

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.

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- 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**

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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:

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(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*).

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: _____