ILSI North America

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ILSI North America Implementation of the TOP Guidelines

Introduction and Rationale

The Transparency and Openness Promotion (TOP) Guidelines provide actionable steps for institutions to practice and promote transparent, reproducible, and rigorous research. ILSI North America is a TOP Guidelines signatory. By becoming a signatory, ILSI North America is supporting the principles expressed in the guidelines through their implementation by its funded researchers. Furthermore, ILSI North America strives to adhere to the levels specified below, recognizing that this process will take time and effort to achieve. Beginning July 1, 2018, all new projects moving forward will work to adhere to the TOP Guidelines.

Overview

ILSI North America has set a goal of working towards and ultimately achieving each the TOP Guideline standards at the following levels:

1.	Data Citation Standards	Level 3
2.	Data Transparency	Level 2
3.	Analytic Methods (Code) Transparency	Level 2
4.	Research Materials Transparency	Level 2
5.	Design and Analysis Transparency	Level 2
6.	Preregistration of Studies	Level 2
7.	Preregistration of Analysis Plans	Level 2
8.	Replication	Level 1

The Transparency and Openness Promotion Guidelines

1. Citation Standards

Level 3: Citation standards

In experimental or analytical research collaborations in which the ILSI North America funded researchers are involved, all data, program code and other methods must be appropriately cited, and manuscripts will not be published until the citations conform to this standard. Such materials are recognized as original intellectual contributions and afforded recognition through citation.

A. All data sets and program code used in a publication must be cited in the text and listed in the reference section.
B. References for data sets and program code must include a persistent identifier, such as a Digital Object Identifier (DOI). Persistent identifiers ensure future access to unique

published digital objects, such as a text or data set. Persistent identifiers are assigned to data sets by digital archives, such as institutional repositories and partners in the Data Preservation Alliance for the Social Sciences (Data-PASS).

2, 3, 4. Data, Analytic Methods (Code), and Research Material Transparency

Level 2: Data, Analytic Methods (Code), and Research Materials Transparency

The policy of ILSI North America is to report the findings of the work that we facilitate only if the data, methods used in the analysis, and materials used to conduct the research are clearly and precisely documented and are maximally and openly available to any researcher for purposes of reproducing the results or replicating the procedure. When reusing data available from public repositories, ILSI North America and its funded researchers commit to providing program code, scripts for statistical packages, and other documentation sufficient to allow an informed researcher to reproduce all published results.

When using original data, ILSI North America and its funded researchers commit to:

A. Make the data available at a trusted digital repository (Note: If all data required to reproduce the reported analyses appears in the manuscript text, tables, and figures then it does not also need to be posted to a repository.)
B. Include all variables, treatment conditions, and observations described in the manuscript.
C. Provide a full account of the experimental, analytical, and data-processing procedures used to collect, preprocess, clean, or generate the data.
D. Provide program code, scripts, codebooks, and other documentation sufficient to precisely reproduce all published results.
E. Provide research materials and description of procedures necessary to conduct an independent replication of the research.

In rare cases, despite our best efforts, some or all data or materials cannot be shared for intellectual property, legal or ethical reasons. In such cases, the ILSI North America funded researcher/s will make a publicly available statement of this omission at the time of submission. ILSI North America and its funded researchers will anticipate data and material sharing at the beginning of our projects to provide for these circumstances. It is understood that in some cases access will be provided under restrictions to protect confidential or proprietary information. If prevented from open data sharing by ethical or legal considerations, ILSI North America and its funded researchers will:

A. Explain the restrictions on the dataset or materials and how they preclude public access.
B. Provide a public description of the steps others should follow to request access to the data or materials.

C. Provide software and other documentation that will precisely reproduce all published results.
D. Provide access to all data and materials for which the constraints do not apply.

Data, program code, research materials, and other documentation of the research process will be made available through a trusted digital repository. Trusted repositories adhere to policies that make data discoverable, accessible, usable, and preserved for the long term. Trusted repositories also assign unique and persistent identifiers. Author maintained websites are not compliant with this requirement.

A. Dissemination of these materials may be delayed until publication. Under exceptional circumstances, and only if necessary to comply with ethical standards, the ILSI North America funded researchers may request an embargo of the public release of data for at most one year after publication.
B. ILSI North America commits to ensuring that our outputs continue to meet the above conditions, even after formal publication.

5. Design and Analysis Transparency

Level 2: Design and Analysis Transparency

The policy of ILSI North America is to require our funded researchers to report the findings of their work while following standards for disclosing key aspects of the research design and data analysis. We commit to reviewing the standards available for many research applications from http://www.equator-network.org/ and use those that are relevant for the reported research applications.

When such standards are not already available, ILSI North America and its funded researchers commit to abiding by a modified version of the "21 word solution" as published by Simmons, Nelson, and Simonsohn: "We report how we determined our sample size, all data exclusions (if any), all inclusion/exclusion criteria, whether inclusion/exclusion criteria were established prior to data analysis, all manipulations, and all measures in the study."

6. Preregistration of Studies

Level 2: Preregistration of Studies

ILSI North America encourages our funded researchers to preregister their research in an independent, institutional registry (e.g., http://osf.io/, http://clinicaltrials.gov/, http://socialscienceregistry.org/, http://egap.org/design-registration/, http://ridie.3ieimpact.org/). Preregistration of studies involves registering the study design, variables, and treatment conditions. A link to the preregistration in an

institutional registry will be made available prior to publication or other final dissemination. Where applicable, ILSI North America will request that a journal or other third party verify that preregistration adheres to the specifications for preregistration and then provide certification of the preregistration in the manuscript.

ILSI North America commits to confirming that the study was registered prior to the researcher beginning data collection with links to the time-stamped preregistrations at the institutional registry, and that the preregistration adheres to the disclosure requirements of the institutional registry or those required for the preregistered badge maintained by the Center for Open Science.

7. Preregistration of Studies with Analysis Plans

Level 2: Preregistration of Studies with Analysis Plans

ILSI North America encourages our funded researchers to preregister their research in an independent, institutional registry (e.g., http://osf.io/, https://www.crd.york.ac.uk/prospero/, http://clinicaltrials.gov/, http://socialscienceregistry.org/, http://egap.org/design-registration/, http://ridie.3ieimpact.org/). Preregistration of studies involves registering the study design, variables, and treatment conditions. Including an analysis plan that involves specification of sequence of analyses or the statistical models that will be reported. A link to the preregistration in an institutional registry will be made available prior to publication or other final dissemination. Where applicable, ILSI North America will request that a journal or other third party verify that preregistration adheres to the specifications for preregistration and then provide certification of the preregistration in the manuscript.

1. ILSI North America commits to confirming that the study was registered prior to the researcher beginning data collection with links to the time-stamped preregistrations at the institutional registry, and that the preregistration adheres to the disclosure requirements of the institutional registry or those required for the preregistered badge with analysis plans maintained by the Center for Open Science.
    a. Report all pre-registered analyses in the text, or, if there were changes in the analysis plan following preregistration, those changes must be disclosed with explanation for the changes.
    b. Clearly distinguish in text analyses that were preregistered from those that were not, such as having separate sections in the results for confirmatory and exploratory analyses.

8. Replication

Level 1

ILSI North America will encourage submission of replication studies only in response to specific solicitations for replication proposals.