Disclaimer: The following document does not offer legal advice nor is it intended to create any additional legal obligations. The document is intended as an introduction to approaches for obtaining consent for information from research subjects.

USAID implementing partners who perform Human Subjects Research must obtain legally effective informed consent from each person who is a research subject, or the research subject’s legally authorized representative, prior to conducting the study. Informed consent must provide the subject or their representative with sufficient opportunity to consider whether or not to participate, and must minimize the possibility of coercion or undue influence.

This document is intended to highlight only one area of consideration in informed consent clauses—confidentiality of the research subject’s data. This summary is not stating any additional requirements beyond those otherwise found in a partner’s agreement with USAID. More information on informed consent requirements is provided in USAID's regulations on Protection of Human Subjects (see 22 CFR 225), including the role of Institutional Review Boards in reviewing such consents. In addition, there may be country-specific laws applicable to obtaining informed consent.

Under USAID funded awards, there is an obligation to make some data publicly available, in accordance with proper protection and redaction allowable by law. The requirement in the current USAID Standard Provisions provides:

The recipient must submit to the Development Data Library (DDL) at www.usaid.gov/data, in a machine-readable, non-proprietary format, a copy of any Dataset created or obtained in performance of this award, including Datasets produced by a subawardee or a contractor at any tier. The submission must include supporting documentation describing the Dataset, such as code books, data dictionaries, data gathering tools, notes on data quality, and explanations of redactions.

... The recipient must ensure that any Dataset submitted to the DDL does not contain any proprietary or personally identifiable, such as social security numbers, home addresses, and dates of birth. Such information must be removed prior to submission.¹

Participants will generally want to know that sensitive information they provide is being protected. Informed consent statements can address the confidentiality issue in different ways.

Below are examples of what a researcher might say to a potential subject about information gathered in the field. The examples are written at a Fleish-Kinkaid readability level² of

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¹ See for example, ADS 302mas, Special Provisions for Acquisition (see 302.3.5.22) and ADS 303maa, Standard Provisions for U.S. Nongovernmental Organizations (see M25). For applicability to other USAID award types, please see USAID’s Open Data FAQ#16 at https://www.usaid.gov/data/frequently-asked-questions#Q16.
approximately grade 5-7, roughly analogous to the reading level for informed consent used in USAID’s Demographic and Health Surveys (DHS). However, the actual wording used should be clear and contextually appropriate, in order to make any consent truly “informed.”

**Researcher May Disclose Limited Data**

The following examples attempt to balance the public interest of making U.S. government-funded data available, with the research subject’s interest in protecting his/her personally identifiable, sensitive information. These variations of wording for informed consents address the type of information collected that can be disclosed and the scope of such disclosure.

For instance, the request for consent may indicate that the information from the study may be shared publicly or with third parties, without additional informed consent from the subject, once all individual identifiers have been removed that may enable others to readily determine the subject’s identity.

1) All information you provide that identifies you will be kept confidential. I will only share it with those working on this study. Other information you provide, I may share with other people. If I do, I may not ask your consent again. (Fleish-Kinkaid 6.5)

Example 1 indicates that individually identifiable participant information may be disclosed to the researchers assigned to the study, but not necessarily to the funder of the study, while de-identified information may be disclosed to third parties.

2) All information you provide that identifies you will be kept confidential. I will only share it with the funder and those working on this and related studies. The other information you provide, I may share with other people. If I do, I may not ask your consent again. (Fleish-Kinkaid 7.0)

Example 2 indicates that individually identifiable participant information may be disclosed to the funder, to researchers assigned to the study, and to those working on related studies. It indicates that only de-identified information may be disclosed to third parties. This wording may prove beneficial in situations where USAID has funded the creation of a dataset with identifiable participant information, which may need to be shared with other implementing partners to carry out related work.

Conveying the information in statements 1) and 2) above could allow the partner to comply with its obligations in the USAID funded award, while also respecting the subject’s rights to informed consent.

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2 See [https://en.wikipedia.org/wiki/Flesch%E2%80%93Kincaid_readability_tests](https://en.wikipedia.org/wiki/Flesch%E2%80%93Kincaid_readability_tests) and [https://readability-score.com](https://readability-score.com).
**Researcher May Disclose No Data**

At the most restrictive end of the spectrum, a researcher might be tempted to reassure participants with a blanket claim that no information at all will be made available to any third party. **Note:** In the case of a USAID funded award, using this option could violate the terms of the researcher’s agreement with USAID. This would hold true for awards that contain the clause or provision entitled “Submission of Datasets to the Development Data Library,” which require the potential sharing of data with the public. For informed consent, a researcher might include the following wording:

3) *All information that you provide will be kept confidential. I will only share it with those working on this study.* (Flesch-Kinkaid grade: 6.0)

Example 3 would prohibit disclosure to other researchers and other third parties who could benefit from the data.