

International Tobacco Control Data Management Center Usage Guidelines

1. The International Tobacco Control Data Management Core

Data from all ITC Projects are stored at the International Tobacco Control Data Management Center at the University of Waterloo. Access to specified confidential data is given to all ITC Principal Investigators. Country-specific data are available to the host country's designated research team through the host country Principal Investigator. The research team must complete and send the Internal Data Usage Agreement to the contact PM to ensure DMC has the signed agreement for each researcher that has access to the data. In order for research teams outside the ITC Project to gain access to any of the data, the successful completion and approval of an ITC Data Usage Application is required. *Both ITC Principal Investigators, and research teams outside the ITC Project who have received approval to use the data, are required to sign an ITC Data Usage Agreement.* The criteria for data usage approval and the contents of the Data Usage Agreement are described in this document.

Accessing ITC data 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 and regulations that each researcher must follow. This guide is designed to outline the responsibilities of data users, as well as the responsibilities of the ITC Project Data Management Center.

1.1 Confidentiality of ITC 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 and electronic security measures. Data are stripped of identifiers that could permit a direct relationship 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 sample groups and variables required for their particular analyses.

Every researcher must sign a data usage agreement with the ITC Project 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 (e.g. data from certain countries or country groups) that they would like to receive. This document is to be forwarded to the ITC Data Management Center (DMC). Signing this agreement means that the individual and the individual's team agree to:

- Abide by the ITC Project conditions, including those concerning confidentiality and security;
- Submit a copy of the individual institution's ethics certification for proposed projects using this data set to the Data Management Centers;
- Submit copies of all publications, reports, abstracts, etc. that use data from the ITC Project, as well as the syntax or code use in the analysis, to the ITC Project Data Management Center 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 Updated Agreements

The Internal Data Usage Agreement(s) must 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 ITC, a researcher is required to submit a project proposal to the ITC Project (itc@uwaterloo.ca). 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. 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 proposal and only for the purpose of completing that project. A proposal must be submitted for any research project using ITC 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 DMC and any affiliated individuals.

Proposals should follow the format outlined in the ITC Data Request Application, and include 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. The form can be found on the website (www.itcproject.org/forms).

The formal review process will be coordinated by the ITC Project Management group 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 ITC Management Group, who will make a decision to accept or reject the proposal. The review committee will 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 ITC 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, tobacco distributor, or other tobacco-related entity.

3.3 Criteria for Evaluation

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 <https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>)
- 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. This means that the individual agrees to:

- Use the data only 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 ITC conditions, including those concerning confidentiality and security;
- Where applicable, submit a copy of the ethics certification for the proposed project from an FWA registered IRB (see <https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>)
- Provide brief progress reports on research when requested by the ITC Project Data Management Center;
- Submit copies of all publications, reports, abstracts, etc. that use data from the ITC Project, as well as the syntax or code used in the analysis, to the ITC 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 given access to only the specifically requested data. The data will be supplied 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 3.1 #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.
- ITC 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 ITC.
- No data analyses may be carried out for colleagues or other researchers who do not have approved research projects which are not approved

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3.6 Ethics clearance

For some instances, 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>. Where the researchers institution does not require the researcher to have ethics clearance for secondary analysis of the data, this requirement will be waved.

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 ITC data. A separate proposal is required to answer a different question using the same or different data. If the data were obtained with an unclear objective then the ITC proposal analysis form must be completed once the data analysis objectives have been decided. This form can be found on the ITC project website (www.itcproject.org).

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

ITC Project
University of Waterloo
200 University Ave. W.
Waterloo ON N2L 3G1

Email: itc@uwaterloo.ca
Fax: +1-519-746-8631