Human Subject Research Determination Checklist

Project #/Title	
Investigator	
Determination made by (fill in institution**)**	
Name of Person/Title Completing This Checklist	
Date Completed	

Materials provided to the Reviewer to make the determination:		
1.	☐ Yes ☐ No ☐ N/A	Investigator Human Subject Research Determination form
2.	☐ Yes ☐ No ☐ N/A	Detailed Protocol
3.	☐ Yes ☐ No ☐ N/A	Study description
4.	☐ Yes ☐ No ☐ N/A	Other:

Human Subject Research Determination Checklist

Human Subject Research Determination		
OHRP [45 CFR 46.102(d)]		
Research as defined by DHHS Regulations (*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*):		
5.	☐ Yes ☐ No ☐ N/A	Is the activity determined to be an investigation? (*Investigation: a searching inquiry for facts or detailed or careful examination*)
6.	☐ Yes ☐ No ☐ N/A	Is the investigation determined to be systematic? (*Systematic: Having or involving a system, method or plan*)
7.	☐ Yes ☐ No ☐ N/A	Is the systematic investigation designed to develop or contribute to knowledge? (*Designed: done with purpose and intent. Develop: to elaborate or expand in detail. Contribute: to be an important factor in; help to cause. Knowledge: truths, facts, information*)?
8.	☐ Yes ☐ No ☐ N/A	Is the activity designed to generate generalizable knowledge? (*Generalizable: universally applicable*)?
9.	☐ Yes ☐ No ☐ N/A	Does the activity met the definition of research according to DHHS (*were all 4 criteria fulfilled*)?

OHRP [45 CFR 46.102(f), 45 CFR 46.102(f)(1), (2)]		
Human Subject as defined by DHHS Regulations (*a living individual, about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information*):		
10.	☐ Yes ☐ No ☐ N/A	Is the investigator conducting the research gathering information about living individuals?
11.	☐ Yes ☐ No ☐ N/A	Will the investigator gather the data through physical procedures or manipulations of those individuals or their environments for research purposes? (*intervention*)
12.	☐ Yes ☐ No ☐ N/A	Will the investigator gather the data through communication or interpersonal contact with the individuals? (*interaction*)
13.	☐ Yes ☐ No ☐ N/A	Will the investigator gather the data that are about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place? (*Private information*)
14.	☐ Yes ☐ No ☐ N/A	Will the investigator gather the data that individuals have provided for specific purposes in which the individuals can reasonably expect that it will not be made public, such as medical records? (*Private information*)
15.	☐ Yes ☐ No ☐ N/A	Can the individuals' identity be readily ascertained or associated with the information by the investigator? (*identifiable information*)
16.	☐ Yes ☐ No ☐ N/A	Does the activity involve human subjects according to DHHS (*were all 6 criteria fulfilled*)?

Human Subject Research Determination Checklist

OHRP [45 CFR 46.102(f)(2)]		
Coded Information [OHRP] (*Coded means a living individual's identifiable information such as name or social security number has been replaced by a code, such as a number, letter, or combination thereof and there is a key to link the code to the identifiable information of that individual in existence. Coded data are considered identifiable under the Common Rule*): It is **not human subject research** if both the conditions below are met:		
17.	☐ Yes ☐ No ☐ N/A	Private information or specimens will not be collected specifically for the currently proposed research project through an interaction or intervention with living individuals.
18.	☐ Yes ☐ No ☐ N/A	The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because: a) The holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstances, until the individuals are deceased; (***was a copy of this agreement provided?***) **OR** b) The investigator has documentation of IRB approved written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased (***was this documentation provided***); **OR** c) There are other legal requirements prohibiting the release of the key to the investigator, until the individuals are deceased
19.	☐ Yes ☐ No ☐ N/A	The activity involves coded information (*were both the criteria fulfilled*).

Final Determination		
20.	☐ Yes ☐ No ☐ N/A	The activity is **not** Human Research.
21.	☐ Yes ☐ No ☐ N/A	The activity is Human Research and is exempt from IRB review.
22.	☐ Yes ☐ No ☐ N/A	The activity is Human Research and is eligible for expedited review.
23.	☐ Yes ☐ No ☐ N/A	The activity is Human Research and requires review by a convened IRB.
24.	☐ Yes ☐ No ☐ N/A	Was the decision communicated to the researcher?
Institutional Policy		The activity must be determined Human Subject Research according to: ☐ Yes ☐ No OHRP ☐ Yes ☐ No FDA ☐ Yes ☐ No Other:
How much time lapsed from submission to determination to the researchers?		
Comments (note any discrepancies between determination and/or missing/incomplete documents to support IRB determination)		

Human Subject Research Determination Checklist

OPTIONAL FDA Determination Checklist

FDA [21 CFR 56.102(c)]		
Clinical Investigation as defined by FDA Regulations (*any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are **intended to be submitted later** to, or **held for inspection by**, the FDA as part of an application for a research or marketing permit.*):		
25.	☐ Yes ☐ No ☐ N/A	Does the activity involve data regarding subjects or control subjects that would be submitted to or held for inspection by FDA?
26.	☐ Yes ☐ No ☐ N/A	Does the activity involve data regarding the use of a device on human specimens (identified or unidentified) that would be submitted to or held for inspection by FDA?
27.	☐ Yes ☐ No ☐ N/A	Does the activity meet the definition of clinical investigation according to FDA (*were both/either of the criteria fulfilled*)?

FDA [21 CFR 56.102(e)]		
Human Subject as defined by FDA Regulations (*an individual who is or becomes a participant in research, either as a recipient of the test article or as a control*):		
28.	☐ Yes ☐ No ☐ N/A	Does the activity involve the use of a drug in one or more persons other than the use of an approved drug in the course of medical practice?
29.	☐ Yes ☐ No ☐ N/A	Does the activity involve the use of a device in one or more persons that evaluates the safety or effectiveness of that device?
30.	☐ Yes ☐ No ☐ N/A	Does the activity involve human subjects according to FDA (*were both/either of the criteria fulfilled*)?