

## ATTACHMENT F3

### AGREEMENT TO ABIDE BY RESTRICTIONS ON RELEASE OF ZIKA PREGNANCY AND INFANT OUTCOMES SURVEILLANCE AND SURVEILLANCE-RELATED DATA COLLECTED AND MAINTAINED BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

I, \_\_\_\_\_, understand that data collected by the Centers for Disease Control and Prevention (CDC) through the Zika Virus Pregnancy and Infant Outcomes Surveillance and related surveillance activities, projects, and case investigations under Sections 304, 306, and 307 of the Public Health Service Act (42 U.S.C. 242b, 242k, and 242l) are protected at the national level by an Assurance of Confidentiality (Section 308(d) of the Public Health Service Act, 42 U.S.C. 242m(d)), which prohibits disclosure of any information that could be used to directly or indirectly identify any individual on whom a record is maintained by CDC. This prohibition has led to the formulation of the following guidelines for release of Zika case reports and supplemental data collected on such persons to which, in accepting access to data not considered public use, I agree to adhere. These guidelines represent a balance between potential for inadvertent disclosure and the need for the CDC to be responsive to information requests having legitimate public health application. In particular, variables that identify geographic units or facilities have the potential to indirectly identify individuals.

Therefore, I will not release, either inside or outside CDC, state/territorial-, MSA-, city-, county-, or other geographic area-specific data in any format (e.g., publications, presentations, slides, interviews) without the consent of the appropriate state or local agency, except as consistent with the format described in this document and related Zika Response standard operating procedures. Specifically, I will abide by restrictions on the release of data in accordance with the principles of the Assurance of Confidentiality for Zika surveillance and surveillance-related data authorized under Section 308d of the U.S. Public Health Service Act. I will also comply with the terms of the Memorandum of Understanding with INS in Colombia regarding data sharing and publication.

#### Levels of data release:

- **National and regional level** — I am permitted to release national and regional aggregate data without cell size or denominator restrictions.
- **State level (including the District of Columbia and Puerto Rico)** — For any state, the District of Columbia, and Puerto Rico, I am permitted to release one-way frequencies and two-way stratifications of variables of interest (including sex, age group, race/ethnicity and transmission category) by location and year (e.g., living Zika cases by year\*state \* sex\*race) with the denominator rule suppressing data for stratum-specific populations with less than 100. No numerator suppression rule will be applied.
  - o For strata where a population is not available in the U.S. Census (e.g., transmission category) the underlying population that is *most similar to the group* will be checked before data are released. For example, for black men who have sex with men, the underlying population of black men will be checked for that geographic area.
  - o If the totals could inadvertently disclose a case through back-calculation by subtraction, secondary or complementary suppression will be done by either 1) combining two or more categories of data (e.g., aggregation of values within the stratification parameter) or 2)

excluding all data in a subcategory (e.g., blocking disaggregation below a pre-selected value for the stratification parameter) across multiple states.

- **Dependent areas of American Samoa, Guam, Northern Mariana Islands, the Republic of Palau and the U.S. Virgin Islands.** — I am only permitted to release and present data for U.S. dependent areas at the country or territory levels. The release of data below the country or territory level or for additional dependent areas other than the five areas listed above will require permission by the applicable health department(s).
  - o It is permissible to release totals (cumulative and annual) and one-way frequencies (cumulative only) of sex, age group, race/ethnicity and transmission by location (e.g., country) (e.g., Zika pregnancy and infant outcomes, outcome\*country\*race/ethnicity. No suppression rules will be applied at the country level.
- **General Suppression Rule**
  - o A denominator rule of <100 will be applied for all frequencies and stratifications with stratum-specific population denominators <100 (i.e., when the stratum-specific population is <100 for a subgroup, count data will not be presented). In addition, data will be suppressed when numerators are <5 (e.g., cells with 0 – 4 will not be presented); excludes case reports from which potentially identifying information has been excluded.
    - Any requests for data beyond this data release agreement will require permission by the applicable health department.
- **Data stability requirements for release of all data regardless of level of analysis** — I will include a cautionary note on stability for all levels of analyses when estimated numbers are less than 12 or rates are calculated based on numbers less than 12.
  - o A notation in either technical notes or footnotes will read “Reported numbers less than 12, as well as estimated numbers (and accompanying rates and trends) based on these numbers, should be interpreted with caution because the numbers have underlying relative standard errors greater than 30% and are considered unreliable.”

**Variables permitted for release:** — Any requests for variables other than those listed below will require approval by the Incident Manager, Zika Response as appropriate:

General

- Location (e.g. U.S., region, state, Metropolitan Statistical Area, county, dependent area) based on standard definitions
- Year (year of diagnosis [ Zika case classifications], death, prevalence, or report)

Demographic/transmission

- Age group (5-year or 10-year age group, at diagnosis, or calculated age at end of year for prevalence or at death for deaths)
- Race/ethnicity (based on OMB classification)
- Sex
- Transmission or exposure category (see Zika Surveillance Report)

**Data release and publication:**

- I understand that release of data not specifically permitted by this agreement is prohibited unless written permission is first obtained from the Task Force Lead.
- When presenting or publishing state-, city-, county-, MSA-, or dependent area-specific data in accordance with the restrictions outlined above, I will inform the appropriate state(s) and local health department(s) in advance of the release of state or local data, so as to afford them the

- opportunity to anticipate local queries and prepare their response.
- When presenting or publishing data from surveillance-related studies, investigations, or evaluations, I will adhere to the principles and guidelines outlined in this agreement and related standard operating procedures of the Pregnancy and Birth Defects Task Force, Zika Virus Response.

**Release of geocoded ZIKA surveillance data:**

- Any re-release of geocoded Zika surveillance data that identifies the geographic area below the state or for territory or country level for dependent areas is subject to written approval of the applicable health department(s) (re-release of data can be in the form of peer and non-peer reviewed manuscripts, technical reports, manuals, and presentations).
- All publications using geocoded data must be cleared through Zika Response clearance.
- Publication of a manuscript in a journal or as part of conference proceedings requires a CDC clearance of that manuscript, even if an abstract for that manuscript was previously cleared.

**Data Security:**

1. I will not give my access password to any person.
2. I will treat all data at my desk site confidentially and maintain in a locked file cabinet records that could directly or indirectly identify any individual on whom CDC maintains a record. Sensitive identifying information from special case investigations will only be maintained in a locked file cabinet in a locked room which has restricted access.
3. I will keep all hard copies of data runs containing small cells locked in a file cabinet when not in use, shredding them when they are no longer necessary to my analysis.
4. I will not produce a “back-up” data file of Zika case surveillance data or related databases maintained by CDC.
5. I will not remove electronic files, records or databases from the worksite, or access them remotely from home or other unofficial/unapproved off-worksite location.
6. I will not remove hard copies of case reports, survey instruments, laboratory reports, confidential communications, or any records containing sensitive data and information or the like from the worksite.
7. I will not remove from the worksite tabulations or data in any format that could directly or indirectly identify any individual.
8. I will maintain confidentiality of records on individuals in all discussions, communications, e-mails, tabulations, presentations, and publications (and the like) by using only the minimum information necessary to describe the individual case.

9. I will not release data to the press or media without pre-screening of the request by the Joint Information Center-Communications, Zika Response, or the leadership of the Emergency Operations Center.

10. I am responsible for obtaining IRB review of projects when appropriate.

User ID: \_\_\_\_\_

Purpose of investigation (provide a brief statement):

Data base(s) to be accessed:

Estimated time needed for data access/analysis:

**I have read this document, "Agreement to abide by restrictions on release of Zika Surveillance and Surveillance-related data..." and the attached document "Policy for Release of Zika Pregnancy and Infant Outcomes Surveillance and Surveillance-Related Data Collected and Maintained by the Centers For Disease Control And Prevention (CDC)," and I agree to abide by them. Failure to comply with this agreement may result in disciplinary action, including possible termination of employment.**

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

(Requestor)

CIO, Division, Branch \_\_\_\_\_

Approved: \_\_\_\_\_ Date: \_\_\_\_\_

Leader, Pregnancy and Birth Defects Task Force, Zika Response, Emergency Operations Center, or designee