Guidelines for survey researchers at the Graduate School of Medicine of the University of Tokyo

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This document is intended as a guide to proper conduct by survey researchers affiliated with the Graduate School of Medicine at the University of Tokyo. It has guidelines related to planning survey research, conducting it, and reporting its findings. The increasing sophistication and diversity of research in medicine has been accompanied by rapid growth in the complexity of the process of doing research. Some ethical, procedural, and organizational concerns are common to all survey research studies, and the present Guidelines emphasize some that should be particularly important to scientists who are just beginning their research careers. Nonetheless, please note that survey research studies are multifarious, so not all of the points in these Guidelines will apply to all such studies. These Guidelines are also intended to further improve the quality of the scientific research done at the University of Tokyo, and to ensure the propriety of activities done under the University's auspices.

Section 1. Planning survey research

What researchers should do before they begin their work (including applications for permissions, etc.)

Carefully read the University's Code of Conduct for Scientific Research

First, before beginning your research, you should carefully read the "Code of Conduct for Scientific Research." The Code of Conduct sets forth the basic rules and the fundamental attitudes expected of all researchers who are affiliated with the University of Tokyo. Versions in Japanese and in English can be found via <http://www.u-tokyo.ac.jp/ja/administration/codeofconduct/pdf/leaflet.pdf>.

Research involving humans

Everyone who expects to do research that involves human participants (whether those participants are studied as individuals or as groups, including studies that use clinical records), or research that involves samples (including genetic material) taken from humans (whether the humans are patients or healthy people) must first attend the University of Tokyo's prescribed training in human-research ethics and must obtain a certificate of completion of that training. Before starting their research work, researchers must also understand the various guidelines, etc. on this topic that are available via the Internet, which are introduced during the research-ethics training. Depending on the

nature of the research, the researcher may need to first submit to the Research Liaison Officer (*kenkyuu-kyouryoku-gakari*) the appropriate application for an examination of the proposed research from the standpoint of ethics, or for a research-ethics examination specific to studies involving human genetics. The Faculty's committee on research ethics must also give its approval before the research can start. Further information about the research-ethics training and about submission of the appropriate applications can be found at the website of the Research Ethics Committee and the Human Genome, Gene Analysis Research Ethics Committee. Information in Japanese can be found at
<http://www.m.u-tokyo.ac.jp/research/rinri.html>
and at
<http://www.m.u-tokyo.ac.jp/ethics/ethcom/index.html>.
Some information in English can be found at
<http://www.m.u-tokyo.ac.jp/english/research/rinri.html>.

All research involving humans must strictly adhere to the applicable guidelines from the Japanese government, which may include ethics guidelines for epidemiological research, ethics guidelines for clinical research, and ethics guidelines for research in genetics. These guidelines are currently under discussion and will be revised in near future. For research involving biomarkers, determining which guidelines should be followed depends on knowing whether the study involves genetic information or not, but in either case examination by the Research Ethics Committee is required, as are the informed consent of all participants and careful planning for appropriate management of information. Even if you use only pre-existing data, there are still rules that must be followed: for example, you still must protect confidentiality, etc. Some research may be exempt from the requirement for examination by the Research Ethics Committee. Such studies can include those using no information about individuals (for example, studies that use only data at the level of a town or city) or those using only information that is already publicly available (for example, studies of trends in the size of the workforce). Research using only data that are completely anonymous and that can no longer be linked to individuals is also regarded in ethics guidelines for epidemiological research and ethics guidelines for clinical research as exempt from the examination requirements. Nonetheless, before starting any research you must examine your study in the context of all appropriate guidelines on research ethics, and also in the light of your own sense of ethics. Graduate students should discuss these issues in detail with their advisors.

In the aforementioned ethics guidelines for epidemiological research and ethics guidelines for clinical research one can find statements that seem to define conditions under which research plans need not be examined and approved by a research ethics committee before the research begins. (For example, they refer to studies that a person previously designated by the ethics committee approved as research involving only statistical analyses of data from records of patients treated at the medical facility with which the researcher is affiliated, etc.) However, researchers should remember that they

must not make such decisions themselves.

For research that involves human participants and interventions, you will be required to use appropriate methods when you recruit the participants and when you seek their consent to participate. You will also be required to obtain approval from the Research Ethics Committee before you start. After that approval has been given, you may begin explaining the study to potential participants and seeking their consent to participate. Invasive interventional studies done at the University of Tokyo Hospital: Before an invasive interventional study is done at the University of Tokyo Hospital, the Hospital's institutional review board (IRB) must be informed of the study's details, and permission to do the study must be obtained from the IRB. The IRB is part of the Hospital's Clinical Research Support Center < http://www.cresc.h.u-tokyo.ac.jp/en/index.html>. If circumstances require that the information in the application to the Research Ethics Committee be changed before the study ends, the appropriate change-notification form must be submitted and approved.

Important point #1: Begin survey research only after permission to do so has been granted by the Research Ethics Committee.

The application procedures described in these Guidelines may take time, but you may not start your survey research work until *after* the applications have been approved. Even if an application seems to be simple or a mere formality, do not assume that permission will be granted, and never start without permission to do so.

Section 2. Doing survey research

A) Appropriate use of intellectual property (if applicable)

Some psychological tests, quality-of-life scales, etc., are protected by copyright. Before using anything to which a claim of intellectual property rights exists, you should first contact the person or organization that holds those rights and make the necessary arrangements for contracting, registration, etc. Keep in mind that a scale's properties can change in important ways if you use only a part of the original scale, and if you change the wording of a question item, the number of response choices, the order of the items, etc. After any such alteration you may need to measure the altered scale's reliability, validity, etc. If your research requires that you use an altered scale, you would be well-advised to first obtain the permission of (or at least consult with) the author of the original version. As a minimum, in any report of your research you should cite the original version of the scale and you should clearly describe how you altered it.

B) Points to consider when collecting data (if applicable)

If you obtain permission to collect data from an organization, institution, etc., then you can prevent problems by obtaining it in writing from a person who has the

right to grant that permission (for example, the head of the organization or institution). For research that involves sampling of biomarkers or any other fieldwork that could be dangerous, all necessary safety precautions should be taken to protect both the researcher and the study's participants. If you are a graduate student you should discuss this as needed with your advisor, and follow your advisor's instructions.

C) Handling data (if applicable)

C-1 Handling personal information in survey data

C-1a Storing data safely

- Anonymize data as soon as possible. If the data are to be anonymized reversibly (that is, in a way such that individuals could still be identified if necessary), such as via a "mapping" code or a Table of Correspondence, then that code or Table and the reversibly-anonymized data should be stored in separate places. Information that could be used to identify an individual (names, medical-record numbers, and other commonly used personal identifiers) should be stored in a locked place, and access to the key should be strictly limited.
- If you use electronic files to store information that could be used to identify an individual (including the kinds of codes or Tables mentioned above), then those files should be encrypted and password-protected.
- Reversibly-anonymized data (as described above) should also be encrypted.
- If you store data on a portable device (portable USB memory, etc.), then the files or the entire device should be password-protected. Whenever possible, such devices should also have software, etc. that allows them to resist viruses and other malware.
- Your plans regarding the length of time that data will be stored and the method of data destruction should be documented in the application that you submit to the Research Ethics Committee, and you should implement the plans approved by the Committee.

C-1b Managing computers used to analyze data that have not been irreversibly anonymized

- Access to such computers should be limited by user ID and password, and guest accounts should be deleted. Use an appropriate "firewall."
- Install anti-malware software on all such computers. You should check for virus-definition updates and operating-system updates at least once each week, and install those updates when they are available.
- Do not allow Winny or other file-sharing software to be installed on such computers.
- Prevent theft of such computers by physically locking them in place with a security wire, etc.

C-2 Analyzing secondary data

- Before you start, obtain from the data provider all necessary

permissions to report findings. Be aware that some providers may deny permission for certain results to be reported.

- If you analyze secondary data, you are responsible for knowing and understanding those data, and the processes by which they were collected, as well as you would if you had collected them yourself.

D) Other important points regarding data handling in survey research (if applicable)

- If any part of your research requires the employment of an external service-provider, do not begin that work until after an appropriate non-disclosure agreement has been concluded. Be especially careful if the external service-provider has access to any data containing personal information.
- If your research requires the development of new software, you can prevent problems by first concluding a written statement that clearly identifies the holder of the intellectual property rights to that software.

E) Appropriate use of research funds

Misuse of research funds is absolutely prohibited.

If you use KAKENHI refer to the KAKENHI handbook. A new edition is released each year, and a version in English can be downloaded via the link at the bottom of <http://www.jsps.go.jp/j-fellow/j-fellow_14/19_shorei_download.html> or directly from <http://www.jsps.go.jp/j-fellow/j-fellow_14/data/syorei/10.pdf>. Use research funds in a well-planned manner and with care, and only after detailed deliberations with the Principal Investigator and with the administrator in charge.

Important point #2: Prevent and be prepared for unexpected problems in data management.

Pay close attention to all aspects of the management of personal data, and bear in mind that incidents caused by improper handling of data can bring research into disrepute. It is important to prevent unforeseen problems from occurring by thinking ahead with the intention of making things fail-safe and taking preventive action.

Section 3. Writing reports of your research and submitting them for publication

Authorship and co-authorship

- Choosing co-authors: Before submitting a manuscript for publication, it is essential to decide who, of all the people who had some connection with your research, should be included as co-authors. This will depend on how much they contributed to your work. You will also need to obtain their consent to co-authorship and to the order in which their names will be listed. Do not ask for that consent until after they have seen the manuscript.
- Graduate students may submit a Master's or Doctoral thesis that incorporates research done with collaborators or includes content from a manuscript with co-authors, but only after they have obtained written permission to do so from all of

the collaborators or co-authors.

References, text, and Figures

- Handle citations carefully. Ensure that your references to previous research are fair, and that your citations are correct. Do not cite only those previous reports that support your opinion or position. Instead, your decisions about citation should be dispassionate and neutral, and you should refer to opposing views.
- Verbatim copying from previously published or presented materials without proper citations, even verbatim copying of only a small part, is strictly prohibited. Even verbatim copying of as little as one sentence can be considered plagiarism. Exceptions to this rule can be made only if both of the following conditions are met: the copied text is marked as a quotation by enclosure in quotation marks (“”), and the source of the quotation is clearly indicated in, as noted above, a proper citation.
- Rather than showing long lists of numbers in large Tables, it is better to use graphs, diagrams, etc. that clearly illustrate only the points you want to make. Take care to give neither too much nor too little information.

Other points to remember

- The corresponding author has the greatest responsibility for the manuscript, including all the points mentioned above.
- Be sure that you are prepared to respond to requests arising from publication of your report (requests for copies of questionnaires used in your study, etc.).
- Before you name someone in the Acknowledgements (for example, someone who provided data, or was in charge of your fieldwork, or is affiliated with a funding organization), be sure to obtain that person’s permission.

A useful reference

- For further information about preparing reports of your work, refer to the statement on STrengthening the Reporting of OBservational studies in Epidemiology (the STROBE statement).
- The English-language version is available via the link near the top of <http://www.strobe-statement.org/>.
- Versions in Chinese, Spanish, German, Italian, Japanese, Persian, and Portuguese are available via the links on <http://www.strobe-statement.org/index.php?id=strobe-translations>.

Important point #3: Avoid duplicate submission.

Submitting reports of the same findings (i.e. duplicate submission) to more than one journal is prohibited. Presenting the same results (including Tables, Figures, etc.) in more than one original article is also prohibited. However, if, for example, the same

data are analyzed for different purposes or with different methods, then the findings might be publishable separately; in such a case, you should notify the Editor of the journal of the situation and of any relevant publications, and abide by the Editor's decision.

Important point #4: All co-authors must agree on a manuscript before it is submitted for publication.

Before a manuscript is submitted for publication, each co-author must receive a copy of the manuscript and must agree to be included as a co-author. Some journals require all co-authors to sign statements declaring conflict(s) of interest, agreeing to transfer of copyright, etc. To avoid trouble, ensure beforehand that you adhere strictly to the requirements of the journal to which you submit your manuscript. Remember that being included as a co-author is not necessarily desirable; some researchers may prefer not to be co-authors of your paper. If you are asked to be a co-author, be sure to read the paper before it is submitted for publication and to promptly inform the author inviting you to become a co-author whether you do or do not agree to be included among the co-authors. Bear in mind that co-authors share responsibility in the event that any problems should arise.

Important point #5: Handling potential conflicts of interest.

Keep in mind and disclose all conflicts of interest (COI).

Do your research in accord with the COI-related guidelines of the Japan Association of Medical Sciences and of all other relevant groups. When writing a manuscript and preparing it for publication, bear in mind and carefully consider any COI, and comply with the requirements for disclosure.

When researchers affiliated with an endowed department report the results of their work they should include the complete, formal name of the institution with which they are affiliated and they should clearly acknowledge, by name, the company that is the source of their funding. When writing in Japanese, include an acknowledgement such as this: "謝辞：ＸＸＸ寄附講座は、ＹＹＹ製薬の寄附金にて支援されている。" When writing in English, include an acknowledgement such as this: "Acknowledgement: The department of XXX is an endowed department, supported with an unrestricted grant from YYY."

If funding for the research being reported has been received from more than one company, then, to ensure transparency, the acknowledgment should list the name of every company from which funding was no less than a certain sum (e.g., every company that contributed 2 million yen or more).

Section 4. Applying for Patents (if applicable)

Applications for patents based on findings of your research should be filed as

early as possible before the findings are presented at conferences or published in any form. Patent applications related to non-hospital-based, basic-science, and public-health research are handled via the Faculty of Medicine's Research Support Section (kenkyuu-shien-gakari), and those related to clinical research are handled via the University of Tokyo Hospital's Public Relations Center (*paburikku-rireeshon-sentaa*).

Bear fully in mind that once your research findings are made public through presentation or publication, they may lose patentability. In Japan, however, application for a patent can be made up to 6 months after research findings on which the application is based are presented at a meeting (within 6 months after distribution of an abstract) or published.

Further information (in Japanese) on the relevant patent law can be found at < http://www.jpo.go.jp/index/tokkyo.html >.

Section 5. Other things you should do when your findings are disclosed to the public

Feedback to your research collaborators and participants

When a report of your research has been accepted and your results are made public, you should also report the results to people who collaborated with you or participated in your research. If some of those collaborators or participants are patients, members of the general public, or other non-specialists, then you should also report your results in a way that they will understand easily, and you should make that report readily available via, for example, the Internet or one of the University's publications.

For research that requires agreement to participate in a survey, you should make clear beforehand how you expect the results to be made public and whether you plan to report the results to the participants.

Section 6. Doing better research

The points listed below are not requirements, but they should be kept in mind by anyone who is dedicated to doing research well.

Planning your research

Before starting your research, you should have clear ideas of the purpose of the study, of what you are trying to elucidate, and of what you will be able to say on the basis of your results. In accord with those ideas, you collect and analyze data. You should prepare by collecting and reading reviews of the literature and the most recent reports of all relevant previous research related to your topic, to ensure that your work will be novel, creative, and meaningful. The mere fact that a study was never done before does not make it meaningful.

You should state your study's purpose and your hypothesis in writing as clearly as possible. They will directly and closely relate to your study's methods. You should also keep the study's purpose always in mind as you collect data. It is also a

good idea to decide on your analytic methods before you begin collecting data. Remember this: using analytic methods to compensate for limitations in data after they have been collected is extremely difficult. [Don't let yourself get stuck doing an after-the-fact patch-up job!] Even if the data have already been collected, that is, even if you plan to analyze secondary data, it is best to establish a hypothesis-based plan for analysis before you begin.

Before starting, you should subject your questionnaires and other survey tools to scrutiny by others, and if possible you should pilot-test them with a group of people similar to those whom you intend to study. If your study involves an intervention, then you should also consider collecting data to verify its "penetration", that is, the extent to which the intervention is implemented as intended. As much as possible, all of these points should be addressed in the written study protocol. To make the relationships among the variables that you plan to analyze understandable, whenever possible illustrate those relationships graphically.

Points to keep in mind in the course of research

- Quality-control for data entry: To minimize errors, when paper-based data are entered into a computer, the data should be entered separately by two people, whose work should then be compared.
- Appropriate statistical analyses and interpretations: You should perform appropriate statistical analyses, and your interpretations of their results should be objective and based not only on the presence or absence of differences that are statistically significant, but also on the sizes of the effects (the effect size).
- You must understand the premises and assumptions of all statistical tests that you use, and you must show that those premises are met by your data.

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