

Data Management Plan Template: Interdisciplinary Health Software/Technology Development

Abstract

This template is designed for research projects where software or technology is being developed in an interdisciplinary health context. This template was created to represent the many stakeholders (e.g., patients, practitioners, developers, industry) involved in software or technology development, either as advisors or as participants being studied as a product of the research process. As a result, this template is separated into two sections; the first is focused solely on a management plan for the creation of software or technology, and the second on a data management plan designed to describe the methods in which data are gathered, analyzed, and shared from participants based on interventions or testing of the corresponding software or technology. In these studies, research participants can include either patients or practitioners, or both, depending on the software or technology's intended use.

Administrative Details

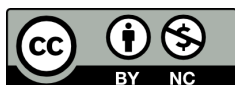
Template Author(s): Kevin B. Read, Shelley Peacock, Tracie Risling, University of Saskatchewan

Published: March 2, 2021

DOI: [10.5281/zenodo.4571655](https://doi.org/10.5281/zenodo.4571655)

Contact: Portage Network - portage@carl-abrc.ca, portagenetwork.ca

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Version:

Version	Date	Changes
1.0	2021-03-02	Formatted for inaugural publication.

Software/Technology Management Plan

Software/Technology Development

Describe the components that will be required to develop the software/technology in question.

What software/technology will be created in this study?

Describe the software/technology being developed for this study, including its intended purpose.

What software/technology development framework or model will be used, if any?

Describe the underlying approach you will take to the development and testing of the software/technology. Examples may include existing frameworks like the systems development life cycle, or user-centred design framework. If you intend to develop your own approach, describe that approach here.

Will you utilize any existing code to develop this software/technology?

If you are using open source or existing software/technology code to develop your own program, provide a citation of that software/technology if applicable. If a citation is unavailable, indicate the name of the software/technology, its purpose, and the software/technology license.

What test cases will you use to develop the software/technology?

Describe the methodology that will be used to run and test the software/technology during the study. This may include: beta testing measures, planned release dates, and maintenance of the software/technology.

How will your software/technology and documentation adhere to disability and/or accessibility guidelines?

Describe the disability and accessibility guidelines you will follow to ensure your software/technology is adaptable and usable to persons with disabilities or accessibility issues.

What dependencies will be used in the development of this software/technology?

Describe the requirements needed to support the software/technology used in the study. This may include: types of operating systems, type of server required, infrastructure necessary to run the program (e.g., SQL database), and the types of devices this software/technology can be used with (e.g., web, mobile).

Software/Technology Documentation

Provide an outline of the documentation and information that would be required for someone else to understand and reuse your software/technology.

What information would be required for someone to understand and reuse your software/technology?

Consider what information might be useful to accompany your software/technology if you were to share it with someone else. Examples may include documented code, user testing procedures, etc. This guide provides simple steps to improve the transparency of open software ([Prlc & Proctor, 2012](#)).

What documentation will you develop to help others write and run tests on your software/technology?

Consider the software/technology development phase and indicate any instructions that will accompany the program. Examples might include test-first development procedures, user acceptance testing measures, etc.

How will you track changes to code and dependencies?

Include information about any programs or steps you will use to track the changes made to program source code. Examples might include utilizing source control systems such as [Git](#) or [Subversion](#) to track changes and manage library dependencies.

Software/Technology Preservation

Describe how your software/technology will be available for the foreseeable future after the study is complete.

How will the software/technology be updated and maintained over time?

Describe any plans to continue maintaining software/technology after project completion. Use this section to either describe the ongoing support model, the intention to engage with industry, or plan to apply for future funding.

Describe the level of risk associated with the use of public web services/infrastructure/databases regarding their stability and sustainability.

Include information about how the software/technology will remain secure over time. Elaborate on any encryption measures or monitoring that will take place while maintaining the software/technology.

Software/Technology Ethical and Legal Restrictions

Provide any ethical or legal restrictions that may impact how you use and/or distribute your software/technology.

Who will own the copyright to the software/technology?

List the copyright holder of the software/technology. See the [Copyright Guide for Scientific Software](#) for reference.

What software/technology license will you choose?

Describe the license chosen for the software/technology and its intended use. See list of license options [here](#).

Software/Technology Responsible Parties

Outline who is responsible for the development and monitoring of the software/technology over the course of the study.

Who will have access to your software/technology throughout the project? Describe each collaborator's responsibilities in relation to having access to the data.

Provide the name(s), affiliation, contact information, and responsibilities of each study team member in relation to working with the software/technology. If working with developers, computer scientists, or programmers outside your immediate team, provide their information as well.

Who is responsible for reviewing and accepting each software/technology release?

Indicate the steps that are required to formally approve a release of software/technology.

Software/Technology Sharing

Describe how you will make your software/technology discoverable and accessible to others once it is complete.

Who are the intended users of your software/technology?

Describe who the intended users are of the software/technology being developed.

What software/technology will be shared at the end of the study?

Describe the specific elements of the software/technology that will be made available at the completion of the study. If the underlying code will also be shared, please specify.

Are there restrictions on how you can share your software/technology related to patents, copyright, or intellectual property?

Describe any restrictions that may prohibit the release of software/technology. Examples may include commercial restrictions, patent restrictions, or intellectual property rules under the umbrella of an academic institution.

Where will you share your software/technology?

Provide the location of where you intend to share your software/technology (e.g., app store, lab website, an industry partner). If planning to share underlying code, please indicate where that may be available as well. Consider using a tool like [GitHub](#) to make your code accessible and retrievable.

Data Management Plan

Data Collection

Outline the processes and procedures you will follow during the data collection process of your study.

What types of data will you be collecting?

Please describe the types of data you will gather across all phases of your study. Examples may include, but are not limited to data collected from surveys, interviews, personas or user stories, images, user testing, usage data, audio/video recordings, etc.

Will you be using any existing data from external sources or previous research?

If you will be combining original research data with existing licensed, restricted, or previously used research data, describe those data here. Provide the name, location, and date of the dataset(s) used.

What data collection instrument or scales will you use to collect the data?

Provide a description of any data collection instruments or scales that will be used to collect data. These may include but are not limited to questionnaires, assessment scales, or persona guides. If using a pre-existing instrument or scale from another study, provide the citation(s) in this section.

Is your data collected longitudinally or at a single point in time?

Indicate how frequently you will be collecting data from participants. For example, if you are conducting a series of user tests with the same participants each time, indicate the frequency here.

What is the time frame over which you are collecting data?

Provide an estimate of when you will begin and conclude the data collection process. List this information in the following format: YYYY/MM/DD - YYYY/MM/DD. If you do not know the exact dates, list YYYY/MM - YYYY/MM instead.

What is the setting and geographic location of where the data is being gathered?

Indicate the broader geographic location and setting where data will be gathered.

What are the steps involved in the data collection process?

Utilize this section to include a descriptive overview of the procedures involved in the data collection process. This may include but not be limited to recruitment, screening, information dissemination, and the phases of data collection (e.g., participant surveys, user acceptance testing, etc.).

What software programs will you use to collect the data?

Include the name and version of any software programs used to collect data in the study. If homegrown software/technology is being used, describe it and list any dependencies associated with running that program.

What file formats will you be generating during the data collection phase?

List any of the output files formats from the software programs listed above.

Data Analysis

Outline the steps, materials, and methods that you will use during the data analysis phase of your study.

How will you document the changes you make to your data on a regular basis during the data analysis phase?

Provide a description of how you will track changes made to any data analysis files. An example of this might include your audit trails or versioning systems that you will follow iterations of the data during the analysis process.

What software will you be using to support your data analysis?

Describe the software you will use to perform any data analysis tasks associated with your study, along with the version of that software (e.g., SPSS, Atlas.ti, Excel, R, etc.).

What file formats will your data analysis files be saved in?

List the file formats associated with each analysis software program that will be generated in your study (e.g., .txt, .csv, .xls, .docx).

What code you will be generating that should accompany the data analysis file(s)?

Include any code or coding schemes used to perform data analysis. Examples in this section could include codebooks for analyzing interview transcripts from user testing, code associated with the functional/non-functional requirements of the software/technology program, or analytical frameworks used for evaluation.

What quality assurance measures will be implemented over the course of the study?

Use this section to describe any quality review schedules, double coding measures, inter-rater reliability, quality review schedules, etc. that you intend to implement in your study.

Documentation and Metadata

This section will focus on including information that would be required for someone else to interpret and re-use your data.

What information would be required for someone else to understand and reuse your data?

Consider what information might be useful to accompany your data if you were to share it with someone else (e.g., the study protocol, interview guide, personas, user testing procedures, data collection instruments, or software dependencies, etc.).

Are there metadata standards which you could use to describe your data?

Metadata standards can provide guidance on how best to document your data. If you do not know of any existing standards in your field, visit this website to search for available standards: <https://fairsharing.org/>.

Who is the target population being investigated?

Describe the target population for which the software/technology is being developed (i.e., end users).

How is the population being sampled?

Describe the processes used to sample the population (e.g., convenience, snowball, purposeful, etc.).

What are the variables being studied?

For any data gathered, list the variables being studied. For each variable, include the variable name, explanatory information, variable type, and values associated with each variable. Examples may include demographic characteristics of stakeholders, components of the software/technology program's functional and nonfunctional requirements, etc. See guidance on [how to create a data dictionary](#).

Are there any acronyms or abbreviations that will be used within your study that may be unclear to others?

Create a glossary of all acronyms or abbreviations used within your study.

Storage and Backup

Describe and outline how and where your data will be stored throughout the research project.

What are the storage requirements needed for your data?

Provide an estimate of how much data you will collect for all data in the form of terabytes, gigabytes, or megabytes as needed. Breaking down the size requirements by data types is advised (e.g., 2 GB required for video files, 500 MB for survey data).

Where will your data be stored during the *data collection* phase?

Indicate where and how data will be stored during data collection. Examples may include storing data in secure, password protected computer files, encrypted cloud storage, software programs (e.g., REDCap), hard copies stored in locked filing cabinets, external hard drives, etc.

Where will your data be stored during the *data analysis* phase?

If different from above, indicate where data is stored during the data analysis process. If data is being sent to external locations for analysis by a statistician, describe that process here.

If your data contains confidential information, how will your storage method ensure the protection of this data?

Indicate the security measures used to protect participant identifying data. Examples may include storing informed consent forms separately from anonymized data, password protecting files, locking unused computers, and restricting access to data that may contain identifying information.

What file naming conventions will you use in your study?

List any specific file naming conventions used throughout the study. Provide examples of this file naming convention in the text indicating the context for each part of the file name. See file naming guidance [here](#).

What backup measures will be implemented to ensure the safety of your data?

Describe how your study data will be regularly saved, backed up, and updated. If using institutional servers, consult with your Information Technology department to find out how frequently data is backed up.

Preservation

Describe the steps that will ensure that your data will be available and usable for the foreseeable future after your study is complete.

Where will data be stored after the project is complete?

Describe where your data will be stored after project completion (e.g., in an institutional repository, an external data repository, a secure institutional computer storage, or an external hard drive).

Who is responsible for managing the data after the study is complete?

Name the person(s) responsible for managing the data at the completion of the project. List their affiliation and contact information.

Will your data be migrated to preservation formats?

Many proprietary file formats such as those generated from Microsoft software or statistical analysis tools can make the data difficult to access later on. Consider transforming any proprietary files into preservation-friendly formats to ensure your data can be opened. Describe the process for migrating your data formats here.

How long do you intend to keep your data after the project is complete?

Provide details on how long you plan to keep your data after the project, and list any requirements you must follow based on Research Ethics Board guidelines, data use agreements, or funder requirements.

What steps will you take to destroy the data after the retention period is complete?

Describe what steps will be taken to destroy study data. These steps may include but are not limited to shredding physical documents, making data unretrievable with support from your Information Technology department, or personal measures to eliminate data files.

Ethical and Legal Compliance

Outline the ethical and legal implications placed on your research data.

How will the informed consent process be carried out within your study?

Outline the information provided in your Research Ethics Board protocol, and describe how informed consent is collected, and at which phases of the data collection process. Examples include steps to gain written or verbal consent, re-establishing consent at subsequent points of contact, etc.

Who holds the intellectual property rights to your data?

Provide the name, institutional affiliation, and contact information of the person(s) who hold intellectual property rights to the data.

What ethical guidelines or constraints are applicable to your data?

Describe any ethical concerns that may be associated with the data in this study. For example, if vulnerable and/or Indigenous populations were studied, outline specific guidelines that are being followed to protect participants (e.g., OCAP, community advisory boards, etc.).

What legal restraints are applicable to your data (e.g., ownership)?

Provide details describing the legal restrictions that apply to your data. These restrictions may include, but are not limited to, details about how your research data can be used as outlined by a funder, institution, collaboration or commercial agreement.

What methods will be used to manage the risk of disclosure of participant information?

List all the steps that will be taken to remove the risk of disclosing personal information from study participants. Include information about keeping data safe and secure, and whether certain information will be removed from the data. If data is being anonymized or de-identified, specify the information type(s) being altered (e.g., names, addresses, dates, location).

Responsibilities and Resources

Indicate who will be working with the data at various stages, and describe their responsibilities.

What financial resources will you require for data management in this study?

Describe any financial resources that may be required to properly manage your research data. This may include personnel, storage requirements, software, hardware, etc.

Who is the main contact and steward for the data collected in this study?

Provide the name(s), affiliation, and contact information for the main study contact.

Who will have access to your data throughout the project? Describe each collaborator's responsibilities in relation to having access to the data.

Provide the name(s), affiliation, contact information, and responsibilities of each study team member in relation to working with the study data.

Will any new members be added or responsibilities be transferred over the course of the study?

Describe the process by which new collaborators/team members will be added to the project, if applicable. Include the type(s) of responsibilities that may require new team members to be added during, or after the project is complete.

Data Sharing

Provide information about how you will make your data available and/or discoverable to the broader community.

Who are the intended users of your data?

Describe who the intended users are of the data. Consider that those who would benefit most from your data may differ from those who would benefit from the software/technology developed.

What data will be shared at the end of the study?

Outline the specific data that can be shared at the completion of the study. Be specific about the data (e.g., from surveys, user testing, app usage, interviews, etc.) and what can be shared.

What restrictions are placed on your data that would limit public data sharing?

Describe any restrictions that may prohibit the sharing of data. Examples may include holding data that has confidentiality, license, or intellectual property restrictions, are beholden to funder requirements, or are subject to a data use agreement.

Where will you share your data?

Provide the location where you intend to share your data. This may be an institutional repository, external data repository, via community approval, or through your Research Ethics Board.

If you have collected restricted data, what steps would someone requesting your data need to follow in order to access it?

If your data is restricted, describe how a researcher could access that data for secondary analysis. Examples of these procedures may include completing a Research Ethics Board application, signing a data use agreement, submitting a proposal to a community advisory board, among others. Be as specific as possible in this section.

What license will you apply to your data?

Select a license that best suits the parameters of how you would like to share your data, and how you would prefer to be credited. See this resource to help you decide:
<https://creativecommons.org/choose/>.