**ROWAN UNIVERSITY**

**PROTOCOL TEMPLATE FOR SECONDARY USE OF BIOSPECIMENS AND IDENTIFIABLE PRIVATE INFORMATION**

* **THIS PROTOCOL TEMPLATE MUST BE USED FOR THE SECONDARY USE OF BIOSPECIMENS AND PRIVATE IDENTIFIABLE INFORMATION**
* **WHEN SUBMITTING THE PROTOCOL, PLEASE DELETE ITEMS LABELED AS GUIDANCE (IN BLUE) ONLY PROVIDE INFORMATION REGARDING YOUR STUDY UNDER EACH OF THE TITLES ON THIS TEMPLATE**
* **EXEMPT REVIEW MAY BE APPLICABLE FOR SOME RESEARCH**
* **RECORD/CHART REVIEWS MAY BE REVIEWED AS EXPEDITED REVIEW**
* **SOME PRIVATE IDENTIFIABLE INFORMATION MAY FALL UNDER HIPAA REGULATIONS. SUCH REQUESTS REQUIRE PRIOR APPROVAL FROM ROWANSOM PRIVACY OFFICE AND IRB**
* **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 review for secondary use of biospecimens and identifiable private information. Protocol template provides guidance for 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(s) 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 bio-specimens or private identifiable information that are existing or prospectively collected.
* Describe in a tabular form what medical data elements that will be collected.
* How subjects are 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 must upload the protocol into CAYUSE IRB. Instructions to upload the protocol are posted on Rowan IRB website: [**https://research.rowan.edu/officeofresearch/compliance/irb/submissions/initialsubmissions/index.html#A1**](https://research.rowan.edu/officeofresearch/compliance/irb/submissions/initialsubmissions/index.html#A1)

**Upon completion of your protocol, please remove all instructions, guidance, and examples text before attaching to your Cayuse IRB submission.**

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**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 you are 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 approved by the principal investigator and submitted.

\*\*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. **SECONDARY USE OF BIOSPECIMENS AND PRIVATE IDENTIFIABLE INFORMATION**

GUIDANCE: This guidance provides examples of research projects that may fall under the definition of secondary use of bio-specimens and private identifiable information. These include:

1. Use of publicly available bio-specimens and identifiable information.
2. Secondary use of bio-specimens and private identifiable information that are recorded as de-identified for secondary use purposes.
3. Use of bio-specimens and private identifiable information are recorded with identifiers with or without containing protected health information.
4. Secondary use of bio-specimens and private identifiable information where identification is removed or identification is unclear.
5. You should work closely with the IRB to determine the requirements for secondary use of bio-specimens and private identifiable information for both existing and prospective collection.
6. For prospectively collecting bio-specimens and identifiable private information as part of a research you must use the standard protocol template and adult/parental consent form and if necessary, child’s assent.
7. Sometimes bio-specimen and private identifiable information may have been collected as part of another IRB-approved study. In such cases, it is imperative that investigators review the original consent to ensure that subjects have agreed to use or provide their samples and private identifiable information for another research project or other researchers. IRB will make sure that the secondary use of existing bio-specimens and private identifiable information has been agreed upon at the time of consent.

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

**II. PROTOCOL TEMPLATE FOR SECONDARY USE OF BIOSPECIMENS AND IDENTIFIABLE PRIVATE INFORMATION**

**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 to solve a specific problem or advance knowledge in the specific area of research.

**Example**

The purpose of this research study is to evaluate ………… with the following specific aims:

A. To compare……………….

B. To determine…………………..

C. To determine whether age and gender have any effect with respect to …..

The rationale behind the study is to understand ……………………………………….

**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. Secondary use of bio-specimens and identifiable private information 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.

**Example:** I have conducted an appropriate survey using very pertinent references to justify the proposed study. I have included 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.

**Biospecimen 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 includes measurable outcomes/endpoints as described in the Research Design and Methods section of the protocol. Hypotheses correspond directly to the objective(s).

**Example:** We hypothesize that analysis of those bio-specimens will yield the following information…..

**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 your design specific to your study and how you will be interpreting results. Describe the database(s) that will be utilized, including the specific sources from which you will collect data or samples. Include in your description whether you will use data from RowanSOM or its affiliated clinical entities or from an IRB protocol that was previously approved [provide IRB protocol number].

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. If biological materials are involved please describe all the experimental procedures and analyses in which they will be used. Describe how your research methods that are specific to the study affect research risks, harms and benefits 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 (private identifiable information or PHI) 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.

If you wish to perform genetic analysis of the bio-specimen, please contact the IRB Office to obtain appropriate guidance. The guidance to inform subjects about genetic analysis is also provided on the adult consent form and parental consent form. Go to the following link:

<https://research.rowan.edu/officeofresearch/compliance/irb/submissions/consenttemplates/index.html>.

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

* 1. **Duration**

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 bio-specimens and identifiable private information will be used. Do not include the estimated time for the data analysis phase since data analysis time is no longer required by the IRB.

**Example:** We anticipate that the study may take approximate to complete all of the analysis.

**6.2. Enrollment**

GUIDANCE: Describe total number of bio-specimens and identifiable private information you anticipate to use. Describe if there are gender, age, race, religion, etc. and specific information you will be collecting. Justify why?

**Example:** We are not directly enrolling subjects. However, we are collecting specimens from gender, age, race etc. for this study.

**6.3 Specimen Repository**

GUIDANCE: List locations/sites where bio-specimens and identifiable private information are held and the process for obtaining such specimens and information. If you are obtaining bio-specimens and identifiable private information from a non-Rowan site or another investigator at Rowan or a collaborator from another institution, you must upload the permission letter from the non-Rowan source or another Rowan or non-Rowan Collaborator in the CIRB application**.**

**Example:** Specimens are held in my collaborator’s repository at……………….

**7. SUBJECT INFORMATION**

**7.1 Population**

GUIDANCE:Identify study populations (including age range, gender, ethnic background and disease characteristics), 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 use of bio-specimens and identifiable private information on vulnerable population.

**Example:** I am specifically interested in samples from patients who have………… These are not vulnerable population.

**7.2 Recruitment**

GUIDANCE: Please consider the following ethical question for secondary use strategies. Make sure that the use of bio-specimens and identifiable private information meets the individual’s reasonable expectations for privacy and confidentiality.

**Example**: There is no direct recruitment of subjects in this study.

**7.3 Accessing bio-specimens and identifiable private information**

GUIDANCE: For studies involving ………… describe how bio-specimens and identifiable private information will be accessed, what you will doing with the identifiers, explain whether a consent/HIPAA authorization is needed (for prospective collection) 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.

**Example:** I do not require any identifiable information associated with the specimen.

**7.4 Inclusion Criteria**

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

**Example:** We plan to collect/use data from 100 specimens and information 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 by taking into consideration their demographic, biomedical or disease characteristics.

**Example:** We will use specimens and information specific to ……….. 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 for the 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.

Bio-specimens and identifiable private information with protected health information containing 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**

GUIDANCE:Most bio-specimens and identifiable private information studies fall under expedited review according to 45 CFR 46.110 category 5 of 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 should be requested if bio-specimens and identifiable private information do not contain identifiers.

**8.2 Honest Broker:**

GUIDANCE: Please NOTE that researchers may use an honest broker system. In such cases, the honest broker accesses the desired bio-specimens and identifiable private 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 systems and limited data sets.

**Example:** This study involves the analysis of bio-specimens and private identifiable information. In order to extract private medical information from 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.

**9.0 RESEARCH COSTS TO SUBJECTS AND COMPENSATING RESEARCH SUBJECTS**

GUIDANCE: Most bio-specimens and identifiable private information research studies do not involve costs to participate in a research or providing compensation to research subjects.

**Example:** This study involves secondary use of bio-specimens and private identifiable information; 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.

**Example:** Our justification for sample size is as follows…….

**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 independent variable. For example, if you want to explore whether diet impacts on 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.

**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 by keeping the data and signed consent forms in separate cabinets with access only to the 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.

**Example:** There is no physical risk of harm. However, there may be a distinct possibility of breach of confidential information that was collected. The procedure to preserve confidentiality is as follows….. I will store 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, therefore, 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.

**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.

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.

**12. OBTAINING AND TRANSFER OF BIOSPECIMENS AND PRIVATE IDENTIFIABLE INFORMATION**

GUIDANCE: Transfer of bio-specimens from Rowan University to another organization for research purposes and receipt of bio-specimens from an outside organization for your researchmust adhere to policies for material transfer and biological materials (<https://research.rowan.edu/officeofresearch/commercialization/inventor/forms.html>.)

**12.1 Obtaining Bio-specimens**

GUIDANCE: Describe your plan if you are receiving bio-specimens from an external entity for this research. If yes, please confirm that you have secured Material Transfer Agreement (MTA) from Rowan’s Technology Commercialization Office. This generally includes the nature of the research collaboration with the external entity and the rationale for the transfer. This also must include an explanation of your intellectual contribution to the design of the research study, resulting data and sharing, and participation in the planned publications. If not, state that you will not be receiving bio-specimens from an external source.

**Example:** I will be obtaining bio-specimens and private identifiable information from……

Specimens are de-identified before they are sent to me. I do not require associated clinical or other information with specimens. I have secured the MTA for this purpose.

**12.2 Transferring Bio-specimens**

GUIDANCE: If you are transferring bio-specimens collected at any of the premises of Rowan University, you intend to transfer were originally collected at Rowan University, please complete the Bio-specimen Transfer Information sheet and upload the completed form and relevant IRB approval letter and consent form.

**Example:** I am transferring de-identified bio-specimens to my collaborator at …….. The specimen transfer form is attached.

**13. 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