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|  | **Public Health Surveillance/Not Research Determination Form** | |
| *Activities that meet the definition of “Public Health Surveillance” are not “human subjects research” and do not require ongoing IRB oversight. Whether or not they meet this definition, they must be conducted in accordance with institutional ethical standards. If you believe that your activity meets the definition, please answer the questions below and submit this form for consideration by the JHSPH IRB.* | | |
| IRB Number |  | |
| Study Title |  | |
| Principal Investigator |  | Email: |
| Administrative Contact |  | Email: |

***The "activity" referred to throughout the remainder of this document, and to which your responses/explanations pertain, refers to the surveillance, data collection, monitoring, evaluation "activity". It does not refer to the program, procedures, clinical services, or other action that is itself the target of the surveillance, data collection, monitoring, or evaluation. Please make clear this distinction in your responses.***

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| 1. Please provide a general description of the proposed activity and its objective(s): |
| 1. To meet the definition of “public health surveillance”, the activity must be “conducted by”, “supported by”, or “requested, ordered, required, or authorized by” a public health authority; this authority must have an official mandate with responsibility for public health matters.   *Please describe the public authority and its relationship to the activity and those carrying out the activity:* |
| 1. The activity must be limited to that which is necessary to allow the public health authority to achieve its mandate to protect and maintain the health and welfare of the population for which it is responsible.   *Please describe the mandate of the public health authority, and how the proposed work is limited to activities that allow the public authority to achieve its mandate:* |
| 1. Is the activity surveillance? While the Revised Common Rule does not explicitly define surveillance, the IRB will consider if the activity(ies): “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).”   *Please describe the activity in sufficient detail such that the IRB can determine whether or not the activity can be considered public health surveillance:* |
| 1. Who is funding this activity, and for what period of time? |
| 1. Please clarify the role of each partner/collaborator, and make clear the specific responsibilities of JHSPH personnel and subcontractors. |
| 1. For new data collection, comment on any ethical issues you foresee associated with recruitment, consent, privacy protections, and study procedures. What are the risks of this activity? |
| 1. Please describe your data security protections. In particular, clarify what personal identifiers will be collected, retained, and/or removed. Make clear the risks, if any, associated with data collection, storage, sharing and general management. |
| 1. What is the scale of this activity? How many individuals/households do you anticipate will be involved? |
| 1. Will your data be stored or saved for future use? If yes, what kind of use do you anticipate, and by whom? |
| 1. Please describe your data sharing plan. Will the data be made publicly accessible, and if so, how? If by publication, will your partners/collaborators be co-authors? |
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