they eat to obtain a baseline eating volume.  
 The food journal will include various measures of their daily mealtime habits (see attached) such as: ratings of hunger and satiety before and after meals, predominant affective state before and after eating, what triggered the start and stop of eating, and the physical environment during eating. All questions will use either a line scale or check boxes. They will make an entry each time they eat a meal or substantive snack 200 or more calories.

**Week 2:**  
 All participants will be brought back individually for the intervention session. As with the first week, they will be asked not to eat prior to coming in so that they can be weighed. Participants in the experimental condition and the control condition will view an informational video on the power of external cues to shape eating behavior and also listen to an audio recording of some guided mindfulness exercises. During the mindfulness exercises the experimental condition will also hold a fork. Participants will be instructed to imagine practicing the mindfulness techniques described in the audio segment while it is being played. No food will be provided during this meeting.

**End of Week 2:** All participants will be asked to come in for their final visit first thing in the morning and told, once again, not to eat beforehand. After each participant leaves the food remaining will be weighed in order to calculate how much food has been consumed. Total time for participation = approx 3.5 hours.

d. Is information on any of the following included? (check all that apply):

- |  |  |
|--|--|
| <input type="checkbox"/> Sexual behavior   | <input type="checkbox"/> Drug use/abuse  |
| <input type="checkbox"/> Alcohol use/abuse   | <input type="checkbox"/> Illegal conduct |
| <input type="checkbox"/> Information about the subject that, if it became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability. |  |

e. Means of obtaining the information (check all that apply). **Attach questionnaire or survey instrument**, if used:

- |   |   |
|---|---|
| <input type="checkbox"/> Field/Laboratory observation   | <input checked="" type="checkbox"/> In-person interviews/survey                         |
| <input type="checkbox"/> Blood/Tissue/Urine/Feces/Semen/Saliva Sampling (IBC Application must be submitted) | <input checked="" type="checkbox"/> Telephone interviews/survey                         |
| <input type="checkbox"/> Medical records (require HIPAA form)   | <input type="checkbox"/> On-site survey   |
| <input type="checkbox"/> Measurement of motions/actions   | <input type="checkbox"/> Mail survey  |
| <input type="checkbox"/> Use of standard educational tests, etc.  | <input checked="" type="checkbox"/> Online survey (attach Statement of Confidentiality) |
| <input type="checkbox"/> Other means (specify):   | <input type="checkbox"/> Examine public documents, records, data, etc.                  |
|   | <input type="checkbox"/> Examine private documents, records, data, etc.                 |

f. Will subjects be (check all that apply):

- |                                     |                                      |                                       |   |
|-------------------------------------|--------------------------------------|---------------------------------------|---|
| <input type="checkbox"/> Videotaped | <input type="checkbox"/> Audio-taped | <input type="checkbox"/> Photographed | <input checked="" type="checkbox"/> N/A |
|-------------------------------------|--------------------------------------|---------------------------------------|---|
- (securing an additional signature is recommended on consent/assent/permission forms)

Explain how above media will be used, who will transcribe, and how/when destroyed:

g. Discuss the benefits (does not include payment for participation) of the research, if any, to the human subjects and to scientific knowledge (*if the subjects will not benefit from their participation, so state*):

Participants may potentially benefit from the information on mindful eating that they are presented while in the lab. Whether or not this information has any effect is dependent on whether the participant chooses to implement those techniques. The scientific benefit of this study is furthering what is currently known about the phenomenon of embodied cognition as well as exploring it's uses in the context of obesity prevention.

h. Cite any payment for participation (payment is not considered a benefit):

There is no payment for participation.

i. Outline, **in detail**, the risks and discomforts, if any, to which the human subjects will be exposed (*Such deleterious effects may be physical, psychological, professional, financial, legal, spiritual, or cultural. As a result, one can never guarantee that there are no risks – use “minimal.” Some research involves violations of normal expectations, rather than risks or discomforts; such violations, if any, should be specified*):

I do not anticipate any serious risks to participant's physical well-being. There may be a chance that they will experience eye strain while viewing the video on mindful eating. Participants will be screened for food allergies and hypo/hypoglycemia so as to avoid complications with postponing breakfast on the days when they will be asked to come to the lab on an empty stomach they will be provided with breakfast on those days. Again I do not anticipate any serious risks to psychological well-being. However, journaling every day may be perceived by some participants to be stressful. If the study becomes too stressful or if they feel that they are psychologically compromised at any time they may drop the study.

j. Describe, **in detail**, the means taken to minimize each such deleterious effect or violation::

Participants can call into the lab at any point in the study if they have concerns about the way the study is being run or how they are being affected by virtue of participating. Each participant will be assigned a number. Any information that can be tied back to the individual will only be associated with their ID number. The ID number will be kept separate from the participants name. All files will be kept in secure, locked filing cabinets. Computers with participant information will be accessible only to those working in the lab.

## 8. Informed Consent

An informed consent form (ICF) is usually required, unless subjects remain anonymous or a waiver is otherwise justified below. (*Templates and examples of Informed Consent, Parental Permission, and Child's Assent Forms are available at <http://www.umt.edu/research/complianceinfo/irb/forms.aspx>*).

- A copy of the consent/assent/permission form **must be offered to all subjects**, including parents/guardians of subjects less than 18 years of age (minors).
- Use of minors
  - All minor subjects (under the age of 18) must have written parental or custodial permission (45 CFR 46.116(b)).
  - All minors from 10 to 18 years of age are required to give written assent (45 CFR 46.408(a)).
  - Assent by minor subjects: All minor subjects are to be given a clear and complete picture of the research they are being asked to engage in, together with its attendant risks and benefits, as their developmental status and competence will allow them to understand.
  - Minors less than 10 years of age and all individuals, regardless of age, with delayed cognitive functioning (or with communication skills that make expressive responses unreliable) will be denied involvement in any research that does not provide a benefit/risk advantage.
    - Good faith efforts must be made to assess the actual level of competence of minor subjects where there is doubt.
    - The Minor Assent Form must be written at a level that can be understood by the minor, and/or read to them at an age-appropriate level in order to secure verbal assent.

- Is a written informed consent form being used?  Yes (*attach copy*)  No (*justify below*)  
To waive the requirement for written informed consent (45 CFR 46.117), describe your justification:

- Is a written parental permission form being used?  Yes (*attach copy*)  No  
(*If yes, will likely require minor assent form*)

- Is a written minor assent form being used?  Yes (attach copy)  No  
(If yes, will likely require parental permission form)

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*The Principal Investigator agrees to comply with all requirements of The University of Montana-Missoula IRB, the U.S. Department of Health and Human Services Office of Human Research Protection Guidelines, and NIH Guidelines. The PI agrees to ensure all members of his/her team are familiar with the requirements and risks of this project, and will complete the Human Subject Protection Course available at <http://www.umt.edu/research/complianceinfo/irb>.*

**Principal Investigator's Statement**

I certify that the statements made in this request are accurate and complete. I also agree to the following:

- If I receive approval for this research project, I agree to inform the IRB in writing of any emergent problems. I further agree not to proceed with the project until the problems have been resolved.
- I will not make any significant procedural changes to procedures involving human subjects without submitting a written amendment to the IRB and will not undertake such changes until the IRB has reviewed and approved them.
- It is my responsibility to ensure that every person working with the human subjects is appropriately trained.
- I will not begin work on the procedures described in this protocol until I receive notice of approval from the IRB.
- I will keep a copy of this protocol (including all consent forms, questionnaires, and recruitment flyers) and all subsequent correspondence.

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Signature of Principal Investigator: see attached signature Date: 7/26/10

**NOTE:** I AM AWARE that electronic submission of this form from my University email account constitutes my signature.



**Students Only** (students must submit hardcopy of IRB application complete with original signature of faculty supervisor)

Faculty Supervisor: Christine Fiore PhD Date: 7/12/10

Signature: Christine Fiore

My signature confirms:

- 1) I have read the IRB Application and attachments.
- 2) I agree that it accurately represents the planned research.
- 3) I will supervise this research project.

Department: Psychology Phone: X2081 Email: christine.fiore@umontana.edu





## Subject Information and Informed Consent

**Study Title:** Effects of Embodied Cognition on Hunger and Satiety Cue Awareness

**Sponsor:** Stanford University Undergraduate Advising and Research

**Project Directors:**

*Principal Investigator:* Linda Ruiz, Stanford University, [ldruiz@stanford.edu](mailto:ldruiz@stanford.edu), 845-380-4814

*Supervisor:* Christine Fiore, PhD, University of Montana, [christine.fiore@mso.umt.edu](mailto:christine.fiore@mso.umt.edu), 243-2081

**Purpose:** The purpose of this research is to learn how to augment the effects of an intervention on mindful eating as well as to learn more about the phenomenon of embodied cognition.

**Procedure:** You are invited to participate in a research study in psychology. You will be asked to perform various tasks which may include: watching a video on a computer screen, listening and participating in some guided audio exercises, keeping a daily record of various eating behaviors, delaying eating breakfast on two occasions, being weighed, and eating a complimentary breakfast at the lab on the mornings that you do delay breakfast. All information collected will remain confidential. Your participation in this experiment will include two 1-hour long follow up visits to the lab, one 30 minute long visit and daily journaling for 2 weeks. Journaling may take 10-15 minutes a day.

**Payments:** There will be no payment for participation in this study.

**Risks/ Discomforts:** Risks involved in this study involve mild eye strain from viewing a video on a computer monitor and possible health complications from delaying breakfast. If you have any pre-existing ocular or metabolic conditions (e.g. diabetes) please let the experimenter know as it may affect your ability to participate in the study. If at any point during the study you feel unable to participate because you are experiencing eye strain, you feel faint, or any other form of discomfort you may end your participation without penalty. **Your decision whether or not to participate in this study will not affect your employment or your grades in school.**

**Benefits:** The benefits of participating in this study include learning about research being conducted in mindfulness. The scientific benefit of this study is furthering what is currently known about the phenomenon of embodied cognition as well as exploring it's uses in the context of obesity prevention. **We cannot and do not guarantee or promise that you will receive any benefits from this study.**

**Voluntary Participation/ Withdrawal:** **If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You have the right to refuse to answer particular questions. Your individual privacy will be maintained in all published and written data resulting from the study.**

**Confidentiality:** Your records will be kept private and will not be released without your consent except as required by law. Only the researcher and her faculty supervisor will have access to the files. Your identity will be kept confidential. If the results of this study are written in a scientific journal or presented at a scientific meeting, your name will not be used. The data will be stored in a locked file cabinet.

**Compensation for Injury:** Although we believe that the risk of taking part in this study is minimal, the following liability statement is required in all University of Montana consent forms: In the event that you are injured as a result of this research you should

Approval Expires On 7/26/2011

Date Approved By UM-IRB 7/27/10

Judith A. Frederick, IRB-Chair

individually seek appropriate medical treatment. If the injury is caused by the negligence of the University or any of its employees, you may be entitled to reimbursement or compensation pursuant to the Comprehensive State Insurance Plan established by the Department of Administration under the authority of M.C.A., Title 2, Chapter 9. In the event of a claim for such injury, further information may be obtained from the University's Claims representative or University Legal Counsel. (Reviewed by University Legal Counsel, July 6, 1993)

**Disclosure of Personal Health Information**

My individual health information that may be used to conduct this research includes: weight/weight and medical history. I authorize Linda Ruiz and the researcher's staff to use my individual health information for the purpose of conducting the research project entitled "Effects of Embodied Cognition on Hunger and Satiety Cue Awareness."

**CONTACT INFORMATION:**

**Questions, Concerns, or Complaints:** If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, you should ask the Protocol Director, Linda Ruiz at 845-380-4814 or contact the supervisor of this research, Christine Fiore, PhD at 243-2081

**Independent Contact:** If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-2480 or toll free at 1-866-680-2906. You can reach the University of Montana IRB at (406)243-6670. You can also write to the Stanford IRB, Stanford University, Stanford, CA 94305-5401.

**Statement of Consent:** I have read the above description of this research study. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. I voluntarily agree to take part in this study. I understand I will receive a copy of this consent form.

PRINTED NAME \_\_\_\_\_

SIGNATURE \_\_\_\_\_ DATE \_\_\_\_\_

Sincerely,

Linda Ruiz

B.A Candidate in Psychology, Stanford University  
(845) 380-4814

Under the supervision of:

Christine Fiore, Ph.D.

Professor, University of Montana  
(406) 243-4521

Greg Walton, Ph.D.

Associate Professor, Stanford University  
(650) 725-2445

Stanford University IRB approvals:

Protocol Approval Date: 6/17/10

Protocol Expiration Date: 5/31/11

**\*The extra copy of this consent form is for you to keep.\***

Approval Expires On 7/26/2011  
Date Approved By UM-IRB 7/27/10

*Judith M. ...* IRB Chair