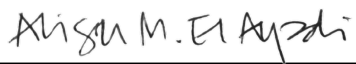


Self-Certification Form: Determining Whether Human Subjects Are Involved in Research When Obtaining Coded Private Information (Data) and/or Biological Specimens

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.

Principal Investigator:		
Name and Degree	Institution	Department
Mailing Address	Phone Number	E-mail Address
Study/Grant Title/Award No.:		
If your research meets the following conditions, the use of <u>de-identified or coded</u> private information (data) and/or biological specimens does not meet the definition of a human subject and does not require IRB review at UCSF:		
1. The research is not regulated by the Food and Drug Administration (FDA) <u>AND</u> 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): ☐ The researcher(s) receive de-identified data or specimens. ☐ The researcher(s) receive coded data or specimens AND one or more of the following apply: • The key to decipher the code is destroyed before the research begins, OR • The PI and holder of the key enter into an agreement prohibiting the release of the key under any circumstances, OR • There are IRB-approved written policies for the repository or data management that prohibit the release of the key, OR • There are other legal requirements prohibiting the release of the key under any circumstances.		
Principal Investigator's Certification: I certify that the information provided in this application is complete and correct.		
		4/18/2021
Principal Investigators Signature		Date