**Public Health Surveillance Determination Worksheet**

*This worksheet should be completed by investigators whose project may qualify as a public health surveillance activity and would therefore not constitute human subjects research. Only the JHU IRBs may establish that a project led by or involving a JHU faculty member, staff member, or student qualifies as a public health surveillance activity. To assist the JHM IRB in making this determination, please complete this worksheet thoroughly, ensuring a comprehensive response is provided for each question. Please visit the* [*JHU guidance for investigators on Public Health Surveillance Activities*](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/public_health_surveillance_activities.html) *for additional information to help with completion of this worksheet.*

*To be considered a “Public Health Surveillance Activity”1 your project must meet each of the following criteria:*

* The activity must be a public health surveillance activity (45 CFR 46.102(*l*)(2));
* The activity must be conducted, supported, requested, ordered, required, or authorized by a public health authority (45 CFR 46.102(k) and 46.102(*l*)(2)); and,
* The activity must be limited to that 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) (45 CFR 46.102(*l*)(2)).

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| **Q1. Please describe your activity and address each of the following:*** What the activity entails

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* How the activity will provide timely and useful evidence to public health authorities

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* How the activity will enable public health authorities to be more effective in their efforts to protect & promote public health

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* How the activity is limited to that **necessary** to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onset of disease outbreaks, or conditions of public health importance

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* Whether there is a direct link between the surveillance activity and the decision-making and action by a public health authority

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| **Q2.** **Please identify the public health authority connected to this activity and address each of the following**: * The name of the Public Health Authority

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* Whether the named authority has, as part of its official mandate, a responsibility for public health matters [If so, please explain]

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* Whether the public health authority is conducting, supporting, requesting, ordering, required or authorizing this project [Please review the corresponding [guidance on Public Health Surveillance Activities](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/public_health_surveillance_activities.html) for information on the potential roles of a public health authority and use this guidance to describe the role of the public health authority]

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 <https://www.hhs.gov/ohrp/draft-guidance-public-health-surveillance-activities.html>