**Checklist for Data Steward-Level Approval of Research Proposal**

**DEPARTMENT OF HEALTH and HUMAN SERVICES**

This form may be used as the Data Steward’s indication of support of a Research Proposal being submitted for Utah Department of Health and Human Services (DHHS) Institutional Review Board (IRB) review. Indication of support on this form means that the data steward has discussed this project with the researcher, reviewed the protocol, and in general supports the research. If a study involves more than minimal risk and no direct benefit to the subject, attach a separate justification statement. A copy of the completed form must be submitted by the Principal Investigator with the IRB proposal***. This form does not bind the data steward in any way; it only acknowledges that appropriate discussions have been held with the principal investigator before the protocol is submitted to the IRB (this form can be submitted in lieu of a data sharing agreement (DSA) which may take longer the complete or data stewards may wish to wait to complete DSA until IRB approval is obtained).***

Date of Review: Click or tap to enter a date.

Title of Study: Click or tap here to enter text.

Principal Investigator’s Name: Click or tap here to enter text.

Principal Investigator’s Email: Click or tap here to enter text.

Data Steward Completing Review: Click or tap here to enter text.

Data Steward E-mail: Click or tap here to enter text.

Data Steward Work Phone: Click or tap here to enter text.

Research Start Date: Click or tap to enter a date. Anticipated End Date: Click or tap to enter a date.

**1. DESCRIPTION OF STUDY: (include clients or databases/data elements PI wishes to access)**

Click or tap here to enter text.

**2. REVIEWED FOR THE FOLLOWING:**

the research is in the best interests of DHHS and DHHS’s clients or will inform DHHS work in support of the vision/mission of the agency;

the researcher has made adequate provision for obtaining all required informed consents/informed assents or there is legal authority to release data/information to Researcher (cite legal authority Click or tap here to enter text.);

Data is available and accessible for time frame requested

List of data elements requested was provided and was reviewed

the research protocols and procedures are designed to protect individual privacy and ensure confidentiality, respect, and ethical treatment during the researcher’s gathering of the data, storage and retrieval of the data, and publication of the data;

the research study involves no more than minimal risk1 to subjects, or the direct benefits to the subjects outweigh the risks;

the research methodology is sufficiently sound to yield results that offer a potential benefit to the Department; and

my program/bureau can provide resources to support or the PI is able to cover the costs for program/bureau to be able to support

**3. PROGRAM/BUREAU SUPPORTS THIS PROJECT:**  Choose an item.

Data Steward Signature: Date:

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1According to 45 CFR § 46.102 (j), “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”