



International Tobacco Control Data Repository Usage Guidelines

December 2006 (Updated Feb. 2009)

1. The International Tobacco Control Data Repository

Data from all ITC Projects are stored at the International Tobacco Control Data Repository (ITCDR) at the University of Waterloo. Access to the confidential data at ITCDR is given to all ITC Principal Investigators and their research team members indicated on the ITCDR Internal Data Usage Agreement. Country-specific data are available to the host country's designated Research Team through the host country Principal Investigator. In order for research teams outside the ITC to gain access to any of the data, the successful completion and approval of an ITCDR Data Usage Application is required. ***Both ITC Principal Investigators, and research teams outside of ITC who have received approval to use the data, are required to sign an ITCDR Data Usage Agreement.*** The criteria for data usage approval and the contents of the Data Usage Agreement are described in this document.

Accessing data in the ITCDR will greatly increase the ability of investigators to make cross-national comparisons of tobacco use, cessation and prevention programs as they develop over time. To ensure this privilege will be available to scientific researchers, there are rules & regulations that each researcher must follow. This guide is designed to outline the responsibilities of data users, as well as the responsibilities of the ITCDR.

1.1. Confidentiality of ITCDR data

The ITC Project has taken great care to protect the identity of its participants and to safeguard the privacy and confidentiality of the information that these participants provide. Any secondary analyses to be performed using these data sets must also maintain the confidential nature of this data.

1.2. Legal requirement to maintain confidentiality of data

Confidential data are safeguarded by the application of various levels of both physical & electronic security measures. Data are stripped of identifiers that could permit a direct relation to be established between data holdings and specific respondents. Identifiers such as name, specific geographic location, etc. are suppressed. Researchers will receive only subsets of the data, consisting of the groups and variables required for their particular analyses.

All researchers must sign a data usage agreement with ITCDR in order to access confidential data. As part of this process the researcher agrees not to disclose or knowingly cause to be disclosed any information that relates the particulars obtained from any individual return to any

identifiable individual person, family or organization. Material to be presented or published must be examined carefully to make sure it does not disclose such information.

2. Data Requests from ITC Principal Investigators

2.1 Internal Data Usage Agreement

ITC Principal Investigators should complete an Internal Data Usage Agreement for each data set (i.e. individual countries or country groups) that they would like to receive. This document is to be forwarded to the ITC Data Management Core (DMC). Signing this agreement means that the individual and their team agree to:

- Abide by the ITCDR conditions, including those concerning confidentiality and security;
- Submit a copy of their institution's ethics certification for proposed projects using this data set to the ITC/Roswell Park TTURC Data Management Core.
- Submit copies of all publications, reports, abstracts, etc. that use data from the ITCDR, as well as the syntax or code use in the analysis, to the ITC Project/Roswell Park TTURC Data Management Core and country-specific ITC investigators
- Abide by the conditions of each country-specific Data Sharing Agreement, including the acknowledgement of the funders listed on the Data Sharing Agreement, in all publications, reports, abstracts, etc.

2.2. Updating Agreements

The Internal Data Usage Agreement(s) need to be updated whenever a new researcher or student joins the institution's ITC team, in order to ensure the DMC has a signed agreement for each researcher that has access to the data.

3. Data Requests from researchers other than the Country-Specific Research Team and ITC Principal Investigators

3.1. Project proposal

To be granted access to data housed in the ITCDR, researchers are required to submit a project proposal to the ITC Project Data Management Core. The approval of proposals will be based on the merit of the research project and security provisions in place at the researcher's institution to protect the confidentiality of data. Specific criteria appear in Article 2.3. The results of the review will generally be communicated to the successful applicant as soon as is feasible, normally within two weeks of the date of application.

It is important to note that the successful applicant will have access only to the data specified in the approved research project and only for the purpose of completing that project. A proposal must be submitted for any research project using ITCDR data. A separate proposal is required if the research aims to answer a different question using the same or different data.

Proposals for student research must be submitted by the student's academic supervisor. The supervisor will be the point of contact for all communication with the ITCDR and any affiliated individuals.

Proposals should follow the format outlined in the Data Request Application, including the "Variables Requested" Excel spreadsheet. The Proposal Summary is expected to include the following items:

1. A statement of objectives, including a statement of the research question(s) and an indication of how the proposed research will advance understanding in the area of tobacco control;
2. A statement of the proposed statistical/research methodology, including software requirements;
3. A description of how disclosure of data on individuals will be avoided in the publication of the results;
4. Names of funding sources;
5. Disclosure of any connections to the tobacco industry;
6. A statement of security provisions for the computer in which the data subset will reside;
7. Two professional references to be contacted regarding the application.

3.2. Submission & review

Applications for proposed research projects should be sent by email as indicated on the submission form. In the future, the ITC plans to accept applications by electronic submission using a form directly on the ITCDR web site, from which the application will automatically be sent to the ITCDR and a receipt of the submission issued upon reception of the application. The ITC will notify applicants in advance when this application procedure is to take place. The web site is found at <http://www.itcproject.org>.

The formal review process will be co-ordinated by the ITC Project Data Management Core at the University of Waterloo. Each application will be evaluated for its scientific merit by a review committee, with statistical and subject-matter expertise. The application and the recommendation of the reviewers will be conveyed to the TTURC management group, who will make a decision to accept or reject the proposal. The review committee shall include at least one member from the country from which the data is being requested.

Should an application be rejected, the rationale for the decision will be included in a short report, which will be sent to the applicant. A rejected application may be revised and resubmitted. To avoid any real, potential, or perceived conflict of interest between researchers using ITC data and tobacco-related entities, no ITCDR data will be provided directly or indirectly to any researcher, institution or consultant that is in current receipt of any grant monies or in-kind contribution from any tobacco manufacturer, distributor, or other tobacco-related entity.

3.3. Criteria for evaluation

Those applications that have been reviewed, and certified for the absence of connections to the tobacco industry, will then be evaluated according to the following criteria:

- Clarity of objectives and statement of the research question(s);
- The extent to which the proposed research will advance understanding in the area of tobacco control;
- The extent to which the proposed questions are new, without undue overlap with those already being addressed in ongoing research;
- The suitability of the proposed statistical/research methodology, including software requirements;
- The resources and capacity of the research team to accomplish the goals.
- The ability to submit the research proposal for ethical clearance to an FWA registered Internal Review Board (see http://www.hhs.gov/ohrp/assurances/assurances_index.html)
- Successful reference checks.

The proposed project will also be reviewed to ensure that issues of confidentiality and disclosure avoidance have been addressed.

3.4. External Data Usage Agreement

All individuals who are approved to access any ITC data must sign a Data Usage Agreement. This is true for ITC Project team members, country-specific team members, and external research team members requesting access to the data.

Research teams outside of ITC will sign an External Data Usage Agreement means that the individual agrees to:

- Only use the data for the proposed project described in the Data Request Application, unless additional written permission from the supplier of the data is obtained;
- Abide by the ITCDR conditions, including those concerning confidentiality and security;
- Submit a copy of the ethics certification for the proposed project from an FWA registered IRB (see http://www.hhs.gov/ohrp/assurances/assurances_index.html)
- Provide brief progress reports on research when requested by the ITC Project/Roswell Park TTURC Data Management Core.
- Submit copies of all publications, reports, abstracts, etc. that use data from the ITCDR, as well as the syntax or code use in the analysis, to the ITC Project/Roswell Park TTURC Data Management Core and country-specific ITC investigators;
- Acknowledge the owners of the data from the ITC Project in all publications, reports, abstracts, etc. resulting from the analysis.

Once the External Data Usage Agreement has been signed, the researcher(s) will be sent only the specific requested data. The data will be sent in the researcher's preferred statistical package format, as indicated by the applicant in the Data Request Application.

3.5. Data security

As per Article 2.1 #6, the researcher is required to provide, within the proposal, a statement of the data security provisions for the computer on which the requested data subset will reside.

ITCDR data sets must be stored in a password-protected location on the computer.

Other researchers must not be given access to data sets without permission from the ITCDR.

No data analyses may be carried out for colleagues or other researchers who do not have approved research projects.

3.6. Ethics clearance

As indicated in Article 2.3, ethics clearance must be obtained from an FWA registered IRB for the proposed secondary data analysis. This is to ensure institutional review of the conditions under which access to the data are granted. In the application for ethics clearance, reference may be made to the package of documents pertaining to ethics clearance of the primary data collection, available at <http://www.itcproject.org>.

3.7. Obtaining new data and/or carrying out a different research project

It is important to note that the researcher will have access only to the data specified in the approved research project and only for the purpose of completing that project. A proposal must be submitted for any research project using ITCDR data. A separate proposal is required to answer a different question using the same or different data.

To obtain access to different data or to conduct further analyses of the same data, the researcher must provide the ITCDR with:

- A data request form with an accompanying description of the data set;
- A description of how the new data will fit with the original research project, how its use may affect the schedule, and how its use may affect the foreseen output.

3.8. Progress reports

Periodically the ITC Project may ask for brief progress reports on the research.

Please send your request package to:

Data Processing Analyst

ITC Project, Population Health Research Group
Lyle S. Hallman Institute
University of Waterloo
200 University Ave. W.
Waterloo ON N2L 3G1

Email: itcdata@healthy.uwaterloo.ca

Fax: 519-746-8171