



**Institutional Review Board New Protocol Application**

For information on deadlines & types of review, see [http://ora.ra.cwru.edu/orc\\_humansubjects\\_CWRU\\_IRB.asp](http://ora.ra.cwru.edu/orc_humansubjects_CWRU_IRB.asp)

\*Please type \* Do not alter format \* Attach additional sheets as necessary \* Label all attachments

**Protocol Title:**

**Responsible Investigator (RI):**

(faculty member or RI certified only)

**RI Email:**

(only if used)

**RI Phone:**

**RI Fax:**

**RI Dept.:**

**Co-Investigator (CI):**

(faculty, staff, student, post doc., etc.)

**CI Email:**

(only if used)

**CI Phone:**

**CI Fax:**

**CI Dept.:**

**Does the RI have a faculty appointment?**

- Yes  
 No

If no, has the RI submitted a RI Authorization Form?

- Yes  No

**Co-Investigator Status**

- |  |  |
|--|--|
| <input type="checkbox"/> Faculty       | <input type="checkbox"/> Medical Student       |
| <input type="checkbox"/> Post Doc.     | <input type="checkbox"/> Undergraduate Student |
| <input type="checkbox"/> Grad. Student | <input type="checkbox"/> Staff                 |

**Special Participation Populations**

- Minors (under 18)  
 Pregnant Women  
 Prisoners  
 Physically Challenged  
 Cognitively Impaired  
 University Students or Employees  
 No Special Subject (check if nothing else applies)

**Is this research federally funded in any way?**

- Yes (respond to items 1-3 below)  
 No (go to next box)

**1. What is(are) the federal source(s) of funding?**

(e.g., NIH). \_\_\_\_\_

**2. What is(are) the Grant Number(s)?**

**3. Submit one copy of the full grant application, including the face sheet (salary information may be redacted).**

**Participant Age**

- 0-7 (parent Perm. & Oral Child Assent)  
 8-17 (Parent Perm. & Written Child Assent)  
 18-65  
 65+

**Participant Gender**

# of females  
# of males

**Estimated Project Duration**

Start Date  
Completion Date

**Will Participants be Compensated?**

- No  
 Yes, What Type?

**NOTE:** Does this research involve only the analysis of **publicly available OR non-identifiable existing** human subjects data/tissue/teeth?

- No - Complete all application questions  
 Yes - Complete the following steps. [1] fill out this page, [2] answer item #9 (indicating the database or location from which the data/tissue/teeth will be drawn), and [3] complete the signature page on p.4.

.....Case IRB Use Only.....

IRB Protocol Number \_\_\_\_\_

Date Received (stamp):

Education requirement met? (circle one) YES NO  
Grant requirement met? (circle one) YES NO N/A

**1. Describe in detail how and where you will identify, recruit, and engage participants for this study, being sure to include a detailed description of your process for contacting, selecting, and excluding subjects. If the proposed study will include children, describe the process for meeting requirements for parental permission and child assent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. Attach all advertisements, notices, emails, announcement scripts, recruitment letters, etc.**

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**2. Check YES or NO for each item below to indicate if your research will involve the corresponding procedure:**

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Deception/Punishment
<input type="checkbox"/>	<input type="checkbox"/>	Use of drugs or devices
<input type="checkbox"/>	<input type="checkbox"/>	Covert observation
<input type="checkbox"/>	<input type="checkbox"/>	Special participant populations (see previous page for list)
<input type="checkbox"/>	<input type="checkbox"/>	Induction of mental and/or physical stress
<input type="checkbox"/>	<input type="checkbox"/>	Procedures that may cause physical harm to the participant
<input type="checkbox"/>	<input type="checkbox"/>	Materials/Issues commonly regarded as socially unacceptable
<input type="checkbox"/>	<input type="checkbox"/>	Procedures that might be regarded as an invasion of privacy

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**3. For each item checked YES above, justify the necessity for it, and describe the precautions that will be taken to minimize risk. If your study involves DECEPTION, describe when and how the participants will be debriefed, and attach a copy of the DEBRIEFING SCRIPT. Any research involving DECEPTION must also include a waiver/alteration of informed consent.**

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**4. Will any data be gathered with audio and/or visual recording devices?**     No (go to item #5)  
 Yes (see below)

**If YES, (a) Describe how the security of the audio/video tapes will be protected and (b) state when the materials will be destroyed. *Case IRB Suggestion: destroy within 3 years of the completion of the research.***

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**5. Describe how you will maintain the confidentiality of the data. Specifically, (a) Will the data be individually identifiable, or will it be coded to mask participant identity? (b) If the data is coded, will there be any links to individually identifiable data (e.g., master list)? (c) Where will you keep the data? (d) How long will you keep the data and codes? (e) Who will have access to the data and codes?**

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**6. Will there be any reasonably foreseeable risks, discomforts, and inconveniences to participants in this research? If YES,**  
**(a) describe the procedures to minimize risks, discomforts and/or inconveniences and**  
**(b) justify why these risks, discomforts, and/or inconveniences are reasonable in relation to the anticipated benefits.**  
**What additional safeguards will you implement that will protect the rights and welfare of participants who are likely to be vulnerable to coercion and undue influence, especially for vulnerable populations? Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.**  
**Describe planned procedures for protecting against or minimizing potential risks, including risks to confidentiality. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. If the research involves greater than minimal risk, please describe the availability, if any, of compensation for research-related harms/injuries. If it involves greater than minimal risk, please provide provisions for monitoring the subjects response to research to ensure safety.**

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**7. Will there be any benefits to participants or to the community because of this research?**  
*Examples: therapy, education, information, resources, empowerment*  
*Note: Monetary compensation is not considered a benefit of participation.*

<p><b>8. Will you compensate research subjects? If YES, please explain how. If compensation is monetary, please provide the payment amount and the proposed method and timing of disbursement. Please include if payment will be pro-rated.</b></p>
<p><b>9. Attach a brief summary (two-page max.) of your research, being sure to include its purpose. <u>Include current research questions, methods and procedures to be used, citations, and any current findings, if applicable.</u> Use lay language, which can be understood by someone unfamiliar with your area of research. Attach all survey instruments, interview scripts, IRB approvals or letters of cooperation (if recruiting from institutions that do not have an IRB), tests, etc.</b></p>
<p><b>10. How will you protect the privacy of participants? Describe specifically how you will gather information from or about them. (NOTE: While confidentiality concerns data, privacy concerns people). EXAMPLES: People may be uncomfortable answering questions about their employer in an open cubicle, so investigators may arrange for a more private interview location. Or, people may not want to be seen in a place that might be stigmatizing to them, such as a pregnancy counseling center, so investigators may arrange for questionnaires to be mailed to subjects.</b></p>
<p><b>11. In accordance with HIPAA, please indicate if you will collect data that includes Protected Health Information (PHI, see definition below)? <u>PHI</u> - Information, including demographic information, collected from an individual, that: 1) Is created or received by a health care provider, health plan, employer or health care clearinghouse [*see examples below*]; and 2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and 3)(i) That identifies the individual; or ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual; and 4) is transmitted or maintained in any form or medium. (45 CFR 160.103) *For example, Dental Clinics, Student Health Services, and Governmental Health Agencies</b></p> <p>___ Yes (contact the IRB Director, Isabel Sánchez-Cummings: <a href="mailto:ias5@case.edu">ias5@case.edu</a> or 368-6993) ___ No (go to next item)</p>
<p><b>12. Per federal regulations, <u>written and signed</u> informed consent is required unless an alteration is justifiable under 45 CFR 46.116(d), or §46.117(c).</b> <b>Are you requesting an alteration or waiver?</b>  <input type="checkbox"/> No (go to item #13)  <input type="checkbox"/> Yes (see below)  <b>If YES, draft a justification statement, in which you describe <u>EITHER</u> why one or more of the required elements of informed consent must be waived for this research to be conducted, <u>OR</u> why the requirement to obtain a <u>signature</u> on the consent form must be waived for this research to be conducted.</b></p>
<p><b>13. Will you be obtaining consent from non-English speaking participants?</b>  <input type="checkbox"/> No (go to item #14)  <input type="checkbox"/> Yes (see A &amp; B below)  <b>If YES,</b>  <b>A Describe (1) how the consent will translated</b>  <b>(2) the language and cultural expertise of the investigators</b>  <b>B Submit a translated consent document, in addition to the English version.</b></p>

**14. Do any investigators participating in this study have a significant financial interest(s)\* in any organization that would reasonably appear to be affected by the outcome of this research?**

*\*A financial interest is a "significant financial interest" which must be disclosed if income from one company is expected to exceed \$10,000 or more, or represents 5% or more ownership interest (total ownership interest of the faculty member, spouse and dependent children.)*

- No (go to item #15)  
 Yes (see A and B below)

**A. Was this interest reported on that individual's most recent conflict of interest disclosure form?**

- No (contact IRB Office for more information & complete Part B)  
 Yes (complete Part B)

**B. Please include the following statement in the informed consent document:**

*"Please note that the responsible investigator and/or other members of the research team have a significant financial interest in [choose one: the sponsor of this research OR the product being investigated in this study]."*

**15. Provide a description of the informed consent process, being sure to indicate, (a) how and from whom the potential subjects will receive the consent information/document; (b) who would be approached for consent/assent/permission (c) where the informed consent interaction will occur; (d) timing and waiting periods (see note below); (e) steps taken to minimize the possibility of coercion or undue influence; (f) the language used by those obtaining consent; (g) the language understood by the prospective participant or the representative. Include a copy of the informed consent document (ICD) that you plan to use. When drafting the ICD, use at least a 12-point font, write in 2<sup>nd</sup> person and at a reading level that is not greater than 8<sup>th</sup> grade or appropriate to subject population. Avoid using jargon and technical terms. *Note: for your assistance, an ICD template is provided at the following URL: [http://ora.ra.Case.edu/orc\\_humansubjects\\_CASE\\_IRB.asp](http://ora.ra.Case.edu/orc_humansubjects_CASE_IRB.asp)***

***Note to investigator: Timing and Waiting Periods.*** *The "informed consent process" should include sufficient time for the participant to review and consider participating with the assistance of family members, research partners or representatives if necessary. Other items to consider regarding time/waiting periods are:*

- *Is the potential participant given a copy of the consent form to read prior to the discussion of the study?*
- *Is the consent document presented in person or mailed (where they can review it in the privacy of their own home)?*
- *How much time elapses between the presentation of the study and informed consent form and the actual signing of the form?*

*The answers to these questions will ensure the RI has considered this component of the process and will reassure the IRB that the RI is allowing adequate time for the participant to make an informed decision and minimize the possibility of coercion or undue influence.*

**16. Is this a multi-site research study?**

No (go to item #17)

Yes

Is/are the external site(s) deferring review of this protocol to the Case IRB?

No (provide IRB approval letters, including contact information, for all external sites.)

Yes (provide letters of cooperation, including contact information, for all external sites.)

**17. Has this proposal, or a substantially similar one, been submitted, approved or disapproved by another IRB?**

No

Yes (Please provide a full explanation.)

**18. Before you obtain the three required signatures, ensure that you have...**

- completed all of the education requirements  
(see [http://ora.ra.cwru.edu/orc\\_humansubjects.asp](http://ora.ra.cwru.edu/orc_humansubjects.asp) for more information)
- attached all advertisements, flyers, recruitment emails
- (if deception will be involved) attached the debriefing script or letter
- attached a summary, as well as all tests, interview scripts, instruments
- attached copies of IRB approvals or (if the institution does not have an IRB) letters of cooperation, if applicable
- attached the informed consent document (ICD) and (if applicable) child assent forms
- attached one copy of the full grant/funding application (if applicable)

**SIGNATURE PAGE**

*ORIGINAL SIGNATURES ARE REQUIRED. COPIES OR FAXES WILL NOT BE ACCEPTED*

**By signing this application, investigators agree to abide by all of the University rules and regulations to protect human subjects in research. Investigators also agree to report to the Case IRB any and all adverse events and/or unanticipated problems with relation to this research.**

"As the Responsible Investigator, I certify that all faculty, staff, and students involved with this proposal have or will receive appropriate training with regard to the protection of human subjects prior to the initiation of the research. I understand that I may be asked to provide written documentation of such training at any time during the study."

\_\_\_\_\_  
**Signature of Responsible Investigator (RI)**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Signature of Co- Investigator (CI)**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Signature of Department Chair or Dean**

\_\_\_\_\_  
**Date**

**(If Chair is an investigator, the Dean's signature is required)**

Return completed application to: Case Western Reserve University IRB  
Office of Research Compliance  
Sears Library 6<sup>th</sup> floor, Room 662  
Cleveland, OH 44106-7230

*campus mail  
location code: 7230*

**Questions?**

Case IRB Website: [http://ora.ra.cwru.edu/orc\\_humansubjects\\_CWRU\\_IRB.asp](http://ora.ra.cwru.edu/orc_humansubjects_CWRU_IRB.asp)  
Case IRB Assistant: Maureen Dore-Arshenovitz, [mx4@Case.edu](mailto:mx4@Case.edu) OR 216.368.6925  
Case IRB Director: Isabel Sánchez-Cummings, [CWRU-IRB@Case.edu](mailto:CWRU-IRB@Case.edu) OR 216.368.6993

**-----CASE IRB USE ONLY-----**

<input type="checkbox"/> <i>Exempt</i> <input type="checkbox"/> <i>Expedited Review</i> <input type="checkbox"/> <i>Full Review</i> <i>Meeting Date:</i> _____ <input type="checkbox"/> <i>Tabled</i> <input type="checkbox"/> <i>Disapproved</i>	<u><i>Informed Consent</i></u> <i>Waiver of signed IC is approved based on: [§46.117(c)(1-2) ____]</i> <i>Waiver/alteration of informed consent is approved based on:</i> <b>45 CFR 46.116(d)</b> _____ ]
	<u><i>HIPAA</i></u> <i>PHI? Y__ N__</i> <i>Waiver? Y__ N__</i>
<b><i>Exempt Rev. Determination</i></b> [45 CFR 46.101b(1-6) _____]	

<b><i>Expedited Rev. Determinations</i></b>	[§ 46.110(1-9) _____] [children §46.40(4-7) _____] [prisoners §46.306a2(A-D) _____]
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**APPROVED**

\_\_\_\_\_  
*Signature of Chair or Designated Reviewer*

\_\_\_\_\_  
*Date*

**Revised December 2010**

