

## 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](mailto: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	Institution	Department
Mailing Address	Phone Number	E-mail Address
<b>Study/Grant Title/Award No.:</b>		
<p><b>If your research meets the following conditions, the use of <span style="color: blue;">de-identified or coded</span> 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></p>		
<p>1. The research is not regulated by the Food and Drug Administration (FDA) <b>AND</b></p> <p>2. No one on the UCSF research team has access to identifiable information because one or both of the following apply (check all applicable boxes):</p> <p><input type="checkbox"/> The researcher(s) receive de-identified data or specimens.</p> <p><input type="checkbox"/> The researcher(s) receive coded data or specimens AND one or more of the following apply:</p> <ul style="list-style-type: none"> <li>• The key to decipher the code is destroyed before the research begins, OR</li> <li>• The PI and holder of the key enter into an agreement prohibiting the release of the key under any circumstances, OR</li> <li>• There are IRB-approved written policies for the repository or data management that prohibit the release of the key, OR</li> <li>• There are other legal requirements prohibiting the release of the key under any circumstances.</li> </ul>		
<b>Principal Investigator's Certification:</b>		
I certify that the information provided in this application is complete and correct.		
<hr style="width: 100%;"/> <b>Principal Investigators Signature</b>		<hr style="width: 100%;"/> <b>Date</b>