

## NIH Applicant, Offeror or Investigator Instructions

Although NIH is considered a public health authority NIH anticipates it will be extremely rare for NIH-funded activities to qualify for a public health surveillance exclusion. NIH rarely supports or conducts research involving public health surveillance activities that meet the criteria for a public health surveillance exclusion.

All requests for NIH-funded research for applications, including competing applications, contract solicitations, and NIH Intramural Research studies after the effective date of January 25, 2022 per the NIH Guide Notice [NOT-OD-22-001](#), must receive approval by NIH to be considered as a public health surveillance activity deemed not to be research under [45 CFR Part 46.102\(k\), 46.102\(l\)\(2\)](#).

In the rare event that an NIH applicant or offeror submits a public health surveillance exclusion request, the NIH application or proposal must be under consideration for funding.

The NIH applicant, offeror, or NIH Intramural Research Program (IRP) investigator should follow the instructions below:

1. Notify your NIH Program Official/Program Director (PO/PD), Contracting Officer (CO), or NIH's Intramural Office of Human Subjects Research Protections (OHSRP) of your intent to request a public health surveillance exclusion request **before** you submit the request.
2. Check the study for which you plan to request an exclusion and confirm that the study activities do not comprise or include any of the following:
  - A. They do not include an [NIH-defined clinical trial](#); *or*
  - B. They do not include any other activity that does not meet the requirements of the exclusion, such as the intent to store biospecimens and/or data for future use.

If either A or B apply, **STOP**. You should not submit an exclusion request. A request involving an NIH-defined clinical trial or a study which will store biospecimens and/or data for future use will not be considered for a public health surveillance exclusion.

3. Include the following information in your public health surveillance exclusion request (less than 2,000 characters is recommended):
  - A. Identify and describe all activities proposed in your NIH application or proposal for which you are requesting a public health surveillance exclusion. Remember that the study cannot include any activities other than those that qualify for a public health surveillance exclusion.
  - B. A compelling justification as to why your NIH-funded or -conducted activities should be considered public health surveillance and *not research* for the purposes of the revised Common Rule. The compelling justification **must** include information that explains how all activities in the request meet the three criteria below:
    1. All the activities are necessary for NIH to identify, monitor, assess, or investigate:

- Potential public health signals; or
- Onsets of disease outbreaks; or
- Conditions of public health importance, such as trends, signals, risk factors, or patterns in diseases.

*AND*

2. The activities will provide timely and useful evidence to the NIH during an event or crisis that threatens public health (such as natural or man-made disasters).

*AND*

3. The activities will directly inform *NIH public health decision making or action*.

If your justification does not explain how the activities in your study meet these three criteria, **STOP**. You should not submit an exclusion request since your request will not be approved for a public health surveillance exclusion.

4. Submit your public health surveillance exclusion request **ONLY** if you have verified the information in your request includes all information identified in the 3A and 3B instructions above **AND** your NIH application or proposal is under consideration for funding.
  - A. If you are a grant applicant, submit the exclusion request **during the Just-in-Time period** following [Just-in-Time procedures](#). See the NIH Grants Policy Statement, [Section 2.5.1](#), for additional information.
  - B. If you are an offeror for Research & Development (R&D) contracts, follow the instructions in the Request for Proposal (RFP).
  - C. If you are an applicant for awards issued under Other Transactions (OTs), follow the instructions in the Research Opportunity Announcement (ROA).
  - D. If you are an NIH IRP investigator, submit the complete protocol and all required review materials, including the exclusion request, in the [NIH electronic submission system](#) using the same process and review path (non-exempt or exempt) as if it were a typical research protocol. Include “PHSE” in the protocol title and short title. The exclusion request, as described in section 3 above, should be a separate document titled “PHSE exclusion request” and uploaded as an attachment in the electronic submission system.

If you are an applicant, offeror, or recipient, your NIH grants specialist, agreements officer, or contracting officer will notify you of the final decision, prior to award. If you are an NIH IRP investigator, the OHSRP will notify you of the final decision.

If you are an applicant, offeror, or recipient, contact your PO/PD, or CO if you need assistance with your request. If you are an NIH IRP investigator, contact OHSRP ([irb@od.nih.gov](mailto:irb@od.nih.gov)) if you need assistance.

For general PHSE questions, contact the NIH OER Human Subjects mailbox at [OER-HS@nih.gov](mailto:OER-HS@nih.gov).

## NIH PUBLIC HEALTH SURVEILLANCE EXCLUSION REQUEST WORKFLOW

Requests **must** come through the NIH Program Officer (PO)/Program Director (PD), Contracting Officer (CO) or the Intramural Office of Human Subjects Research Protections (OHSRP). See Guide Notice [NOT-OD-22-001](#) for additional information.

Do not submit a request that is incomplete or otherwise does not meet the requirements below.

