**Institutional Review Board**

**Determining Human Research**

The purpose of this worksheet is to help Researchers and Reviewers determine if the study involves human research and requires IRB review. Please note: an activity that is not considered human subjects research under 45 CFR 46 may still fall under other Federal, State, and local laws and/or regulations. Please see the Standard Operating Procedures for more information.

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| **The Following Activities are Deemed NOT to be Research (check all that apply)** | |
|  | Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected |
|  | Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). |
|  | Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes |
|  | Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions |

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| **Is the Study Considered Research?** **(all must be checked)** | | | |
|  | Is the study a systematic investigation? | | |
|  | Does the study involve research development, testing, and evaluation? | | |
|  | Is the study designed to develop or contribute to generalizable knowledge? | | |
| **Is the Study Considered *Human Subject* Research under HHS Regulations?** | | | |
|  | Is the research being conducted about a living individual? | | |
|  |  | Will the PI/Researcher obtain information or biospecimens through intervention or interaction with the individual, and use, study, or analyze the information or biospecimens | |
|  |  |  | Does the research include both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes? (*Intervention* definition) |
|  |  |  | Does the research include communication or interpersonal contact between PI/Researcher and subject (*Interaction* definition) |
|  |  | Will the PI/Researcher obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens? | |
|  | Does the institution hold an FWA which applies 45 CFR 46 to all its human subjects research regardless of the source of support? | | |

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| **The study is NOT considered Human Subjects Research if:** | |
|  | The study does NOT obtain information about living individuals |
|  | The information is NOT individually identifiable |
|  | The information is individually identifiable but is NOT private |