**MHC RECORD REVIEW PROTOCOL TEMPLATE v12.6.16**

**HOW TO USE THIS TEMPLATE**

This **template** is a guide designed to assist you in developing a protocol document for an investigator-initiated clinical trial; it should be **tailored according to your study procedures / specifications.**

**General instructional text is provided in blue text boxes throughout this document**:

* When you see this symbol some instructions may also be here , click on it an enter text as directed.
* Text within a blue box that is in Arial font (and in black) indicates that language is being provided for you to copy and paste into your document*, if it is applicable to your study*.
* Language that is NOT in a blue box is language that MUST be present in ALL protocol documents, and must remain in your document as is.
* Instructional text boxes are intended to provide you information on what should be included in a particular section and should be deleted once read and replaced with your information.

**TIPS FOR PREPARING YOUR PROTOCOL DOCUMENT**

* Ensure the headings and content remain in the order provided in this template.
* Be mindful of redundancy and repetitive language, as this can lead to an unnecessarily lengthy document.
* Ensure the final protocol document is in Arial 11 pt. font; and in black
* Carefully review the final protocol document to ensure ALL information regarding your project is relayed accurately.

**PRIOR TO SUBMISSION TO THE IRB:**

* **PROOFREAD YOUR DOCUMENT FOR SPELLING, GRAMMAR, AND FORMATTING ERRORS**
* **REMOVE ALL INSTRUCTIONAL TEXT BOXES BY CLICKING ON THE BORDER OF THE BOX AND HITTING THE DELETE BUTTON**

**TO REMOVE INSTRUCTIONAL TEXT BOXES:**

**Click on the border of the box and hit the delete button**

**Title:** Click here to enter text.

**Principal Investigator:** Name

 Address

 Telephone

**Co-Investigator(s):** Name

 Address

 Telephone

**Protocol Version Date:** Month/Day/Year

**Provide requested information for EACH of the following, as applicable**, **then copy and paste into your document. For any non-local personnel, include the name of their institution.**

**Sub-Investigator(s):** Sub-I Name

**Biostatistician:** Name

**Study Drug/Study Device: Generic name followed by marketed name**

**IND/IDE Number: IND / IDE#**

**IND/IDE Holder Name: IND / IDE Holder Name**

**Funding Source**: **Also provide grant #, if applicable**

**NOTE: List ALLsources of funding for investigational agent / device (from sponsor, etc.)**

**Amended: Date revised**

**TO REMOVE INSTRUCTIONAL TEXT BOXES:**

**Click on the border of the box and hit the delete button**

 **document. For any non-local personnel, include the name of their institution.**

**Sub-Investigator(s):** Sub-I Name

**Biostatistician:** Name

l

**Complete any of the following that apply to your study, then copy and paste into your document:**

**Study Drug/Study Device: Generic name followed by marketed name**

**IND/IDE Number: IND / IDE#**

**IND/IDE Holder Name: IND / IDE Holder Name**

**Funding Source**: **Also provide grant #, if applicable**

**NOTE: List ALLsources of funding for investigational agent / device (from sponsor, etc.)**

**Amended: Date revised**

**TO REMOVE INSTRUCTIONAL TEXT BOXES:**

**Click on the border of the box and hit the delete button**

**Introduction:** **Background and Rationale**

***Provide the background of the problem and justification for the study. It is essential to clearly describe the need for research. The following questions will help guide you in completing the background:***

***Why it this study necessary to generate further knowledge?***

***Will this study contribute to existing knowledge?***

***Will this study confirm the basis for additional future research?***

**Hypothesis/Key Questions:**

***Include the following in this section:***

* ***Hypothesis being evaluated***
* ***Key questions being asked in the research.***

**Study Objectives:**

***Describe the purpose, specific aims, and overall objectives of the study. Be sure to include all primary and any secondary objectives****.*

**Study Design:**

**Is your study retrospective or prospective?**

**Retrospective** – A retrospective study uses *data that was* ***already in existence*** *prior to the date the study is submitted to the IRB*

If your study is a retrospective chart review, complete the following and copy and paste the information into this section of your document:

**Retrospective Record Review:** Data (records/charts/patient care episodes) generated between **MM/DD/YY and MM/DD/YY** will be accessed/viewed for the purpose of this study.

**Prospective –** *A prospective study uses data that is not yet in existence prior to the date the study is submitted to the IRB (i.e. events that will occur in the future)*

If your study is a prospective chart review, complete the following and copy and paste the information into this section of your document:

**Prospective Record Review:** Data (records/charts/patient care episodes) generated between **MM/DD/YY and MM/DD/YY** will be accessed/viewed for the purpose of this study.

If the time period for data collection (for prospective studies) does not have an end date, provide an explanation as to why.

**If your study includes both retrospective AND prospective chart review (i.e. you are collecting pre and post procedure data for a particular group of patients):**

* Include the date range for EACH.
* Be very clear in the Study Methods section what charts / data will be accessed and/or collected retrospectively and which will be done prospectively.

**Data Criteria:**

**Proposed sample size** ***(number of records to be reviewed)*:** Insert #

In this section, describe the statistical method/justification for why this sample size is sufficient for you to reach the listed objectives.

**NOTE:** You must have IRB approval to increase your proposed sample size.

**Inclusion Criteria:**

Describe all criteria for inclusion in your study

**Exclusion Criteria:**

**For studies that may involve pregnant women, prisoners, or children: T**he IRB must review all studies involving pregnant women, prisoners or minors in accordance with Subpart B, C or D of the federal regulations:

* If it can be presumed that no subjects will be pregnant, incarcerated, or under the age of 18 during the study, these subparts do not apply.
* If a subject’s status changes during the study (i.e. is incarcerated or becomes pregnant) and the PI is aware, they must either exclude data for that subject, or notify the IRB, as they must re-review the study in accordance with the requirements of subparts B, C or D to ensure proper safeguards are in place for these vulnerable populations.

Describe all criteria for exclusion in your study

**Study Methods:**

Describe:

* The source of records to be reviewed (e.g. McLaren Flint, McLaren Bay Region, etc.)
* How investigators will access records (e.g. will other departments pull charts for the investigator? Will the investigator access charts themselves?)
* How the records to be reviewed will be identified. (i.e. will a unique identifier be used to identify subjects? Will there name be listed?)
* What method will be used to record the data (e.g. spreadsheet )

**Specific data elements to be collected/recorded:**

Describe what information will be collected, for example:

* Unique code (code used to identify each subject individually)
* Personal identifiers (name, DOB, procedure date, account #, etc.)
* Demographics
* Lab tests
* Procedures
* Length of stay
* Drug / Device Utilized
* Diagnosis

**Data analysis:**

Describe how the data will be analyzed and by whom.

**Note:** The IRB will need to see what data points you are collecting and what tools you will be using, such as a data collection form / spreadsheet. Create your form based on the data elements as listed in the section above and upload it to the “Attachments” section of the eProtocol application.

**Confidentiality, Data Management and Storage:**

Describe how data will be stored / confidentiality maintained. Identify whether you will be recording identifiable or de-identifiable information, as shown below.

**Recording identifiable information:**

**Describe the plan to preserve the confidentiality of the data collected:**

* Physical location (e.g. McLaren Flint Family Medicine Clinic)
* Security measures to be implemented (e.g. stored in a locked file cabinet)
* Process for linking coded information (describe your process for coding)
* Storage of master list of codes and coded data (you will want to ensure these are stored separately)
* Storage of electronic data (where / how it will be stored and how it will be labeled)

**NOTE:** Data should not be stored on removable media or mobile devices (e.g. laptop, PDA, portable hard drive, USB/flash drive) if possible. If subject identifiers will be stored in this manner, you must provide justification for the necessity to do so. For more detailed information, see MHC policy MHC\_CC0106 Acceptable Use of Technology Resources Policy

**Specify who will have access to the data. If there is a key for coded information:**

* Who will hold the key?
* Where will the information will be stored?
* Who will have access to the key?

**If identifiable information will be separated from data:**

* How will it be separated?
* At what point in the study will it be separated?

**Describe plans for data retention:**

* How long will data be retained after study completion?
* What is the plan for destruction of data?

\*\*\*For detailed information, see section 6.2 of HRPP Policy [MHC\_RP0114 IRB Documentation and Research Record Retention](http://www.mclaren.org/Uploads/Public/Documents/Corporate/MHC_RP0114_IRBDocumentationAndResearch.pdf))

**OR**

**Recording de-identifiable information: There will be NO link or code associated with the collected/recorded data which could identify the data directly or indirectly.**

**Consent:**

**Describe your plans for consenting of subjects, choosing from the options below:**

**Informed Consent Form**

If your project involves obtaining a signed informed consent form from subjects, describe your process:

* How will information be presented to subjects?
* Who will present the information?
* What process will be used to ensure subjects fully understand? (e.g. subjects will be asked to repeat back the information they have been given)
* Where will the signed consent form be kept?
* Does your consent form contain all elements of consent as outlined in [45 CFR 46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116)?

**NOTE:** Ensure this is consistent with the information you provide in the eProtocol application.

**Waiver or alteration of the informed consent requirements**

If your project includes a consent process that alters any of the informed consent requirements or not obtaining informed consent from subjects, the IRB must ensure that certain criteria are met. You must provide the IRB with justification for **each** of the criteria listed below: (For more detailed information see [Guidance on Requesting a Waiver of Informed Consent Requirements](http://www.mclaren.org/uploads/Public/Documents/waiverofinformedconsentrequirements.pdf))

1. **The research is no more than minimal risk**

Describe why the study poses no more than minimal risk to subjects. Since you are conducting a record review, consider the following while assessing risk and formulating your justification:

* Is the information sensitive in nature?
* Is the data being collected derived from clinically indicated procedures?
* Could information regarding this study pose harm to the subject’s status, employment or insurability?
* Since breach of confidentiality is a common risk in record review scenarios, what precautions are you taking to ensure there is no breach of confidentiality?
1. **The research could not practicably be carried out without the waiver or alteration**

Describe why it would not be feasible to conduct your study without a waiver or alteration of informed consent requirements. Consider the following:

* Are you reviewing a large number of charts?
* Would identifying and contacting each subject to obtain consent be prohibitive?
* Would the information being collected change the care the subjects would have already received?
1. **The waiver or alternation will not adversely affect the rights and welfare of the subjects who are involved in the research.**

Describe why waiving consent or altering the required elements of consent for this project will not adversely affect subjects. Consider the following:

* Are tests / procedures being done only for the purpose of your project or are you collecting data on past (completed) procedures?
* Could the results of your research potentially affect the subject’s care? (keep in mind that data is being gathered / analyzed after the fact)
* Would use of their information deprive subjects of regular care?

**CONT’D ON NEXT PAGE**

1. **Whenever appropriate, the subject will be provided with pertinent information after participation.**

Describe whether information resulting from the study will be disclosed to subjects. Consider the following:

* Will the results from the research have any effect on subjects or their regular care?
* Are there any anticipated benefits with your study that would change care already received?

**Waiver of Documentation of Informed Consent**

If your you are requesting that the IRB waive the requirement of the PI to obtain a signed informed consent form from some or all subjects, your project must meet specific criteria set forth in [45 CFR 46.116c](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116). You must provide the IRB with adequate justification for the criteria you choose. (For more detailed information see [Guidance on Requesting a Waiver of Documentation of Informed Consent](http://www.mclaren.org/uploads/Public/Documents/waiverofdocumentationconsent.pdf) )

**Choose ONE of the following**:

1. **The only record linking the subject and the research would be the consent document and the principal risk of the research would be potential harm resulting from a breach of confidentiality.**

Describe how data will be collected and how the subject’s signature on the consent could result in breach of confidentiality as the primary risk of participation. Consider the following:

* Aside from the subject’s signature on the consent form, is there anything else that may link subjects to this study?

**OR**

1. **The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.**

Describe how participation in your project poses no more than minimal risk to subjects. Consider the following:

* The only risk with record review is the potential breach of confidentiality, which is minimal
* Are you collecting identifiable data?
* Collection of data on past events, requires no procedures to be performed, therefore there would be no necessity for written consent

**Risk and Benefit Assessment:**

**Risks:**

**Describe potential risks and how they will be minimized. For example:**

The potential for a breach of confidentiality exists when conducting a record review.

**Benefits:**

**Describe potential benefits of participation. For example:**

Subjects whose records are reviewed are not likely to benefit from the proposed research; however, society and investigators will benefit from the knowledge gained.

**References:**

Provide a list of all references used while designing your study.

**Appendices:**

List each appendix individually and sequentially, for example:

**Appendix “A”:** **Data Collection Form**

**Appendix “B”: Coded Identifier List**

**Appendix “C”:** **Eligibility Checklist**

Appendices to the protocol document are those documents that support the research plan as described. For example:

* **Data collection forms** – form on which all data elements will be collected, such as a spreadsheet
* **Coded identifier list** – form that would serve as the link between the unique subject code and identifiers collected (e.g. name, medical record number, etc.)
* **Eligibility checklists** - checklists that outline all inclusion and exclusion criteria for your study. The researcher would use the checklist to document their verification of each subject’s eligibility by completing the checklist and keeping it with each participant’s research record. The form may look something like this:

**Inclusion Criteria** – Individuals are eligible to be included in the study only if they meet **all** of following criteria:

\_\_\_ Criteria 1

\_\_\_ Criteria 2

\_\_\_ Criteria 3

**Exclusion Criteria** – Individuals will be excluded from the study if they meet **any** of following criteria:

\_\_\_ Criteria 1

\_\_\_ Criteria 2

\_\_\_ Criteria 3

**NOTE**: Ensure each document listed here is also attached to the eProtocol submission.