

Utah Environmental Public Health Tracking Program

***Third Party Application for Access to
Secure IBIS-PH for Research Projects***

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Utah Environmental Public Health Tracking Program
Third Party Application for Access to Utah’s Secure Indicator-Based Information System for Public
Health (IBIS-PH) for Research Projects

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I. Overview of the Utah Tracking Network

A. Background. In 2002, Congress provided the Centers for Disease Control and Prevention (CDC) funding to begin developing a National Environmental Public Health Tracking Network (National Tracking Network) and to develop environmental health capacity within state and local health departments. With CDC funding, the Environmental Epidemiology Program (EEP) within the Utah Department of Health (UDOH) implemented a statewide Utah Environmental Public Health Tracking Network (Utah Tracking Network). The Utah Environmental Public Health Tracking Program (Utah Tracking Program) participates with the National Tracking Network.

B. Definition of Third Party Users

1. The data contained within the Utah Tracking Network is provided by data owners. The data owners, having authority and stewardship over their agency's data, are first-party users of their agency's data. The Utah Tracking Program serve as custodians of the data and are second-party users for activities involved in preparing data for the Utah Tracking Network. A third-party user is any person or agency who accesses Utah Tracking Network data that they do not own through Utah's Secure Indicator Based Information System for Public Health (Secure IBIS-PH) or in any other way for the purpose of conducting public health investigations or research (This includes the Utah Tracking Program and any data sharing partners accessing other agencies' data.). Secure IBIS-PH (further described below) contains data that are not made available to the public because they are aggregated at a fine enough granularity to require additional protections. Public data are made available to the public through IBIS-PH and do not require the protections instituted through these policies and procedures.
2. Researchers are defined as any third-party users who need to access the data in Secure IBIS-PH for a research paper or any other academic or research-oriented project. These individuals may include public health professionals at all levels when they are performing research outside of the activities directly related to routine surveillance and other job-related duties. Public health professionals performing activities directly related to their work must follow the guidelines outlined in the *Third Party Application for Access to Secure IBIS-PH for Public Health Professionals*.

C. Description of the Utah Tracking Program

The Utah Tracking Program consists of four major components:

1. **Data Warehouse:** A data warehouse of relevant public health outcome, biomonitoring, population, environmental monitoring, environmental hazards, and geographic data. Initially, the Utah Tracking Network started with limited data around specific data topics. Prioritization for implementing additional data content is conducted in concert with CDC. The Utah Tracking Network data warehouse content continues to grow as funding and resources are made available.
2. **Data Sharing:** Data sharing refers to methods to transmit data between the data warehouse, data owners, the National Tracking Network infrastructure, and data users. Different methods are used depending on the role of the connecting entity.

Where possible, the Utah Tracking Program takes advantage of other UDOH data transaction capabilities. For example, the public can access indicator data derived from data contained in the data warehouse through IBIS-PH (<http://ibis.health.utah.gov>). Bulk transactions of data to the National Tracking Network occur through the Utah Department of Environmental Quality's National Environmental Information Exchange Node (NEIEN). For researchers and public health professionals who receive Utah Tracking Program Scientific Review Board (SRB) approval, data at finer granularity is made available through a Secure IBIS-PH data query module.

3. Analytic Tools: The Tracking Program also provides a number of tools for researchers and public health professionals to manipulate, analyze, and model the data. The Utah Tracking Program works within the National Tracking Network framework to prioritize, acquire, and develop tools for the Utah Tracking Network. Additional tools are added as they become available.
4. Staff: The Utah Tracking Program consists of a small staff with experience and expertise in environmental epidemiology, toxicology, geographic information systems, analytical methodology, health education, and data management.

D. Organization of the Utah Tracking Program

1. The National Tracking Program (<http://www.cdc.gov/ephtracking/> for more information) works with the funded state and local health agencies, collaborating federal agencies (e.g., the Environmental Protection Agency), and collaborating public health organizations (e.g., the Association of State and Territorial Health Officials) through a series of work groups, semi-annual conferences, and progress reporting. There are three work groups with participation from all of the collaborating or funded partners: the Program, Marketing and Outreach (PMO) workgroup; the Standards and Network Development (SND) workgroup; and the Content Workgroup (CWG). Within the workgroups, teams are organized to research specific topics and present recommendations to the National Tracking Network forum.
2. The Utah Tracking Program is composed of staff within the EEP. Staff include research scientists, health educators, and information technologists. The Utah Tracking Program is responsible for participating within the National Tracking Network, implementing and maintaining the Utah Tracking Network, recruiting and working with data sharing partners, and providing support to IBIS-PH users. The Utah Tracking Program serves as the custodian for the data maintained in the data warehouse.
3. The Utah Tracking Program recruits and collaborates with other agencies in Utah who collect and register data of interest to the network as data sharing partners. Based on a data sharing agreement between the Utah Tracking Program and the data owner, the data owner provides data to the Utah Tracking Network on a cyclic basis. The Utah Tracking Program provides services to the data and then aggregates the data for incorporation into the data warehouse. Data services include standardization to national data standards, geocoding and georeferencing, some statistical summarization, and connecting with corresponding aggregated

data within the warehouse. Some of the initial data sharing partners include the Utah Cancer Registry, the UDOH Office of Vital Records and Statistics, the UDOH Office of Health Care Statistics, the UDOH Blood Lead Registry, and the UDEQ. Data sharing partners maintain their responsibilities and rights as owners of the data maintained in the Utah Tracking Network data warehouse. Those responsibilities and rights extend to the source, derived, aggregated, and summarized data.

4. The Utah Tracking Program is governed by an executive committee composed of department and division level administrators from the UDOH, UDEQ, and the Utah Department of Technology Services. The role of the executive committee is to ensure that the Utah Tracking Network meets the state architectural, data quality, and system security standards. The executive committee also guarantees executive support for the project.
5. Use of data within the Utah Tracking Network is regulated by the SRB. The SRB includes a representative from each of the data owners with decision making authority. The SRB reviews and approves data suppression rules and Secure IBIS-PH access requests in order to ensure that data use and security standards are met. The SRB acts as an advisory body to the Utah Tracking Program and is the forum to resolve disputes over Utah Tracking Network data operations. The SRB, working within the Tracking Network Advisory Committee (TNAC), also assists the Utah Tracking Program in long-term planning issues and policy development.
6. The TNAC consists of technical experts in environmental epidemiology and information technology recruited from data owners, data users, and other collaborating partners. The TNAC is a technical forum to assist the Utah Tracking Program in identifying and resolving implementation challenges.

E. Data Structure in the Utah Tracking Network Data Warehouse

1. **Source Data:** Data sharing partners provide source data to the Utah Tracking Program as described in the data sharing agreement between the data owners and the Utah Tracking Program. The data sharing agreement outlines the roles and responsibilities of the data owner as the steward for their data and the Utah Tracking Program, as the custodian, acting for the data owner, to service and protect the data. Source data are not available through Secure IBIS-PH.
2. **Derived Data:** The Utah Tracking Program derives additional data from the source data through standardization and data services. Examples of derived data are assignment of standardized diagnostic groupings, assignment of standardized demographic information, linkage to census or other population-based data, and geocoding and georeferencing the data. The Utah Tracking Program may also compute measures of quality for the data. These data may contain identifying information carried over from the source data. Unless otherwise specified by the data owner, derived data may be acquired through Secure IBIS-PH with specific approval from the data owner. The data owner may require the identifying data to be removed or masked when released to third-party researchers or public health professionals.

3. Aggregated or Summarized Data: The Utah Tracking Program further aggregates or summarizes the data using SRB approved schema and computes additional summary statistics for the data. The aggregated or summarized data are de-identified. These are the data that are generally available through IBIS-PH. Aggregated or summarized data usually include the following elements:
 - a. Area location unit
 - b. Time location unit
 - c. Demographic unit (for health outcome or biomonitoring data)
 - d. Analyte identity (for environmental monitoring data)
 - e. Diagnostic unit (for health outcome or biomonitoring data)
 - f. Measure unit (for environmental monitoring data)
 - g. Case count (for health outcome or biomonitoring data)
 - h. Concentration (for environmental monitoring data)
 Other data that may be included with the aggregated or summarized data include:
 - i. Standardized population count
 - j. Census-based socio-economic indicators
 - k. Rate statistics (incidence/prevalence, 95% confidence)
 - l. Summary statistics (count, range, standard deviation)
 - m. Geographic assignment success score
4. Connecting Corresponding Data: The Utah Tracking Program connects data from different sources by geographic location unit (i.e., 2000 census block group) and time unit (i.e. year). Individuals with records in two or more health outcome registries will NOT be linked without specific SRB approval.

F. Standards-based Data Security

1. State confidentiality and protected public health information definitions and security requirements for data collected and maintained by the UDOH, including all subordinate agencies and activities, are promulgated in the Utah Health Code (Title 26) and UDOH rules.
2. The following laws specifically apply to the protection of confidential health data:
 - a. 26-3-7: Disclosure of health data – limitations.
<http://www.le.utah.gov/UtahCode/getCodeSection?code=26-3-7>
 - b. 26-3-10: Department measures to protect security of health data.
<http://www.le.utah.gov/UtahCode/getCodeSection?code=26-3-10>
 - c. As per 26-23-6, any entity that violates any provisions of these laws is guilty of a class B misdemeanor for the first violation, and for any subsequent similar violation within two years, is guilty of a class A misdemeanor. This entity may be assessed a penalty not to exceed \$10,000 per violation.
<http://www.le.utah.gov/UtahCode/getCodeSection?code=26-23-6>
3. The following rules apply to the protection of confidential health data under specific circumstances:
 - a. R380-25: Submission of data through an electronic data exchange.
<http://www.rules.utah.gov/publicat/code/r380/r380-025.htm>

- b. R380-250: HIPAA privacy rule implementation.
<http://www.rules.utah.gov/publicat/code/r380/r380-250.htm>
 - c. As per FR Doc 06-1376 (except as provided in subsection (b)), any person who violates a provision of HIPAA shall be assessed a penalty of not more than \$100 for each violation, except that the total for all violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000.
<http://www.hhs.gov/ocr/privacy/hipaa/administrative/enforcementrule/enforcementfinalrule.html>
4. In addition, rules allowing the collection of data by UDOH programs and agencies and UDEQ programs and agencies have additional data security provisions that apply to data contained within the Utah Tracking Network.
5. National standards for public health data security are implemented by the Public Health Information Network (PHIN; see <http://www.cdc.gov/phinf/> for more information). The PHIN is CDC's forum for public health information system standards. The physical and programmatic architecture of the Utah Tracking Network complies with PHIN standards.
6. The Utah Tracking Program receives data that contain identifiable and confidential or protected information from some data owners. This information is used by the Utah Tracking Program to assist in the services (particularly geocoding and georeferencing) provided to the data. Typically health outcome or biomonitoring data are aggregated by the Utah Tracking Program in terms of demographics (age/sex groupings), location (area-based scales such as county, zip code, or census areas), time (year or multi-year periods), and diagnostic groups. The Utah Tracking Program works with the SRB to determine appropriate aggregation schema for health data. All information that may increase the risk of identifying persons or patients is stripped from the data before implementation. Aggregated case counts not meeting a standard minimum (typically 5 or more) by the SRB for that data set are masked. The Utah Tracking Program will not connect case information from one data sharing partner to case information from another data sharing partner without review and approval from the SRB. This will ensure that the connection does not result in disclosure of confidential information. The Utah Tracking Program may connect population based (i.e., population counts, area socio-economic status indicators, etc.), exposure based (i.e., proximity indicators), or summary based (i.e., rates, counts, etc.) data to aggregated health outcome tables.
7. The Utah Tracking Network shares architectural resources with the Utah National Electronic Disease Surveillance System (NEDSS) and has adopted NEDSS standards and policies for
 - a. Acceptable use
 - b. Data disaster and recovery
 - c. Data encryption
 - d. HIPAA security implementation
 - e. Information sensitivity

- f. Intrusion response
 - g. Password
 - h. Perimeter security
 - i. Physical security
 - j. Security compliance
 - k. User authentication and administration
8. The Utah Tracking Network supports several levels of access. The least restrictive levels of access provide data aggregated at higher levels of granularity. More restrictive levels provide access to data at finer granularity. The levels of access are
- a. Public (through IBIS-PH)
 - b. Public Health (through Secure IBIS-PH)
 - c. Researcher (through Secure IBIS-PH)
 - d. National (through the National Tracking Network)

Generally, publicly available data are aggregated to the county level for broad diagnostic groupings. Publicly accessible data may or may not provide age/sex stratification depending on the level of security required by the data owner. Public health professionals and researchers may apply for Secure IBIS-PH access to query data. Source data may not be accessed through Secure IBIS-PH. Secure IBIS-PH data are aggregated to support analysis at a finer resolution than the data available through IBIS-PH. The system will present only the analytical results (generally standardized rates or rate ratios). The Utah Tracking Program will exchange data with the National Tracking Network in bulk through the NEIEN node. Those data may be used for regional and national environmental health studies. The aggregation schema for those data will be developed through collaboration with the CWG and implemented after review and approval by the SRB. SRB approved researchers and public health professionals can access and retrieve subsets of data aggregated at finer resolution than provided through the National Tracking Network or IBIS-PH. Since those data are considered potentially identifying by the SRB, the public health professionals and researchers who access secure data through Secure IBIS-PH or in any other way must meet requirements set by the SRB.

II. Application for Access to Secure IBIS-PH: Research Projects

A. The Application Structure to access Utah Tracking Network data through Secure IBIS-PH or in any other way for research projects consists of the components that follow.

While each researcher involved in the project must submit a Data-use Agreement Form, only one complete application is required per research project. This application must be submitted both electronically (PDF) and on paper (with signatures).

1. Instructions for Obtaining Secure IBIS-PH Access: Research Projects (Appendix 1).
2. Research Proposal Cover Sheet. The researcher should attach a sheet providing the name of the project, the sponsoring organization, and contact information.

3. Secure IBIS-PH Access Request: Research Projects (Appendix 2). Researchers may request access to the specific query modules (for specific time periods, geographic regions, and data topics) applicable to their research projects.
 - a. *Use of Secure IBIS-PH data for surveillance and other routine public health activities requires submission of a separate application and research proposal for review and approval by the SRB. That Application can be found in the document Third Party Application to Secure IBIS-PH for Public Health Professionals.*
4. Research Proposal. This is a narrative of the proposed research project for which Secure IBIS-PH Access is requested. The Research Proposal Guidelines (Appendix 3) can be used to guide preparation of this document. If the proposed study requires Institutional Review Board (IRB) approval, the documentation submitted to the IRB must be submitted with the Research Proposal. The documentation submitted to the IRB may be used in place of or in conjunction with the research proposal, so long as all the points in the Research Proposal Guidelines are addressed.
5. The Data-use Agreement Form: Research Projects (Appendix 4). This is essentially the binding contract between the researcher and the data owner(s) to comply with SRB data security protocol and other requirements. All research project personnel (whether they need to directly log into Secure IBIS-PH, otherwise directly handle secure data, or they will perform an administrative function or be involved in discussions related to the data) must complete and submit a separate signed Data-use Agreement Form.
6. IRB Approval: The researcher should submit a copy of the IRB approval letter with the application if it has already been received. Otherwise, the letter should be submitted once it has been received.
 - a. As explained above (II-A-4), the documentation submitted to the IRB must be submitted with the Research Proposal.
 - b. All research that will involve human subjects requires review by an IRB, as per Title 45 Code of Federal Regulations Part 46.
(<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>)
Research that will involve human subjects must receive IRB approval before commencing research. IRB approval must be obtained from all institutions participating in the research in any way. The participatory functions of institutions may include sponsoring, collaborating, playing an advisory role, providing data and other resources, or any other involvement not listed here. *The SRB does not serve as an IRB. Applications requiring an IRB must apply for IRB approval separately.*
 - c. *The SRB does not serve as an IRB. Applications requiring an IRB must apply for IRB approval separately. While these applications may be submitted concurrently, the SRB will not grant data access until they have received proof of IRB approval.*
7. Letters of Support: Letters from research collaborators or other interested parties are optional but may strengthen an application.

B. Application Review Procedures

1. Researchers requesting access to data contained in Secure-IBIS PH for research projects should submit a completed application to the Utah Tracking Program manager. The Utah Tracking Program will forward copies of the application to the SRB for review. The SRB may approve or deny access, may determine additional conditions for access, and/or may meet to discuss the application before approving access. The Utah Tracking Program will represent the researcher at the next SRB meeting unless the SRB members request that the researcher attend. In all matters, the data owner(s) whose data will be accessed, through Secure IBIS-PH or in any other way, will have the final say in approving or denying access.
 - a. The Utah Tracking Program, on behalf of the SRB, will keep a written record of the standards used by the SRB to grant or deny data access. Additionally, the Utah Tracking Program will keep written minutes of all meetings and discussions regarding the application.
 - b. The Utah Tracking Program anticipates that the criteria for approving or denying data access will develop as a living document the SRB gains experience with processing data applications.
2. Whatever the decision, the researchers will be contacted within two weeks of submitting an application.
3. The SRB will direct any questions, concerns or requests for clarification about the research proposal to the Utah Tracking Program manager who will then provide those comments to the researcher. The researchers can respond to those issues by modifying and resubmitting the research proposal or by submitting a memorandum of response for reconsideration by the SRB.
4. The SRB members, and particularly the data owner(s) whose query module(s) will be accessed, will review and recommend approval or denial of Secure IBIS-PH access for the research project and/or will identify additional information needed from the researcher to facilitate review of the proposed project. Approval must be obtained from each data owner whose query module(s) will be accessed.
5. The SRB does not serve as an IRB. Applications requiring an IRB must submit for IRB approval separately. The applications can be submitted concurrently, but the SRB will not grant data access until they have received proof that the IRB has approved the research project. The SRB may conditionally approve access to Secure IBIS-PH pending IRB approval. The SRB ensures that the research proposal meets all of the data owner(s)'s requirements.
6. Upon SRB approval, the Utah Tracking Program will register an account for the researcher to access Secure IBIS-PH. The Utah Tracking Program will provide the researcher a memorandum of instruction which may include details about accessing appropriate query modules in Secure IBIS-PH, data security requirements, and the process the SRB will use to monitor Secure IBIS-PH access and data use.

7. The UDOH and associated programs, including the Utah Tracking Program and the SRB, do not guarantee the accuracy of the data they provide through Secure IBIS-PH or in any other way.
8. The UDOH and associated programs, including the Utah Tracking Program and the SRB, do not guarantee that Secure IBIS-PH and other forms of data access will be functional. The Utah Tracking Program, the SRB, and the UDOH members are not liable for problems accessing or processing data or failures by public health professionals to meet deadlines because of problems with data or access.
9. The Utah Tracking Program will be available by phone and email during regular business hours to assist the researcher with problems accessing Secure IBIS-PH.
10. The Utah Tracking Program tracks and logs Secure IBIS-PH access and activity. The SRB can review those logs.
11. The Utah Tracking Program will deactivate the researcher's accounts once the researcher has retrieved the needed data.

III. Monitoring Data Access and Use

- A. General.** All researchers must agree to SRB review of their access and interpretation of Secure IBIS-PH data. The Utah Tracking Program will give approved researchers a memorandum of instruction that details the review process.
- B. The SRB** will review the researcher's access to and use of Secure IBIS-PH data to ensure:
 1. Maintenance of data security and protection of confidential information.
 2. Appropriate acknowledgement of the data owner agency.
 3. Status of findings that relate to or impact the data owners' public health objectives.
- C. Periodic Status Reports.** At the request of the data owner(s) and/or SRB, the Utah Tracking Program will coordinate with the researcher to review their Secure IBIS-PH access and use. Reviews may include information about new research team members, changes in team members' responsibilities and need to access the data, changes in the research protocol or timeline, preliminary findings, and updates in regard to publishing findings. The researcher should respond and provide requested information to the Utah Tracking Program manager within 10 days.
- D. Public Presentations.** The researcher will provide copies of all intended public presentations or publications that incorporate any form of Utah Tracking Network data for SRB review and approval. This requirement ensures both the synchronization of data owner agency objectives with findings that use their data, as well as the appropriate acknowledgement of the data owner and the Utah Tracking Network. The researcher will submit those documents to the Utah Tracking Program manager at least 30 days before the anticipated public release. Public release includes submission for publication (even though the actual publication may not result immediately after submission). The researcher agrees to satisfy any SRB concerns regarding intended public presentation of findings before the presentation can occur. The Utah Tracking Program will provide the researcher a memorandum of approval for public presentation after the SRB has approved the presentation.

IV. Third Party Consent Policies

- A.** This section addresses the responsibilities of researchers regarding data obtained from Secure IBIS-PH or otherwise obtained from the Utah Tracking Network. The researcher agrees to comply with these policies through the Data-use Agreement Form: Research Projects (Appendix 4).
- B.** Data is defined to include the original tabulated data obtained from the Secure IBIS-PH, as well as all manipulations, tabulations, aggregations, and summarizations that the researcher generates and that are derived from Utah Tracking Network data obtained through Secure IBIS-PH or in any other way.
- C.** Public presentations are defined as any published paper, abstract, brief, report, letter, poster, speech, article, or other presentation that discloses data, information about the data, the data owner, or the Utah Tracking Network that is made available to the public (including organizational peers) through peer-reviewed or un-reviewed journals, magazines, newsletters, professional or public conferences, public or organizational meetings, or other forums or events to which persons not associated with the research project (i.e., any individual who has not submitted a Data-use Agreement Form and received SRB approval) could be in attendance or have access.
- D.** The researcher agrees to comply with applicable federal, state, department and program statutes, rules, policies, use restrictions and requirements regarding security, management, use, and disclosure of data obtained from the Utah Tracking Network through Secure IBIS-PH or in any other way.
- E.** The researcher will provide the SRB with draft and final copies of public presentation materials for approval at least 30 days before the public presentation or submission for publication (even if submission will not immediately result in publication).
- F.** Data obtained from the Utah Tracking Network, through Secure IBIS-PH or in any other way, will only be used as outlined in the Secure IBIS-PH Access Request (Appendix 2). The data will not be used for research objectives not disclosed to or approved by the SRB. The researcher will disclose all intended data uses and research objectives to the SRB through either the initial study proposal or by written amendments to the study proposal as described previously.
- G.** The researcher will not provide, distribute, disclose, or otherwise share Utah Tracking Network data, obtained from Secure IBIS-PH or in any other way, to or with other persons, researchers, research projects unless approved by the SRB.
- H.** Computer systems to which the data is loaded for use and storage will be maintained in a secure environment with controlled access. The computer system will use, as a minimum, a password access protocol. Computer systems will not be removed from the secure controlled environment while containing stores of the data (i.e., computer systems will not be taken home, etc.).
- I.** Electronic (i.e., flash drives, portable hard drives, CD-ROMs), paper (i.e., print-outs), or other forms of the data not stored on a computer system storage device (i.e., a hard drive), will be stored in a locked storage container (i.e., a locked filing cabinet or drawer).
- J.** The researcher agrees to restrict access to researchers who have submitted a Data-use Agreement Form (Appendix 4) to the SRB and whose access to the query modules on Secure IBIS-PH or to otherwise handle secure data has been approved by the SRB. New

researchers joining the project must complete the agreement and be given approval from the data owner(s) before being given access to Utah Tracking Network data through Secure IBIS-PH or in any other way.

- K.** The researcher agrees to comply with additional restrictions, requirements, and stipulations described by the SRB and any IRBs of universities, colleges, hospitals, or other institutions connected with the research project.
 - L.** The researcher agrees to be monitored by the SRB through the Utah Tracking Program, to provide progress and status reports as requested, and to meet other review process requirements as requested by the SRB.
 - M.** The researcher will acknowledge the Utah Tracking Network and the data owner(s) in all public presentation of Utah Tracking Network data and the findings derived from this data.
 - N.** The research project personnel have an affirmative obligation to notify the Utah Tracking Program within 24 hours of any change in employment, personnel or of associated research personnel (specifically, as listed in the form Secure IBIS-PH Access Request: Research Projects [Appendix 2]). Upon notification, the Utah Tracking Program will terminate all data rights for those individuals no longer involved in the tasks for which data access was granted.
 - 1. The Utah Tracking Program will terminate Secure IBIS-PH access for all research personnel whose responsibilities no longer warrant data access. Under the supervision of the Utah Tracking Program, those research project personnel whose access is terminated agree to erase or return all forms of data and data storage under the supervision of the Utah Tracking Program. Approval of any impending publications or presentations will be at the discretion of the SRB.
 - O.** At the discretion of the SRB, the Utah Tracking Program has the right to terminate the research project personnel's access to Utah Tracking Network data, through Secure IBIS-PH or in any other way, with or without cause. Any breach by the research project personnel, or any associated individuals or organizations, warrants termination of access.
 - 1. Upon access termination, the Utah Tracking Program will oversee the erasure of all documents, databases, and all other electronic storage units containing any form of Utah Tracking Network data. Any other data or storage devices will be returned by the Utah Tracking Program. Approval of any impending publications or presentations will be at the discretion of the SRB.
- V. Accessing Secure Data**
- Upon approval of the application, data will be made available in one of the following ways:
- A.** The Utah Tracking Program will create an account for the researcher on Secure IBIS-PH and will notify the researcher of the account. Separate instructions on how to navigate through Secure IBIS-PH will be provided in a memorandum of instruction.
 - B.** Access to data query modules will generally be through Secure IBIS-PH. All decisions on permitting other means to access data (CD, DVD, secure FTP account, etc.) will be at the discretion of the data owner(s). The data owner(s) may also impose additional restrictions to access certain data (e.g., allowing review of data only under direct supervision of the data owner(s)).

Appendix 1: Instructions for Obtaining Secure IBIS-PH Access: Research Projects

Instructions for Obtaining Secure IBIS-PH Access: Research Projects

The Utah Environmental Public Health Tracking Program (Utah Tracking Program) is an activity within the Utah Department of Health that makes data available from health outcome registries, biomonitoring registries, environmental monitoring information systems, and environmental hazards databases in a data warehouse. The Utah Tracking Program serves as a custodian of the data which is owned by several agencies and programs. The data owners retain the role of data owners/stewards for data stored within the Utah Environmental Public Health Tracking Network (Utah Tracking Network) data warehouse.

Research projects using data in Utah's Secure Indicator Based Information System for Public Health (Secure IBIS-PH) require the approval of a research proposal from the data owner(s) through the Utah Tracking Program's Scientific Review Board (SRB). The instructions below pertain to specific research projects. (Please see separate instructions contained in the *Third Party Application for Access to Secure IBIS-PH for Public Health Professionals* for more information about obtaining surveillance and work-related access to Secure IBIS-PH.)

All research that will involve human subjects requires review by an Institutional Review Board (IRB), as per Title 45 Code of Federal Regulations Part 46 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>). If your research will involve human subjects, you must receive IRB approval before commencing research. IRB approval must be obtained from all institutions participating in your research in any way. The participatory functions of institutions may include sponsoring, collaborating, playing an advisory role, providing data and other resources, or any other involvement not listed here.

Applications for research projects that require an IRB must submit for IRB approval separately. The applications may be submitted concurrently, but data will not be released until proof of IRB approval has been received. The SRB does not substitute for an IRB.

To apply for SRB approval to access and use Utah Tracking Network data, through Secure IBIS-PH or any other means, please complete the items that follow. While each researcher involved in the project must submit a Data-use Agreement Form, only one complete application is required per research project.

- 1. Research Proposal Cover Sheet.** Attach a cover sheet that provides the title of your project, the organization sponsoring the research project, and the primary contact information for your project.
- 2. Secure IBIS-PH Access Request.** Completely fill out the Secure IBIS-PH Access Request, including which data query modules or datasets you need to access. Provide the specific details (data topic, geographic area, time period, etc.) you will need to study.
- 3. Data-use Agreement Form.** Review the Secure IBIS-PH Access Agreement form and submit signed and dated copies for all research project personnel as Attachment A to the Research Proposal Cover Sheet. All research project personnel (whether they need to directly log into Secure IBIS-PH, otherwise directly handle secure data, or they will perform an administrative function or be involved in discussions related to the data) must complete and submit a separate signed Data-use Agreement Form.

Appendix 1: Instructions for Obtaining Secure IBIS-PH Access: Research Projects

- 4. Research Proposal.** Use the Research Proposal Guidelines to create a Research Proposal. The Research Proposal should be submitted as Attachment B to the Research Proposal Cover Sheet. If the proposed study requires IRB approval, the documentation submitted to the IRB must be submitted with the Research Proposal. The documentation submitted to the IRB may be used in place of or in conjunction with the research proposal, so long as all the points in the Research Proposal Guidelines are addressed.
- 5. IRB Approval.** If the research proposal requires IRB approval, a copy of the approval letter should be attached as Attachment C to the Research Proposal Cover Sheet. If the IRB has not yet approved the proposal, the approval letter should be submitted to the Utah Tracking Program once it is received. Data will not be released until IRB approval has been received.
- 6. Letters of Support.** Letters of support, particularly from research collaborators, can strengthen the proposal. Letters of support are optional. If provided, Letters of Support should be attached as Attachment D to the Research Proposal Cover Sheet.

Completed applications with all of the above items attached should be submitted to the Environmental Epidemiology Program at the Utah Department of Health in BOTH of the following formats:

- one original, signed, paper copy.
- one electronic copy as a PDF.

Completed applications should be submitted to:

Environmental Epidemiology Program
ATTN: Utah Tracking Program Scientific Review Board
Utah Department of Health
P.O. Box 142104
Salt Lake City, Utah 84114-2104
Fax: (801) 538-6564

AND

EEP@utah.gov

The Environmental Epidemiology Program will coordinate the SRB review process. The SRB will review complete applications and approve and/or provide feedback on the application within two weeks of submission. After the SRB has approved your request, the Utah Tracking Program will provide specific instructions on accessing the data you requested.

Appendix 2: Secure IBIS-PH Access Request: Research Projects

Secure IBIS-PH Access Request: Research Projects

Name of Principal Investigator/Project Authority: _____

Study Title: _____

Purpose of the Study: _____

Start date: _____ End date: _____

Department: _____

Phone: (____) _____ E-Mail Address: _____

Mailing Address (for research organization): Street _____

City _____ State _____ Zip Code _____

Please indicate which **data topic(s)** that will be studied in this research project. **If you need to access data topics at different geographic areas (e.g., if your research project required you to access mortality data at a state level, but to access birth defect data only for certain local health districts), please attach a detailed explanation of the specific geographic areas needed for each data topic requested.**

- | | | | |
|------------------------|--------------------------|--------------------------------------|--------------------------|
| Cancer Registry | <input type="checkbox"/> | Blood Lead Levels | <input type="checkbox"/> |
| Mortality | <input type="checkbox"/> | Inpatient Hospital Discharges | <input type="checkbox"/> |
| Births | <input type="checkbox"/> | Emergency Department Visits | <input type="checkbox"/> |
| Birth Defects | <input type="checkbox"/> | Air Monitoring Data | <input type="checkbox"/> |
| | | Drinking Water Sample Data | <input type="checkbox"/> |

Please indicate which **geographic area(s)** that will be studied in this research project:

State of Utah

or specific geographic areas(s): _____

Please indicate the **geographic unit(s)** by which you need the data stratified:

Local Health Districts **Counties**

Appendix 2: Secure IBIS-PH Access Request: Research Projects

Zip Codes **Census Tracts**
Census Blocks

Please indicate the **time period** that will be studied in this research project:

Start Year: _____ **End Year:** _____

Please indicate the **time unit(s)** by which you need the data stratified (i.e., by day, by year, by 3 year groups, etc.):

Please indicate the **demographic and diagnostic characteristics or environmental pollutants** that will be studied in this research project (i.e., 0-14 year old children & leukemia, ozone, etc.):

Please indicate the **Unit** by which you need the demographic and diagnostic characteristics or environmental pollutants stratified (i.e., 5-year age/sex strata, 24-hour $\mu\text{g}/\text{m}^3$, etc.):

Research Project Personnel

Please list all research project personnel that will have access to any form of the Secure-IBIS data, or other Utah Tracking Network data, and their role in the use of the data. (Attach additional sheets if necessary.)

All individuals who are involved in the research project in any way (whether they need to directly log into Secure IBIS-PH, otherwise directly handle secure data, perform an administrative function, or be involved in discussions related to the data) must complete a separate Data-use Agreement Form (Appendix 4). These research project personnel are not required to submit a separate application. Only one complete application is required per research project.

Research Project Personnel (Name) Position Title Role in access to Secure-IBIS-PH data

Appendix 2: Secure IBIS-PH Access Request: Research Projects

Signature of Principal Investigator/Project Authority

Date

Attachment A: Data-use Agreement Form (required)

Attachment B: Research Proposal (required)

Attachment C: IRB Approval (must be submitted upon receipt)

Attachment D: Letters of Support (optional)

(This section to be completed by the Data Owner(s) and Utah Tracking Program)

Data Owner Signature and Comments

Query Module

Signature

Access Approved

Access Denied

Need Additional Information

Comments:

Appendix 2: Secure IBIS-PH Access Request: Research Projects

(Each data owner will be provided a separate copy to sign and provide comments.)

Data Owner Signature and Comments		
<hr/>		
Query Module		Signature
Access Approved <input type="checkbox"/>	Access Denied <input type="checkbox"/>	Need Additional Information <input type="checkbox"/>
Comments:		

Data Owner Signature and Comments		
<hr/>		
Query Module		Signature
Access Approved <input type="checkbox"/>	Access Denied <input type="checkbox"/>	Need Additional Information <input type="checkbox"/>
Comments:		

Your application has been reviewed and approved.	
<hr/>	<hr/>
Utah Tracking Program Manager	Date approved

Appendix 3: Research Proposal Guidelines

Research Proposal Guidelines

Note: Documentation used for IRB approval or other application processes involved with this project may be used for some or all of these research proposal requirements, so long as all items in this guideline are addressed. While organization is flexible, it is easier for the Utah Tracking Program to ensure completeness if the documentation follows these guidelines.

1. **PROJECT PERSONNEL AND ADMINISTRATION:** List the name and contact information of the principle investigator, principle collaborators, and all participating personnel. Include a summary of related studies previously conducted by the project personnel. Describe all agencies supporting this project. Synopses or portfolio documents can be used as part of the agency descriptions. Attach Curriculum Vitae (CV) or biographical sketches for the principle investigator, study director, project coordinator/manager, and principle collaborators. Include all participating personnel from any collaborating agencies involved in this study.
2. **EXECUTIVE SUMMARY/ABSTRACT:** Provide a brief (300 words) executive summary of the project. The summary should include a hypothesis statement, data and methods for data connections, analytical methods, anticipated analytical results, and details of any anticipated publications, presentations, or other distributions of the research results and reports.
3. **FUNDING:** Briefly describe how this project is or will be funded.
4. **BACKGROUND:** Briefly describe (500 words) the literature background supporting and guiding this project. Background should describe the population at risk, known and hypothetical exposure pathways, and environmental hazards related to the health outcome to be studied.
5. **OBJECTIVES:** Briefly outline the objectives, problem statement or hypothesis, anticipated outcomes, significance of the results, knowledge gaps this study is intended to fill, and the importance of this study.
6. **STUDY DESIGN, EXPERIMENTAL PLAN AND METHODS:** Describe the study design, experimental plan, and analytical methods to be used to manipulate and link data topics and/or analyze the data for this project in order to achieve the objectives. If appropriate, discuss the environmental hazards, exposure pathway, and health outcomes to be studied in this project. Describe the study population, study area, and study period. Describe selection, inclusion criteria, and exclusion criteria for data records to be used. Describe the criteria for accepting or rejecting the hypothesis. Describe sampling and data connection protocols. Describe anticipated biases or confounding that may impact the study results and how those biases and confounding factors will be accounted for. Describe the statistical methods to be used, how those methods will be interpreted, and the appropriateness of those methods to the hypothesis or study problem. Justify modifications to standard methods. Outline anticipated weaknesses, study constraints, and limitations in the chosen study design, experimental plan, and methodology. Describe proposed remedies or alternative approaches for those weaknesses.
7. **DATA MANAGEMENT AND PROTECTION:** Describe the access, use, protection, and final disposition of data used for this project. Describe employee training related to the access, use, protection, and management of data provided to all personnel involved in this project. Describe policies and procedures that are and will be used to assure non-disclosure of the confidential data. Describe policies and procedures that are and will be used to manage security intrusions. Describe

Appendix 3: Research Proposal Guidelines

policies for electronic storage of data. Describe policies and procedures for paper copies of data, work products and records. Describe study protocol change management and procedures. Describe the institutional oversight and review process used for this research proposal.

8. **UTAH TRACKING PROGRAM PARTICIPATION:** Describe anticipated roles, responsibilities, activities, or requirements for the Utah Tracking Program and/or the data owners (agencies who provide data to the Utah Tracking Network).
9. **TIMELINE:** Describe the proposed timeline for this project.
10. **PROPOSED PUBLICATION OF RESULTS:** Briefly describe the anticipated means for publishing or reporting the findings from this project. Describe the intended audience(s) of the publication. Describe the anticipated time for publication(s). Public presentations are defined as any published paper, abstract, brief, report, letter, poster, speech, article, or other presentation that discloses the data, information about the data, information about the data owner, or information about the Utah Tracking Network that is made available to the public (including organizational peers) through peer-reviewed or un-reviewed journals, magazines, newsletters, professional or public conferences, public or organizational meetings, or other forums or events to which persons not directly associated to the research project (i.e., any individual who has not submitted a Data-use Agreement Form and received SRB approval) could be in attendance or have access.
11. **HUMAN SUBJECTS:** The Utah Tracking Program does NOT provide identifying information on human subjects. Projects that require case identifying information will need to coordinate directly with the data owner for those data. If the project intends to link Utah Tracking Program data with identifiable case data (regardless of the data topic), briefly describe those linkages and the Human Subjects assurances required for IRB approval. Describe the IRB approval process being pursued or completed. Include the IRB chair contact information.
12. **BIBLIOGRAPHY:** The standard bibliography format standards can be used for this section.

Appendix 4: Data-use Agreement Form: Research Projects

Data-use Agreement Form: Research Projects

This agreement must be completed by all research personnel will have access to Utah Tracking Network data in any form and in any phase of the project.

Name: _____ Role: _____

By initialing the following boxes and signing this agreement form, you (the research personnel member named above) agree to comply with the following agreements and assurances supporting application for access to Utah Tracking Network data through Secure IBIS-PH or in any other form (to include manipulations, tabulations, aggregations, summarizations, and verbal communication generated from the data).

Please initial each box.

I have read and shall comply with the Utah Tracking Program's consent policies. (Refer to the *Third Party Application for Access to IBIS-PH for Research Projects* <http://health.utah.gov/enviroepi/activities/EPHTP/NewEPHT/securedata.html>).

I will comply with all data use stipulations provided in writing by the data owner(s) as part of the approval of this application for access to data.

I will provide the SRB with draft and final copies of public presentations (defined as any published paper, abstract, brief, report, letter, poster, speech, article, or other presentation that discloses data or information about the data, the data owner, or the Utah Tracking Network that is made available to the public (including organizational peers) through peer-reviewed or un-reviewed journals, magazines, newsletters, professional or public conferences, public or organizational meetings, or other forums or events to which persons not associated with the research project (i.e., any individual who has not submitted a Data-use Agreement Form and received SRB approval) could be in attendance or have access) as described with the SRB authorization to access the data. The SRB will have opportunity to comment on or approve those reports prior to any publications or presentations.

I will provide the SRB with copies of public presentation materials for approval 30 days before the publication or submission for publication (even if submission will not immediately result in publication).

I will comply with all state and federal laws, as well as department and program statutes, rules, policies, use restrictions, and requirements regarding security, management, use, and disclosure, particularly those that protect the privacy of individuals and research subjects. I understand that violation of any local, state, or federal laws may subject me to criminal or civil prosecution or other penalties.

Appendix 4: Data-use Agreement Form: Research Projects

- I will use Secure IBIS-PH, and any other form of Utah Tracking Network data, only for the research-related purposes stated in the Secure IBIS-PH Access Request and approved by the SRB.
- I will make no use of the data for work-related or research objectives, analyses or other uses not described in the approved Research Proposal without prior written authorization from the SRB. I understand that I may request an amendment to the SRB application, if needed. I will not make any changes to the research project without written authorization from the SRB.
- I will not provide, distribute, disclose, or otherwise share Utah Tracking Network data, obtained from Secure IBIS-PH data obtained from Secure IBIS-PH or in any other way, to or with other persons, researchers, or research projects unless approved by the SRB.
- I will follow the procedures and methods described in the Secure IBIS-PH Access Request and in any modifications made by the SRB.
- I will assure the integrity, confidentiality and the security of all Utah Tracking Network data in all forms. (See the online Policies and Procedure Manual for standards of data protection.)
- I will comply with any and all restrictions, requirements, and stipulations described by the SRB and any institutional review boards (IRBs) of universities, colleges, hospitals, or other institutions connected with the research project.
- I agree to be monitored by the SRB through the Utah Tracking Program, to provide progress and status reports as requested, and to meet other review process requirements as requested by the SRB.
- I will acknowledge the data owner(s) and the Utah Tracking Network in all public presentations (defined above) of Utah Tracking Network data and the findings derived from the data.
- I understand that I have an affirmative obligation to notify the Utah Tracking Program within 24 hours of any change in employment for either myself or any associated research personnel so that data rights may be adjusted accordingly.
- I understand that the Utah Tracking Program, the SRB, and the Utah Department of Health (UDOH) do not guarantee the accuracy of the data they provide through Secure IBIS-PH or in any other way.
- I understand that the Utah Tracking Program, the SRB, and the UDOH do not guarantee that Secure IBIS-PH and other forms of data access will be functional. The Utah Tracking Program, the SRB, and the UDOH members are not liable for problems accessing or processing data or for failures by research project personnel to meet deadlines because of problems with data or access.

Appendix 4: Data-use Agreement Form: Research Projects

I understand that the failure to abide by any of these agreements, by myself or any associated individuals or organizations, will result in an immediate termination of data access, as well as a denial of rights to data publication or presentation. Upon termination of access, I agree to erase all documents, databases, and all other electronic storage units containing any form of the data. I will return any other data or storage devices to the Utah Tracking Program. I understand that the SRB will have the discretion to approve or deny any impending publications or presentations involving Utah Tracking Network data.

Signature of Research Personnel Member

Date: _____

Project's Principal Investigator (or University Faculty Sponsor)
(PLEASE PRINT)

Signature of Project's Principal Investigator
(or University Faculty Sponsor)

Date: _____