In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR SECONDARY USE OF PARTICIPANT DATA/MEDICAL RECORDS

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1. PURPOSE

The purpose of this SOP is to describe the requirements for IRB approval and informed consent for previously obtained participant data used for secondary research.

2. SCOPE

This SOP applies to P.Is who wish to submit a request for approval to use data for research purposes other than what they were initially obtained for.

3. INTRODUCTION

SERU approval is required for secondary research uses of previously obtained participant data, to ensure that such use is in keeping with human participants' protection requirements and that it does not compromise the participants' rights in any way

4. TERMS & DEFINITIONS

4.1 Anonymous data: - participant data for which identifiers/personally identifiable information were never collected

4.2 Anonymized data: - participant data from which all direct and indirect identifiers were removed irretrievably such that they cannot be linked directly or indirectly *by anyone* to their source(s).

4.3 Coded data: - participant data for which direct personal identifiable information has been removed and replaced with words, letters, figures, symbols, or a combination of these (not derived from or related to the personal information) for purposes of protecting the identity of the source(s); but the original identifiers are retained in such a way that they can be traced back to the source(s) by someone with the code.

4.4 De-identified data: All direct personal identifiers are *permanently* removed from data and no code or key exists to link the data to their original source(s), and the remaining information cannot reasonably be used *by anyone* to identify the source(s).

4.5 Secondary use of participant data: Study of existing data that have been previously collected for a purpose (including non-research purposes) other than the currently proposed research or activity.

5. OBJECTIVES

To ensure secondary use of participants data/medical records applications are received effectively and efficiently.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Emails

7. EXPECTED OUTPUTS

7.1 Agenda
7.2 Record of applications received

8. KEY PERFORMANCE INDICATORS

8.1 No. of applications received

9. RESPONSIBILITY AND AUTHORITY

9.1 **SERU Committee**: - reviews all new applications requesting use of existing data at its next available meeting provided the applications are received by the SERU Secretariat on or before the deadline for submission.

10. DETAILS OF PROCEDURE

10.1 The P.I submits a request for secondary/new uses of existing data obtained for primary research purposes either as an amendment or a new protocol describing the proposed secondary use, depending on the previous approval and the new research objective(s).

10.2 The P.I submits a request for secondary use of existing data detailing the following:

10.2.1 The specific purpose for which the data are to be used

10.2.2 A disclosure of the name of the PI for each of the studies from which the data will be obtained.

10.2.3 A disclosure of the study or studies (give titles and any SERU study identification numbers) from which the data were derived.

10.2.4 Circumstances under which the data were collected

10.2.5 Physical location/equipment and security provisions for data archival and retrieval

10.2.6 Evidence that scientific review of the proposed study has been done to ascertain the merit in conducting the study.

10.2.7 The number and types of data to be obtained from each study for secondary use.

10.2.8 The state of the data e.g. anonymized, de-identified, coded, identifiable, etc

10.2.9 If the data are considered to be/linked to individually identifiable protected health information

10.2.10 Evidence of an assessment of the integrity of the data to be used to ensure that the data in question are suitable for use in the proposed study and that they will yield meaningful results.

10.2.11 An analysis on the limitations (of the new study) presented by the criteria for collecting and storing the data and how these limitations will be addressed.

10.2.12 A disclosure of whether the PI of the new study can link the specific data to the individuals or the community from which they were obtained either directly or indirectly through an existing code, coding system or by a combination of variables that can result in identification of an individual or community or whether anonymized data (i.e. stripped of all direct and indirect identifiers) will be used.

10.2.13 The arrangements for obtaining participant consent and/or privacy protections where the data are identifiable.

10.2.14 The identification of the data must be limited to the extent necessary to achieve the study objectives and a justification should be provided.

10.2.15 A detailed description of the agreements between the investigators concerning transfer and storage of the data, ownership of data, findings or intellectual property rights (IPR)/patents.

10.2.16 A copy of the previously approved consent document used for the initial collection of the data indicating that the participant was consented for collection, future use and/or long-term storage of their data.

10.2.17 Process for destruction or de-identification of identifiable or coded data at the end of the storage period

10.3 Informed consent considerations:

10.3.1 Research using existing data must be consistent with the scope and terms described in the original informed consent process/document, as applicable.

10.3.2 If consent was not obtained (e.g. data obtained for non-research purposes) or the original consent does not adequately include the proposed secondary use, specific informed consent for the new research may be required. (NB: De-identification or coding of data should not be used as a means for circumventing the original terms of consent).

10.3.3 Adequate informed consent is required for secondary use of identifiable data.

10.3.4 For data collected and archived without consenting of the participants for future potential use and long-term storage, the P.I should justify the scientific merit in using the existing data. The P.I should seek SERU's approval for the use of the data provided that the data will be anonymized or coded and the research is being conducted in line with the objectives of the initial study for which the data were collected or a justified public health concern.

10.3.5 For secondary use of data that is likely to produce information relevant to the health or wellbeing of the person who gave the data, the P.I should ensure that appropriate follow-up is done where it is possible to re-contact the study participant.

10.4 Data sharing considerations

10.4.1 The P.I is required to seek SERU approval prior to sharing data with collaborators for secondary research purposes

10.4.2 The P.I should submit material transfer agreements (MTAs), and any other relevant agreements, to be used for the sharing of research data with non-institutional collaborators

10.4.3 The P.I. receives SERU's review outcome, in writing, within six (6) working days of the meeting at which the decision was reached.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk Source	Mitigation
Submission of secondary use of participant data medical records	Rejection of the research application by the SERU centre compliance officer	Failure by the principal investigator to submit all the documents required before the application is accepted by the SERU centre compliance officer	Training of the principal investigator (s)

11.2 Opportunities

Process	Opportunities	Action plan to maximize the opportunity

Submission of secondary use of participant data medical records	Training of the principal investigator (s)	Organizing regular trainings for the principal investigators

12. REFERENCE DOCUMENTS

12.1 **Internal References**

12.1.1 None

12.2 **External References**

12.2.1 Research involving data and/or biological specimens – Ohio State University (http://orrp.osu.edu/files/2012/02/Research-Involving-Data-andor-Specimens.pdf)

13. ANNEXES

13.1 Flow Chart

ANNEX 2: PROCESS FLOW CHART

Players	Activity	Flow Chart
Principal Investigator	Submitting secondary use of participant data/medical records applications	
Centre Compliance Officer	Receives, pre-reviews and records all secondary use of participant data/medical records applications submitted to SERU