

JUSTIFICATION FOR PUBLIC HEALTH SURVEILLANCE EXCLUSION

An Offeror may request exclusion from applicability of the “revised Common Rule”¹ if it believes that NIH-funded or -conducted activities associated with its solicitation may be “public health surveillance activities deemed not to be research” as far as the revised Common Rule is concerned.

Offerors should not assume that approval of an exclusion will be granted when completing the PHS Human Subjects and Clinical Trials Information Form. It is anticipated that NIH-supported or -conducted research will be deemed public health surveillance activities that qualify for exclusion only in extremely rare cases.

NIH will not consider NIH clinical trials for public health surveillance determination and exclusion requests. Additionally, NIH will not consider studies that contain any activity that does not qualify for exclusion, which includes the intent to store specimens and/or data for future use, for any public health surveillance determination and exclusion.

Offerors shall address each of the following topic areas in order to qualify for this exclusion:

1. In order to qualify for a public health surveillance exclusion Offerors shall provide a compelling justification as to why NIH-funded or -conducted activities should be considered public health surveillance activities deemed not to be research for the purposes of the revised Common Rule. All activities for which approval of the exclusion will be sought must be disclosed and described.
2. This justification shall include information/data that demonstrates **all three (3)** of the following:
 - a) The proposed activity is strictly limited to only that necessary for NIH to identify, monitor, assess, or investigate:
 - i. Potential public health signals; or
 - ii. Onsets of disease outbreaks; or
 - iii. Conditions of public health importance (including trends, signals, risk factors, or patterns in diseases).
 - AND**
 - b) The 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).
 - AND**
 - c) The activities will directly inform NIH public health decision-making or action.
3. An Offeror shall submit its compelling justification for exclusion with its technical proposal as a separate attachment, so that the justification can be detached from and evaluated separate from the

¹ Code of Federal Regulations (CFR) Title 45, Public Welfare, Department of Health and Human Services, Part 46, *Protection of Human Subjects*, Revised 19 January 2017, Effective 19 July 2018, with a General Compliance Date of 21 January 2019 (45 CFR part 46)), and not its predecessor, the Pre-2018 Common Rule (Common Rule). The revised Common Rule is also known or referred to as the “2018 Requirements” or the “2018 Rule.”

Offeror's technical proposal. The Government reserves the right to not consider any public health surveillance exclusion requests if the justification is not provided at the time of original proposal submission.

4. References in addition to the footnoted Revised Common Rule, Code of Federal Regulations (CFR) Title 45, Public Welfare, Department of Health and Human Services, Part 46, *Protection of Human Subjects*:
 - NIH Document Generation System, Section L, *Instructions, Conditions, and Notices to Offerors*, Article 4, **Human Subjects**, Sub-Article h., **Public Health Service Exclusion**.
 - NIH Notice NOT-OD-22-001, *NIH Implementation of the Revised Common Rule Provision Regarding Public Health Surveillance Activities Deemed Not to Be Research*, with a release date of 12 October 2021 found at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-001.html>