**ROWAN UNIVERSITY**

**PROTOCOL TEMPLATE FOR MEDICAL RECORD (CHART) REVIEW**

* **WHEN SUBMITTING THE PROTOCOL, PLEASE DELETE ITEMS LABELED AS GUIDANCE (IN BLUE) ONLY PROVIDE INFORMATION REGARDING YOUR STUDY UNDER EACH OF THE TITLES.**
* **EXEMPT REVIEW IS NOT APPLICABLE FOR MEDICAL CHART/RECORD REVIEW**
* **RECORD/CHART REVIEWS REQUIRE PRIOR APPROVAL FROM ROWANSOM PRIVACY OFFICE AND IRB**
* **DETERMINE WHY YOU ARE REVIEWING RECORDS/CHARTS (SCREENING, PREPARATORY TO RESEARCH VS ACTUAL RESEARCH)**
* **TRY TO LIMIT THE PROTOCOL LENGTH TO NO MORE THAN THREE PAGES BY PROVIDING PERTINENT INFORMATION.**

The following template provides an example (color coded) of developing a research protocol for medical chart review. These templates are for guidance purposes only to provide a general idea of how a protocol may be written to describe:

* Background significance
* A research design or methodology
* Study description of what will happen in the study whether the study involve prospective interviews or anonymous surveys or analyzing existing data and what data will be collected and analyzed
* Risks and benefits
* How you will be obtaining medical records either through the use of Preparatory for Research approval or direct IRB approval
* Describe in a tabular form what medical data elements that will be collected.
* How subjects consented, if consent is required.
* Justify if you are requesting for waiver of consent and authorization
* Statistical Considerations
* Reporting results

Before you start completing an IRB application you should write the protocol for your study using the following official Rowan protocol template. You can obtain this template from the following web-link:[**https://research.rowan.edu/officeofresearch/compliance/irb/submissions/initialsubmissions/index.html**](https://research.rowan.edu/officeofresearch/compliance/irb/submissions/initialsubmissions/index.html)**.**

You will be uploading the protocol into the Rowan-IRB electronic submission. Instructions to upload the protocol are posted on Rowan IRB website: [**https://research.rowan.edu/officeofresearch/compliance/irb/index.html**](https://research.rowan.edu/officeofresearch/compliance/irb/index.html)

The next few pages show the protocol document with examples on how to respond to the questions. Please submit the protocol in WORD format.

**ROWAN UNIVERSITY**

**PROTOCOL TEMPLATE**

**Title of Project:** Click or tap here to enter text.

**Short Title:** Click or tap here to enter text.

**\*Principal Investigator:** Click or tap here to enter text.

**College/School and Department:** Click or tap here to enter text.

**Co-Investigators:** Click or tap here to enter text.

**\*\*Funding Source(s):** Click or tap here to enter text.

**Protocol Version Number and date:** Click or tap here to enter text.

\*Principal Investigator is the person in-charge of the study or the principal investigator of a funded project. Students, post-docs, clinical fellows and residents cannot be principal investigators; however, they could be co-investigators. Co-investigators can develop and complete the IRB application; however, they must be submitted by the principal investigator.

\*\*Funding source is the agency that funded the study. For example, National Science Foundation, National Institutes of Health, Nelson Foundation, etc. If your study is not funded by an external agency, mark it as “Internally/Department funded.”

1. **RECORD REVIEW FOR SCREENING OR PREPARING FOR FUTURE RESEARCH (PREPARATORY TO RESEARCH)**

GUIDANCE: Screening or Preparatory to Research involves reviewing medical records to determine eligibility of subjects based on the study's inclusion/exclusion criteria. You must explain why you need to access PHI prior to enrolling subjects in a study. This request must be made for IRB-approved projects and Investigator Representation for review of PHI for preparatory to research using the “Reviews for Preparatory Research” (RPR) Form. Guidance for Preparatory to Research and the RPR Form is available on the following link: <https://research.rowan.edu/officeofresearch/compliance/irb/policiesguidance/guidancelisting/preptoresearch.html>.

The HIPAA Privacy Officer at RowanSOM verifies that the completed RPR Form is in compliance with the Standard Operating Procedure. If changes are required, the HIPAA Privacy Officer advises the Researcher of the changes needed. If no changes are required, the HIPAA Privacy Officer signs and dates concurrence and returns the RPR Form to the Researcher and retains a copy in the office. Signed RPRs will be reported to the Privacy Board.

Medical records may already exist or may be created prospectively as part of the study. You may review existing medical records to identify potential study subjects, whom you may later contact and ask eligible subjects to participate in your study; however, subject recruitment and consenting requires IRB review and approval.

**Honest broker**: Honest brokers may be used to make sure that subject identity is properly protected. Often Privacy Office may serve as an honest broker by providing only the de-identified data - See Section II.8.2 below for further direction

1. **RECORD REVIEW FOR RESEARCH PURPOSES DEFINITIONS**
2. You should work closely with the IRB to determine the requirements for both portions Retrospective Chart Review - evaluates patient data that is existing at the time the protocol is submitted to the IRB for initial approval. This type of chart review uses information that has usually been collected for reasons other than research.
3. Prospective Chart Review - evaluates patient data that DOES NOT YET EXIST at the time the protocol is submitted to the IRB for initial review.
4. Combination - Some studies may involve a combination of both retrospective and prospective chart reviews of the study and develop a plan to stay in compliance if requirements are different for each portion.

**PROTOCOL TEMPLATE FOR RECORD OR CHART REVIEW FOR RESEARCH PURPOSES**

**1. PURPOSE AND RATIONALE**

GUIDANCE: Clearly state the overall purpose and rationale behind the study. Avoid the use of acronyms and highly technical language where possible. Also state the rationale behind the study making it specific to the study. In general, rationale corresponds to closing the gap or solving a specific problem or advance knowledge in the specific area of research.

**Medical Chart review Example:** The purpose of this research study is to evaluate the cumulative survival rate after 10 years of peritoneal dialysis or hemodialysis. This is a retrospective chart review study with the following specific aims:

A. To compare cumulative survival rates after peritoneal dialysis;

B. To determine whether cumulative survival rate after peritoneal dialysis is equivalent or better than hemodialysis based on their residual renal functions and

C. To determine whether age and gender have any effect in cumulative survival in patients on hemodialysis compared to hemodialysis.

The rationale behind the study is to understand why the age and gender are contributing factors to survival in patients undergoing dialysis for kidney diseases.

**2. BACKGROUND AND SIGNIFICANCE**

GUIDANCE: Provide a succinct review of the relevant scientific literature to justify the proposed study. Include key references but not a complete literature review. Medical chart reviews must provide background for research and explain why you are conducting the chart review and why it is significant. Address the importance of obtaining such knowledge to your field of science or society in general.

**Medical Chart review Example:** Provide a literature survey using very pertinent references to justify the proposed study. Include any historical data in support of the proposed study and describe the significance. Try to limit your narration to one page giving pertinent references.

**3. STUDY OBJECTIVES**

GUIDANCE: Primary Objective: Outline specifically what will be achieved by the study—that derive directly from the overall purpose. List the primary objective and secondary objectives in bullets.

**Medical Chart Review Example:**

* **Primary:** The overall objective of this study is to determine whether peritoneal dialysis is equivalent to or better than hemodialysis.
	+ **Secondary:** Our secondary objective is to determine the cumulative survival rates based on their residual renal functions.

**4. HYPOTHESES**

GUIDANCE:State expected relationships between variables— that are testable and include measurable outcomes/endpoints as described in the Research Design and Methods section of the protocol. Hypotheses correspond directly to the objective(s).

**Medical Chart Review Example:** We hypothesize that peritoneal dialysis yields equal or better cumulative survival compared to hemodialysis irrespective of age and gender.

**5. RESEARCH DESIGN AND METHODS**

GUIDANCE: Provide a brief overview of the entire study design including various phases of the study (if more than one). Describe the procedure if randomization or blinding is used. Describe your design specific to your study. Describe how you will be interpreting results. Provide or upload all study instruments that are being used specifically for the purpose of the research. Include copies of all tests and questionnaires. For study specific measurements or data points, list them individually and give a brief justification of why each one is needed. Describe how your research methods that are specific to the study affect research risks, harms and benefit to subjects. Justify how this design addresses the research objectives and hypotheses. If applicable, describe procedures for randomization and blinding. Describe the procedure for obtaining information for charts such as approval from the Privacy Officer using the RPR Form (See link above in Section I of this template) If permission from the privacy office has already been secured, upload the approval letter.

**6. STUDY DURATION, ENROLLMENT AND SITES**

GUIDANCE: It is important that you describe how long the study may take. Estimate the duration as closely as possible. Duration includes the length of time to complete the study as well as length of time with respect to span of years charts will be reviewed. Do not include the estimated time for the data analysis phase since data analysis time is no longer required by the IRB.

**6.1 Duration**

**Medical Chart Review Example:** We will be reviewing approximately 1000 medical charts from September 1, 2008 through August 31, 2019. This study will take approximately one year to complete.

**6.2. Enrollment**

GUIDANCE: Describe total number of charts you anticipate to review. Describe if there are any gender, age, race, religion, etc. and specific information you will be collecting. Justify why?

**Medical Chart Review Example:** In this retrospective chart review we will use existing data that have been recorded in the medical chart. We will be reviewing 1000 charts of patients who have undergone either peritoneal or hemodialysis from year 2004- 2014. We will extract clinical information and survival data, age and gender from each patient’s health records.

**6.3 Medical Chart Repository**

GUIDANCE: List locations/sites where the records are held and the process for obtaining information. If you have secured permission from a non-Rowan site, you must upload the permission letter from the non-Rowan source in the CIRB application**.**

**Medical Chart Review Example:** Medical charts will be obtained from the nephrology clinic at Rowan University School of Osteopathic Medicine.We will obtain permission from the HIPAA Privacy Office using the form entitled “Preparatory to Research” prior to collecting data from charts.

**7. MEDICAL CHART SUBJECT INFORMATION**

**7.1 Population**

GUIDANCE:Identify study populations (including age range, gender, and ethnic background), the inclusion and exclusion criteria. In addition, justify the inclusion of targeted persons (e.g., healthy participants, employees, students or participants with certain medical conditions). Describe if information is gathered from a specific population including using charts of vulnerable population.

**Medical Chart Review Example:** This is a Chart review study involving a population who suffer from kidney diseases. There is no direct recruitment of subjects; however, existing anonymous data from RowanSOM clinic that treats patients with kidney diseases will be extracted and analyzed

**7.2 Recruitment**

GUIDANCE: Please consider the following ethical questions or recruitment strategies. Make sure that the selection of medical charts individual’s reasonable expectations for privacy.

**Medical Chart Review Example:** This is a chart review. We will not be recruiting study subjects rather we will be redacting data from charts with or without identifiers. With identifiers requires proper consenting. Without identifiers requires waiver of consent, waiver of documentation of consent and waiver of HIPAA authorization.

**7.3 Accessing Medical Charts**

GUIDANCE: For studies involving medical chart reviews, describe how medical charts will be accessed, what you will doing with the identifiers, explain whether a consent/HIPAA authorization is needed or a consent/authorization waiver is needed to access records. Provide a data collection instrument even if they are non-clinical charts or data sources in the form of an Excel spreadsheet to indicate what data is being collected. Collection of social security number is not permitted.

**Medical Chart Review Example:** This is a chart review. We will not be recruiting study subjects rather we will be redacting data from charts. A process for accessing charts/records includes the following steps: (Describe the process here). A data collection instrument is also attached. Access requires permission from the Privacy Office. Use PRT form to secure protected health information.

**7.4 Inclusion Criteria**

GUIDANCE: You must specify inclusion and exclusion criteria for selecting charts.

**Medical Chart Review Example:** We plan to collect data from 100O charts irrespective of the age, gender or ethnicity.

**7.5 Exclusion Criteria**

GUIDANCE: Describe who will be excluded from the study, why they will be excluded taking into consideration their demographic, biomedical or disease characteristics.

**Medical Chart Review Example:** We will use all charts without any exception or comorbidity associated with kidney disease.

**8. INFORMED CONSENT**

GUIDANCE: Regulations and ethical considerations require obtaining an informed consent from prospective subjects before they include these subjects in research. Informed consent is a dynamic interactive and educational process that takes place between the investigator and prospective subject, allowing the investigator and the participant to exchange information and ask questions and subjects to make a voluntary and informed decision whether to participate in the study. In all cases a copy of the informed consent must be provided before consent and adequate time must be provided for the subject to make an informed decision. In most cases, federal regulations require informed consent and documentation of the process. In certain circumstances, the federal regulations allow a waiver of informed consent documentation of the process. Request for waiver must be granted by the IRB.

Medical chart reviews with protected health information with identifiers requires HIPAA authorization or HIPAA waiver of authorization when appropriate. RowanSOM Privacy Officer or RowanSOM IRB will make the final determination.

**8.1 Waiver of Consent for Retrospective and Prospective Data Collection/Chart Review:** GUIDANCE:Most retrospective and prospective chart reviews quality for expedited review according to 45 CFR 46.110 category 5 if:

A. the research involves no more than minimal risk AND

B. the research involves materials (data, documents, records, or specimens)

 that have been collected, or will be collected solely for non-research

 purposes.

A Waiver of Informed Consent is frequently requested for both retrospective and prospective data collection. In order for the IRB to approve a Waiver of Consent, the following criteria must be met:

A. research is no more than minimal risk;

B. the waiver or alteration will not adversely affect the rights and welfare of

 the subjects;

C. the research could not PRACTICABLY be carried out without a waiver; AND

D. when appropriate, the subjects will be provided with additional

 information after participation.

Studies that meet the Criteria for Waiver of Consent, also meet the Waiver of HIPAA Authorization.

 **8.2 Honest Broker:**

GUIDANCE: Please NOTE that researchers may use an honest broker system. In such cases, the honest broker accesses the desired medical record information on behalf of the PI and provides the PI with an appropriately de-identified data set - either a completely de-identified data set ("HIPAA Safe-Harbor") or a data set that includes patient-specific dates and/or geographical information ("Limited Data Set"). Contact the Privacy Office for further guidance on honest broker system and limited data sets.

**Medical Chart Review Example:** This study involves review of medical charts. In order to extract medical information form the chart, I have obtained permission from the Privacy Officer that described the data elements I will be extracting without identifiers. I have uploaded the permission from the Privacy Officer at RowanSOM. I am also requesting for waiver consent since my study is minimal risk. This research will not affect the rights and welfare of subjects. I cannot practically conduct this research if consent or authorization is required. I do not believe that this research requires any reporting of results to prospective subjects. I am also requesting waiver of documentation of consent. I understand that IRB will make the final determination on waiving documentation of consenting.

**9. RESEARCH COSTS TO SUBJECTS AND COMPENSATING RESEARCH SUBJECTS**

GUIDANCE: Medical chart review research studies do not involve costs to participate in a research or providing compensation to research subjects.

**Medical Chart Review Example:** This study involves review of medical charts; therefore, there is no cost to participate in the study nor we will provide any compensation to subjects.

**10. STATISTICAL CONSIDERATIONS**

**10.1 Sample size**

GUIDANCE: Sample size refers to how much data is needed to make a correct decision on particular research. When adequate amounts of data are collected, then the decision will be more accurate. There will be less error of the parameter estimate. Provide statistical justification for the sample size (considerations include desired power and, as appropriate, assumed effect sizes for a hypothesis testing study; precision for a study whose objective is to estimate a population parameter.

**Medical Chart Review Example:** For epidemiologic studies using charts and surveys you may use the following website to select sample size determination. <http://smm.sagepub.com/content/4/4/311>.

**10.2 Study Variables and Outcome**

The following sections under 10.2 are only guidance. Include appropriate responses based on your study variables.

GUIDANCE: All research projects are based around variables. A variable is the characteristic or attribute of an individual, group, educational system, or the environment that is of interest in a research study. Variables can be straightforward and easy to measure, such as gender, age, or course of study. Other variables are more complex, such as socioeconomic status, academic achievement, or attitude toward school. Therefore, once the general research topic has been identified, the researcher should identify the key variables of interest.

Outcome variables are usually the dependent variables which are observed and measured by changing independent variables. These variables determine the effect of the cause (independent) variables when changed for different values. The dependent variables are the outcomes of the experiments determining what was caused or what changed as a result of the study.

**10.3 Independent Variables**

GUIDANCE: Describe any behavioral treatments or interventions to be compared for their effects on participants. If the study is chart reviews, indicate how you will be comparing various factors associated with the research question or previous reviews. NOTE: Some behavioral studies may involve interventions to be compared for their effects on participants.

**10.4 Dependent Variables or Outcome Measures**

GUIDANCE: A Dependent variable is what happens as a result of the incidence of kidney diseases, diet is the independent variable while kidney disease is the dependent variable.

**10.5 Confounding Variable**

GUIDANCE: A confounding variable, or confounder, affects the relationship between the independent and dependent variables. A confounding variable in the above example would be differential exposure to other factors that increase kidney disease such as smoking or consuming alcohol.

**10.6 Data Handling and Analysis**

GUIDANCE: Data handling is the process of ensuring that research data is stored, archived or disposed-off in a safe and secure manner during and after the conclusion of a research project. This includes the development of policies and procedures to manage data handled electronically as well as through non-electronic means. Data analysis plan should include data entry and final statistical analysis of data with respect to study endpoints. If data includes protected health information or personal identifiers, provide a plan when the link to data source and data will be destroyed.

**Medical Chart Review Example**: Data will be analyzed using quantitative methodologies. In most instances, only descriptive statistics will be reported, however, when appropriate more advanced data analysis may take place (t-tests) to determine differences based on student populations. All data will be reported in aggregate and confidentiality will be protected. We will keep all our data in a secure or in an encrypted and password protected environment with access limited to the study team. Or, we will store our data in by keeping the data and signed consent forms in separate cabinets with access only to study team.

**11. RISKS AND POTENTIAL BENEFITS**

**11.1 Risks**

GUIDANCE: In human subject research, research is categorized into two categories: Minimal risk or Greater than minimal risk. Research is considered minimal risk when the risks of the research are not greater than those experienced in regular daily life. Researchers are responsible for identifying any possible risks of the research and minimizing risks to subjects whenever possible. Some common types of risks are: physical, economic risk, social, psychological, legal and loss of confidentiality. Include strategies to eliminate risk by keeping data in secure places, limiting access to data by designating individuals who will have access to data and conducting procedures that are specific to the study. Strategies to minimize risk should include use of existing records or specimens, obtaining a Certificate of Confidentiality to minimize the likelihood of forced disclosure of sensitive materials, coding data and samples to conceal identifiers and limiting access to research data.

**Medical Chart Review Example:** There is no physical risk of harm. However, there may be a distinct possibility of breach of confidential information that was collected. Describe a procedure by which you will preserve confidentiality. This may involve collection of anonymous data and storing data in a place that is secure.

**Alternate language example:** This is a minimal risk study. There are no physical dangers to respondents. There is the potential for participants to be identified, given our access to their personal identifiers. These risks will be minimized by maintaining identifying information in separate, password-protected files to which only the research team will have access.

**11.2 POTENTIAL BENEFITS**

GUIDANCE: In the context of research, there may be three types of benefits, use the appropriate type of benefit described below for your study.

1. Direct Benefit: A benefit arising from receiving the intervention being studied. Any study that involves an intervention could have an anticipated direct benefit. In these studies, participants may receive some intervention (medical, behavioral, or other), that they would not otherwise receive. When describing the anticipated benefits of research in the protocol and consent document, it is important that researchers make subjects aware that the benefits of the intervention are not known, and that the research is being conducted to evaluate the effectiveness of the intervention. Whenever possible, the researcher should provide any known information about the probability and magnitude of the anticipated benefit.
2. Indirect Benefit: This occurs when research does not involve an intervention there is little opportunity for direct benefit. When the risks of the research are no greater than those encountered in everyday life, there is no requirement for direct benefit. When the research risks are greater than minimal risk, then the researcher must provide justification that explains how the anticipated benefits of the research justify the risks to the subjects. Indirect Benefits such as collateral benefit arising from being a subject, even if one does not receive the experimental intervention (for example, a free physical exam and testing, free medical care and other extras, or the personal gratification of altruism).
3. Aspirational benefit like benefit to society and or future patients, which arises from the results of the study.

**Medical Chart Review Example:** There may not be any direct benefit. Results of our study may help enhance our ability to develop some guidelines with respect to …………………….that would in general benefit the society.

**12. DATA AND SAFETY MONITORING**

GUIDANCE: This section is not applicable to minimal risk studies such as chart reviews, questionnaires, surveys that are part of social, behavioral and education research.

**13. MOBILE / CLOUD / WEARABLE HEALTH RESEARCH**

When researchers use the online environment and digital tools (apps, wearable technologies, and mobile phones) to obtain data for health-related research they should use privacy-protective measures to protect individuals from the possibility that their personal information is directly revealed or otherwise inferred when datasets are published, shared, combined, or linked.

Mobile health researchers should implement reasonable administrative, physical, and technical safeguards designed to protect the security of participant data. The investigators should review applicable resources, such as, End User License Agreement (EULA), Terms of Conditions, Privacy Policies, etc. to outline the data fields being collected by the device/app and separate it from the data collected by researchers. This should also be included in the consent document so that the subject is aware what information about them is being collected by researchers and what is being collected by the third party.

**PLANS FOR REPORTING OR PUBLISHING RESULTS**

GUIDANCE:It is a good practice to describe your plan for reporting aggregate of results in a publication

**14. BIBLIOGRAPHY**

GUIDANCE: Include all references cited in the text. Keep it specific to the study.

**15. APPENDICES**

GUIDANCE: Include here any additional information such as flow charts, diagrams, instruments, etc., that is related to the protocol, but is not applicable or does not appear to fit into one of the sections such as flow charts, diagrams