



*Institutional Review Board*  
**CONTINUING REVIEW FORM**

**INSTRUCTIONS:**

- ❖ Please type
- ❖ Attach additional pages, as needed
- ❖ Failure to submit timely continuing review materials will result in Administrative Hold/Termination, and loss of IRB privileges. For more information, see Case IRB Guidebook at the Case IRB Web Page: [http://ora.ra.cwrw.edu/orc\\_humansubjects\\_CWRU\\_IRB.asp](http://ora.ra.cwrw.edu/orc_humansubjects_CWRU_IRB.asp)

**Responsible Investigator** \_\_\_\_\_ **E-mail** \_\_\_\_\_  
(faculty member only, or non-faculty who has submitted the Responsible Investigator Certification Form) (only if used)

**Co-Investigator** \_\_\_\_\_ **E-mail** \_\_\_\_\_  
(faculty, staff, student, post-doc., etc.) (only if used)

**Department** \_\_\_\_\_ **IRB Protocol Number** \_\_\_\_\_  
(of Responsible Investigator)

**Title of Study** \_\_\_\_\_

1. Is this research **federally** funded in any way?  YES (see below)  NO (go to item #2)  
What is(are) the source(s) of funding (e.g., NIH, NSF, etc.)? \_\_\_\_\_ Grant # \_\_\_\_\_

2. This study is,

Active  Not Active  Completed or Discontinued  
(will be recruiting or recontacting subjects during the next approval period) (will not be recruiting new subjects and will not be actively contacting any subjects during the next approval period) (requesting that the study be closed-out because will not recruit or recontact subjects and will no longer work with individually identifiable data)

3. Total number of subjects enrolled since the previous approval period. \_\_\_\_\_ (these numbers must accurately reflect how many human subjects were involved in your study on an annual basis)

4. Total number of subjects enrolled in the study to date. \_\_\_\_\_

**SINCE THE PREVIOUS IRB REVIEW, ...**

**NO YES N/A**

- |   |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|
| 5. To your knowledge, have any subjects experienced any unanticipated social (e.g., financial, occupational, legal), psychological (e.g., emotional), or physical problems involving risks to participants or others as a result of this research since the last review? If YES, please describe. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. To your knowledge, have <u>any</u> subjects in your study died (either as a result of your study or not)? If YES, please describe.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Have you asked any subjects to withdraw from this research? If YES, please attach a summary describing the numbers of withdrawals and their reasons.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Have any subjects decided to withdraw from this research? If YES, please describe.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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Date Received (stamp)

Grant Application in File? YES NO N/A

Education Requirement Met? YES NO

- |  | NO                       | YES                      | N/A   |
|--|--------------------------|--------------------------|---|
| 9. Have any participants or others complained about perceived harmfulness or Unfairness regarding the research? If YES please attach a summary describing the number and nature of complaints.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                          |
| 10. Are you aware of any new relevant information, either through the study itself, or through outside sources (e.g., journal articles, conferences, communication with colleagues, etc.) that may indicate a possible increased risk of social, psychological, or physical harm to subjects in this study? If YES, please attach a summary of this information. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                          |
| 11. Have there been any publications that may affect risk/benefit ratio? If YES, please attach a copy of all publications.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                          |
| 12. Have participants experienced any benefits? If YES, please attach a summary of participant benefits.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                          |
| 13. Have the potential risks or benefits of this research changed? If YES, please attach a summary description of those changes.   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                          |
| 14. Please provide a brief summary and description of addenda, amendments or modifications since the last review.  |                          |                          | <input type="checkbox"/>                          |
| 15. Do you have any findings thus far? Please provide a brief summary.   |                          |                          | <i>Provide the Case IRB with a few sentences.</i> |
| 16. Informed Consent (check one below)   |                          |                          |   |
| <input type="checkbox"/> This research is NOT ACTIVE; therefore, a consent form is not applicable to this research. Checking this box means that no consent document(s) (even if previously approved) will be considered approved by the IRB for this research.  |                          |                          |   |
| <input type="checkbox"/> This research is ACTIVE: Submit a copy of the consent form for the next approval period (even if there have been no revisions). If there have been revisions to the consent form since the last approval, please provide TWO copies of the revised consent form, one of which has the changes highlighted.                              |                          |                          |   |
| 17. ORIGINAL Signatures & Dates (**copies and faxes of full application will not be accepted and the RI's signature must be original**)  |                          |                          |   |

Signature of Responsible Investigator _____	Date _____
(faculty member only, or non-faculty who has submitted the Responsible Investigator Certification Form)	
Signature of Co-Investigator _____	Date _____
(faculty, staff, student, post-doc., etc.)	
Signature of Chairperson or Dean _____	Date _____
(if the Responsible Investigator is Chairperson, a designated alternate or the Dean's signature is required)	

**REMINDER:**

All changes to IRB protocols must be approved via an addendum request *prior to initiation of the change* (for more information about addenda requests, see Case IRB Guidebook at [http://ora.ra.cwru.edu/orc\\_humansubjects\\_Case\\_IRB.asp](http://ora.ra.cwru.edu/orc_humansubjects_Case_IRB.asp))

<b>Return completed form to:</b>	Case Western Reserve University IRB 10900 Euclid Ave Cleveland, OH 44106-7230	<i>campus mail code = 7230 Sears Library Building 662</i>
<b>Questions?</b>	See Case IRB Web-page at <a href="http://ora.ra.cwru.edu/orc_humansubjects_CWRU_IRB.asp">http://ora.ra.cwru.edu/orc_humansubjects_CWRU_IRB.asp</a> IRB Assistant, Maureen Dore-Arshenovitz: <a href="mailto:mxd4@cwru.edu">mxd4@cwru.edu</a> OR (216)368-6925 IRB Director, Isabel Sánchez-Cummings: <a href="mailto:ias5@cwru.edu">ias5@cwru.edu</a> OR (216)368-6993	

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\_\_\_\_\_ *Expedited Review* [45 CFR 46.110(1-9)\_\_\_\_\_]  
 \_\_\_\_\_ *Full Committee Review* [children, 45 CFR 46.40(4-7)\_\_\_\_\_]; [prisoners, 45 CFR 46.306a2(A-D)\_\_\_\_\_]

Approved \_\_\_\_\_  
 Case IRB Chairperson or Designated Reviewer

Date \_\_\_\_\_

Revised December 2010