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| Study ID# |       | PI |   |  |

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| **Common Rule Requirements** |
| 1. **Is this project conducted, supported, or required to comply with U.S. Department of Justice requirements or otherwise required to comply with the pre-2018 Common Rule requirements?**

[ ]  No 🡪 Continue[ ]  Yes 🡪 *Do NOT use this form; use HRP-310 - Worksheet – Human Research Determination Pre-2018.* |
| **Human Subject Research Definitions** |
| 1. **Select appropriate option and provide explanation.**
 |
| [ ]  **Activity does not involve research** | *Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:*1. *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.*
2. *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).*
3. *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.*
4. *Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.*
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| Explanation  | [ ]  The activity is a not a systematic investigation.[ ]  The activity is not designed to develop or contribute to generalizable knowledge.      |
| [ ]  **Research does not involve human subjects** | *Human subject means a living individual about whom an investigator (whether professional or student) conducting research:**(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or* *(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.* |
| Explanation | [ ]  Living individuals are not involved.[ ]  The activity is not “*ABOUT*” the living individual.[ ]  Will not obtain information or biospecimens through an intervention or interaction and use, study, or analyze the information or biospecimen.[ ]  Will not obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens.      |

Comments:

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| Determination made by: |
| Name: |       | Date: |       |  |
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