


## Self-Certification Form: Determining Whether Human Subjects Are Involved in Research When Obtaining Coded Private Information (Data) and/or Biological Specimens

**Instructions:**

1. Use this form if you need to provide funding agencies, administrators or collaborators with documentation that your research project does not require IRB review at UCSF. Keep a copy of the form in the PI's research file. Do **not** submit a copy to the IRB.
2. For help making this determination, review the Human Subjects Research Decision Tree and the Not Human Subjects Research guidance page. Contact the IRB at 415-476-1814 or IRB@ucsf.edu with questions.
3. Do not use this form for human stem cell research, which requires review by the GESCR Committee and may require IRB review.

<b>Principal Investigator:</b>		
Name and Degree <b>Caitlin Gerdts, M.H.S., Ph.D.</b>	Institution University of California, San Francisco	Department Advancing New Standards in Reproductive Health
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<b>Study/Grant Title/Award No.:</b>		
Aunty Jane Hotline Evaluation		
<b>If your research meets the following conditions, the use of de-identified or coded private information (data) and/or biological specimens does not meet the definition of a human subject and does not require IRB review at UCSF:</b>		
1. The research is not regulated by the Food and Drug Administration (FDA). <b>AND</b>  2. No one on the UCSF research team has access to identifiable information and one or more of the following apply (check all applicable boxes):  <input checked="" type="checkbox"/> The researcher(s) receive de-identified data or specimens.  <input type="checkbox"/> The researcher(s) receive coded data or specimens AND one or more of the following apply: <div style="margin-left: 20px;"> <input type="checkbox"/> The key to decipher the code is destroyed before the research begins.   <input type="checkbox"/> The PI and holder of the key enter into an agreement prohibiting the release of the key under any circumstances. There are IRB-approved written policies for the repository or data management that prohibit the release of the key.   <input type="checkbox"/> There are other legal requirements prohibiting the release of the key under any circumstances.                 </div>		
<b>Principal Investigator's Certification:</b>		
I certify that the information provided in this application is complete and correct.		
 _____ <b>Principal Investigator's Signature</b>	6/3/2015 _____ <b>Date</b>	