# RESPONSIBLE CONDUCT AND DOCUMENTATION OF RESEARCH:

# A STANDARD OPERATING PROCEDURE TEMPLATE THAT CAN BE CUSTOMIZED


## AUTHORS AND AFFILIATIONS

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## PREFACE

This standard operating procedure (SOP) document was prepared as a template that individual researchers can customize for their own use. Prior to publication, this SOP underwent peer review by the McMaster University Faculty of Health Sciences Research Council. The Council has endorsed the publication of this SOP to encourage researchers to develop procedures that encourage best research practices and can be customized to meet specific needs.

Should you decide to customize this SOP for your own use, please acknowledge the original authors, who include Ms. D'Andra Parker and Mr. Asim Soomro (graduate students in the Hayward laboratory). All items highlighted in yellow in the SOP must be customized.

If you have comments or suggestions for improvements, please direct these to the corresponding author, Catherine Hayward (haywrdc@mcmaster.ca).

| RESEARCH LABORATORY OF INSERT SUPERVISOR'S NAME<br>INSERT LABORATORY Location<br>INSERT LABORATORY Phone number | | |
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## 1.0 Purpose:

This procedure outlines the steps involved in proper recording keeping in the laboratory. This SOP applies any/all data generated while in the laboratory, and any/all the laboratory records.

## 2.0 Scope:

This procedure applies to all researchers (including staff, students and volunteers) using this facility.

## 3.0 Definitions:

3.1 **Research Integrity:** The McMaster University Research Integrity Policy, (links to this document are in item 5.0) states that "researchers at McMaster demonstrate integrity in many ways including:

- They practice intellectual honesty in the process of acquiring and extending knowledge.
- They adhere to ethical requirements in their research
- They strive to ensure that others are not put at a disadvantage in their pursuit of knowledge. They do not withhold material that should rightly be available to all.

Additionally, "the McMaster University Research Integrity Policy aligns with the principles and requirements of the Tri-Agency Framework: Responsible Conduct on Research" (links to this document are in item 5.0)

3.2 **Responsible Conduct of Research:** The Tri-Agency Framework policy states that**;** *"Researchers shall strive to follow the best research practices honestly, accountably, openly and fairly in the search for and in the dissemination of knowledge. In addition, researchers shall follow the requirements of applicable institutional policies and professional or disciplinary standards and shall comply*

*with applicable laws and regulations."* Researchers are expected to use *"a high level of rigour in proposing and performing research; in recording, analyzing, and interpreting data; and in reporting and publishing data and findings."* They are also expected to keep "*complete and accurate records of data, methodologies and findings, including graphs and images, in accordance with the applicable funding agreement, institutional policies and/or laws, regulations, and professional or disciplinary standards in a manner that will allow verification or replication of the work by others."*

3.3 **Laboratory notebook:** a bound notebook, with consecutively numbered pages, kept in the laboratory at all times. This book has **all** detailed information pertaining to the experiments conducted while working in this laboratory, including statistical analyses and interpretation of data. The laboratory notebook must act as a stand-alone, clear and detailed explanation of all laboratory work conducted. The level of detail recorded must be sufficient to allow the work to be reproduced, by others, without the aid of the original researcher who recorded the experiments in their laboratory notebook. If a procedure is used repeatedly, a reference to the detailed protocol (with version date) must be made each time it is performed. If a protocol is later modified (which requires it to be saved with a new version date), a copy of the version that was used for the experiment work must be kept.

3.4 **Inventory binder or notebook:** an inventory book used to record what supplies (including supplier, kit and lot numbers, etc.), samples and materials were used and/or generated by work in the laboratory and their location within the laboratory.

3.5 **Electronic research records:** primary and secondary data files used to record the output of experimental analyses from instruments ("source" or "primary" electronic datafiles) and to further analyze research findings.

## 4.0 Responsibility:

4.1 **It is the responsibility of all research team members (students, volunteers, staff and supervisors) to ensure that they are fully aware of all relevant guidelines and policies on responsible research conduct**. The Tri-Agency Framework: Responsible Conduct of Research states that integrity in research requires "*analyzing, and interpreting data; and in reporting and publishing data and findings; keeping complete and accurate records of data, methodologies and findings, including graphs and images, in accordance with the applicable funding agreement, institutional policies and/or laws, regulations, and professional or disciplinary standards in a manner that will allow verification or replication of the work by others; referencing and, where applicable, obtaining permission for the use of all published and unpublished work, including data, source material, methodologies, findings, graphs and images; including as authors, with their consent, all those and only those who have materially or*

*conceptually contributed to, and share responsibility for, the contents of the publication or document, in a manner consistent with their respective contributions, and authorship policies of relevant publications; acknowledging, in addition to authors, all contributors and contributions to research, including writers, funders and sponsors' appropriately managing any real, potential or perceived conflict of interest."*

4.2 **To properly conduct research, students, volunteers, staff and faculty researchers must be aware of the policies and guidelines that are referenced in this SOP (item 5.0).** Additionally:

- graduate students are expected to complete the training offered by McMaster University pertaining to academic integrity and the responsible conduct of research (e.g. SGS 101, Parts 1, 2 and 3; McMaster Research Integrity Policy Orientation) (https://www.mcmaster.ca/academicintegrity/ResearchIntegrityOrientation.html)
- students, volunteers, staff and faculty researchers are welcomed to ask their supervisor for further clarification, to avoid any misunderstanding and potential for an academic dishonesty charge related to research work
- students, volunteers, staff and faculty researchers need to know that they are responsible for their own behavior, and that they may face penalties if they commit a research integrity offence as detailed in: Tri-Agency Framework: Responsible Conduct of Research and the McMaster University Research Integrity Policy (referenced in item 5.0).
- students, volunteers, staff and faculty researchers are expected to adhere, follow and display demonstrate behaviour that is honest and ethical by abiding by the guidelines and policies for responsible research conduct according to this SOP
- before undertaking any research, students, volunteers, staff and faculty researchers must sign the "Responsible conduct of research signature sheet" (appended at the end of this SOP) in order to confirm that they understand responsible conduct as per this SOP, McMaster University policies and the Tri-Agency Framework document.

4.3 **It is the responsibility of a research supervisor, in collaboration with their students, volunteers and staff, to:**

- *"strive to provide an environment that supports the best research and that fosters researchers abilities to act honestly, accountably, openly and fairly in the search for, and dissemination of knowledge"* in accordance with the Tri Agency Framework: Responsible Conduct of Research.
- ensure that this SOP is up-to-date and reflective of any current policies and guidelines for responsible conduct of research at McMaster University, in accordance to the Tri-Agency Framework: Responsible Conduct of Research.
- ensure that there are appropriate resources in the laboratory (e.g. laboratory notebooks) so that all members of the research team can

readily follow the policies and guidelines in this SOP.
- ensure all members of the research team have access to appropriate training on responsible research as per McMaster University Policy and the Tri-Agency Framework document.

## 5.0 Related Policies/Procedures:

Tri-Agency Framework: Responsible Conduct of Research (http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/)

McMaster University Research Integrity Policy (and related policies referenced within that document) (http://www.mcmaster.ca/policy/faculty/Research/Research%20Integrity%20Policy.pdf)

## 6.0 Equipment/materials:

Laboratory notebook
Laboratory inventory binder or notebook
Laboratory computer for housing electronic data files
Laboratory and personal USB/external hard-drives

## 7.0 Action/Decision-making Framework:

### 7.1 Maintaining/updating laboratory notebooks:

#### 7.1.1 Labeling laboratory notebook:

The cover page of a laboratory notebook must contain the research members full name, the notebook number (sequential) and year (i.e. Book #1, 2014; Book #2 2016, etc.) are clearly marked on the cover of each laboratory notebook. The pages within the notebook must be consecutively numbered. It is recommended that a table of contents be recorded, either at the beginning or end of the notebook, to help organize and locate records.

#### 7.1.2 Entering data into laboratory notebooks:

On a daily basis, experimental plans and any data generated must be entered into the laboratory notebook, with the date that the plans were made and/or the experiment was conducted. The entry should include the location where any primary data files are stored (e.g. “raw data located on main computer by microplate reader; C:\Users\User\Documents\Haywardlab\Cathy\ELISA\20140214.doc). If appropriate (e.g., in the case of multiple instruments in the facility), the make, model, serial number and location of equipment used for analysis should be noted in the records. Each member of the research team is expected to paste a copy of the raw data, the analyzed data (e.g. graphs) and any statistical analysis performed for experiments. Ideally, records should outline the rationale,

hypotheses, all methodologies, results and conclusions. It is expected that research team members record all relevant details (e.g., which subjects' samples were tested, details of dilutions, volumes of materials tested per lane or well, etc), observations, interpretations and comments about single or multiple experiments in laboratory notebooks. This will facilitate repeating experiments and troubleshooting any problems that arise.

**NOTE:** Pens must be used to enter records in laboratory notebooks. The use of pencil or water soluble ink is not acceptable. Removal of pages or "white-out" any content is not allowed. Errors or changes in plans may be indicated by crossed out the information with a single line through the erroneous text. Laboratory notebooks and inventory records must not be removed from the laboratory as primary research records must be maintained by laboratory for research integrity. If an experiment is performed with, or for another research team member, it is recommended that both individuals each keep a copy of the records in their notebooks.

**PRACTICES THAT ARE ENCOURAGED:** Members of the research team are advised and encouraged to create, maintain and continuous update an electronic narrative of their work (as a draft thesis or paper) to help organize their thoughts and facilitate inclusion of sufficient details of their work. It should be organized as: background/introduction, materials and experimental methods, results and discussion. If a procedure is to be used repeatedly without variance in procedure, consider preparation of a standard operating procedure (SOP; with version date). Literature searches should be performed before undertaking work, and periodically during a project, to ensure that the research plans adequately consider current knowledge.

7.2 **Saving files on laboratory computers:** All primary (source) electronic data files, and secondary files (e.g., data analysis or graphs) generated for the experimental work must be saved on the computers in the laboratory (e.g. on the C-drive or network drive, not just on an external drive; never save primary data on USB devices except for transfer). All data must be logically organized into folders and must be clearly labeled (e.g., name of team member, date and type of experiment conducted). **It is forbidden to delete or overwrite data files from the computer records held by the laboratory** (see Section 7.4). Source data files (electronic and hardcopy records) **must** be kept for all experimental work. Files generated on computers outside the laboratory (e.g., from sequencing, real-time PCR files, collaborators instruments) must be copied over to a laboratory computer to ensure that records are complete. If work is done offsite, or if analyses are completed on a personal computer, a copy must be transferred back onto a laboratory computer to ensure the integrity and completeness of records. If data files from multiple experiments are used to create a graph, table or narrative, maintain a record of which experiments were used (by date and type of experiment), and any data for similar experiments that were excluded (e.g., if there were failed experiments, or pilot work to develop a protocol). Inventory

records should list which laboratory computers contain the source and secondary data files. **An experiment that isn't properly document is considered a failed experiment that can never be published or presented.**

7.3 **Creating back-up files of records on the lab computers:** All files on the hard drives of laboratory computers will be back-up on a weekly basis by the senior laboratory personnel to ensure the integrity of record keeping. Access to the external hard-drives or network drives with experimental data files requires permission of both the senior laboratory personnel and the supervisor.

7.4 **Removing data from the lab: Laboratory notebooks and other hard copy experimental records (including inventory records) can <u>never</u> be removed from the supervisor's laboratory. It is also forbidden to delete or overwrite electronic data files that document experimental work on the supervisor's laboratory computers.** Member of the research team are encouraged to make photocopies of hard copy files and to create their own electronic backup files to further ensure the integrity of their research records (e.g. using USB or External Hard Drives to transfer files) and the timely presentation and publication of work.

7.5 **Maintaining/updating a personal laboratory inventory:** Any and all materials used to conduct laboratory work must be listed in inventory records. General project, or personal project binders (in the case of sole users), must be used to store information on product sheets. Ensure that all materials have an acceptable Material Safety Data Sheet (MSDS) in the common laboratory binder with MSDS records (a required safety resource of the laboratory). Use a sample inventory book to keep an organized record of primary and secondary samples and materials and the location where they are stored. If possible, also state the quantity of material remaining and the date this was recorded. This inventory must be updated regularly to ensure accurate and up-to-date information. The purpose of personal laboratory inventories (which <u>do not</u> replace the general laboratory inventory records) to help members of the research team locate any/all samples and materials used for laboratory work on a project. Make sure that these inventories are up-to-date when new samples or supplies are prepared/received, and ensure that all supplies used are listed on the laboratory reagent inventory and MSDS records.

7.6 **Recordkeeping related to samples from human:** The research ethics board (REB) has specific requirements for keeping subject identities anonymous. All subjects that donate samples must be fully informed and provide written consent prior to collecting samples for research purposes. **Research team members are expected to be familiar with the study REB submission and associated donor consent forms for their project to ensure that they follow all REB requirements.** A unique, and anonymized, character code will be created and assigned to each subject used in research studies. Only anonymized codes can be used in laboratory records and on sample labels. Signed consent

forms, and records that link the anonymized code to a subject are kept in a locked filing cabinet in the supervisor's office, in accordance with REB policies. **It is forbidden to indicate name of a patient or control in laboratory notebooks, data files, inventories or publications.** Sample labels should include the type of sample, and date of collection, if a donor is used more than once and/or to prepare more than one type of sample. An inventory of all patient and control samples must be maintained with the following details (not in this specific order): unique anonymized code; who prepared and collected the sample; type of sample; procedure used to collect samples; purpose of an experiment on a sample; and date and details of the experiment. **NOTE:** The REB requires an update each year on the number of recruited subjects. Each member of the team is expected to keep appropriate records for reporting these numbers.

7.7 **Record keeping for work done in collaboration with other laboratories:** All data files generated in other research laboratories as part of collaborative work must be stored in a separate folder on the computers in the collaborating laboratory (in keeping with requirements of the collaborator), and an exact copy of the folder is to be maintained on a computer in the primary supervisor's laboratory. Files must be clearly labelled with the name of the laboratory, collaborator and research team member (e.g. C:\Users\User\Documents\Haywardlab\Rivard\AsimSoomro) and an identical copy must be transferred to the primary supervisor's laboratory within one month of generating the data. All data must be stored and updated as described in sections 7.2 and 7.3. Similarly, all experiments conducted in collaborating labs must be properly recorded in a laboratory notebook. If the collaborator requires that a laboratory notebook be kept in their laboratory for the collaborative experimental work, there must be a complete replica of the record in both laboratories. Frequent updates (minimum: monthly) are recommended to ensure that records at both sites are complete. All data must be recorded as described in sections 7.1.

7.8 **Integrity of data used for reports, research publications and presentations:** Any data used for reports, publications (including a thesis) and/or, presentation (e.g., abstract submission) must be clearly identified in one's laboratory notebook, with a summary of which experiments were used and any experiments that were excluded, with the reason (e.g., failed experiment – standard curve not acceptable). As part of organized record keeping, it is recommended to note where this information is summarized in each laboratory notebook, or in a separate laboratory notebook, if appropriate.
**IMPORTANT:** The Tri-Agency Framework requires that there be proper procedures to ensure the integrity of data. *The supervisor, or delegate, is required to verify that: 1) there are appropriate source data files* for a manuscript, thesis, committee report and/or presentation, and that 2) the graphs, tables, and/or narrative description of findings, accurately convey the experimental findings, without bias. Both individuals (the record keeper and the individual

verifying the records) must sign in the laboratory notebook whenever a data integrity review has taken place. For graduate students, this data integrity review must be done annually, in advance of when new data (or a revised presentation of older data) is incorporated into a committee report.

8.0 **Documentation:**

Each member of the research team is required to sign a "Responsible conduct of research signature sheet" (copy at the end of this document), confirming that they have read the contents of this SOP, and are familiar with the policies on the responsible conduct of research and integrity related to research record keeping as detailed by: their supervisor's research laboratory; McMaster University; and the Tri-Agency Framework. The signature sheet should be kept with other training records.

9.0 **References:**

- McMaster University Research Integrity Policy (http://www.mcmaster.ca/policy/faculty/Research/Research%20Integrity%20Policy.pdf)
- Tri-Agency Framework: Responsible Conduct of Research (http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/)

10.0 **Developed With Consideration of The Policies Described In:**

Tri-Agency Framework: Responsible Conduct of Research
McMaster University Research Integrity Policy

11.0 **Reviewed by the Faculty of Health Sciences Research Council on April 9, 2015**

# Responsible Conduct and Documentation of Research Signature Sheet

By singing this document, you confirm that you have read and understand the information outlined in the
SOP[insert number]: Responsible Conduct and Documentation of Research

| DATE | NAME (PRINTED) | SIGNATURE OF EMPLOYEE, TRAINEE, VOLUNTEER, ETC. | SIGNATURE OF SUPERVISOR |
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