Initial Review Submission Packet (Version 1.0)

1.0 Submission Packet to the Review Board

1.1 IRB Reference Number (Auto Applied):

1.2 Study Title:

Retrospective Chart Review Example

1.3 Principal Investigator:

Ronald Roemer

1.4 * Lay Summary:

This should be a short three to four paragraph summary of the proprosed study.

- Purpose of the study
- How the study will be conducted
- Anticpated results

2.0 Application

2.1 * Attach / Review your completed application for this study:

Edit/ View	Version	Title
	1.0	STUDY APPLICATION (Version 1.0) - Attached

3.0 Informed Consent

3.1 Type of Consent to be utilized for this study:

- ○ Obtaining Informed Consent
- ◉ Requesting a Waiver or Alteration of Informed Consent

4.0 Request for Waiver or Alteration of Informed Consent

Informed consent is one of the fundamental principles that underlie and guide the conduct of ethical research involving human subjects and is mandated by Federal regulations (45 CFR 46). An investigator is permitted to request a waiver of informed consent, or required elements thereof, under certain circumstances in accordance with 45 CFR 46. In each instance, rationale must be provided to the IRB for requesting a waiver of informed consent. The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that ALL of the following conditions are met:

4.1 What type of Waiver is being requested?

- (•) Waiver of Informed Consent
- ( ) Waiver or Modification of specific elements of informed consent

4.2 Waiver of Informed Consent Justification – Proved justification for items 1-4 below:

The research involves no more than minimal risk to the subjects.

This is a retrospective chart review and by definition is minimal risk. The only risk is a breach of confidentiallity which is mitigated by utilitzing a Coded Identifier List and a Data Collection Tool, which will be stored separately with password protection and only study team members will have access.

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

Subjects rights will not be adversely affected as all data collected is retrospective. It will not change any treatment to subjects and all data will be de-identified when published.

The research could not practically be carried out without the waiver or alteration.

As a retrospective chart review obtaining informed consent is impracticable.

Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

There is no direct benefit to subjects and participating subjects will not be contacted and/or provided with any additional information when the study is completed.

5.0 Study Documents

5.1 Attach all study documents to include with the initial review submission packet: Protocol, Informed Consents(s), HIPAA Authorizations (if seperate),Assents, Investigator Brochures, Device Manuals, Recruitment Materials, and all other documents that need to be reviewed and approved by the sponsor.

Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.						

STUDY APPLICATION (Version 1.0)

1.0 General Information

***Please enter the full title of your study:**

Retrospective Chart Review Example

***Please enter the Study Number you would like to use to reference the study:**

Chart Review Example
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add Department(s)

2.1 List departments associated with this study:

Primary Dept?	Department Name
◉	**UMCSN** - CTO

3.0 Assign key study personnel (KSP) access to the study

3.1 *Please add a Principal Investigator for the study:

Ronald Roemer

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

B) Research Support Staff

3.3 *Please add a Study Contact:

Roemer, Ronald

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

4.0 Direction

4.1 * Indicate the Study Type:

- (•) Investigator Initiated Protocol
- ( ) Industry Sponsored Protocol
- ( ) Grant Supported Protocol
- ( ) Government Supported Protocol
- ( ) Central IRB Study

Is this Protocol Funded?

- ( ) Funded
- (•) Non-Funded

4.2 *** Is this a socio/behavioral or allied health study?**

( ) Yes (•) No

4.3 *** Does the activity include the use or storage of tissue or body fluids which will be used only for research purposes and which will be processed at the UMC laboratory?**

( ) Yes (•) No

4.4 *** Does this research involve gene therapy or genetic testing?**

( ) Yes (•) No

If **YES**, are you submitting a separate consent for the gene therapy/genetic testing?

( ) Yes ( ) No

4.5 **Does this study involve the use of an investigational drug and/or device?**

( ) Yes (•) No

4.6 **Is this a chart review protocol?**

(•) Yes ( ) No

If yes,

- (•) Retrospective
- ( ) Prospective

5.0 Protected Health Information (PHI)

5.1 **What are your sources of PHI? (Choose all that apply)**

- [ ] Physician records
- [x] Hospital records
- [ ] Billing records
- [ ] Clinical records
- [ ] Mental health records
- [ ] Laboratory results
- [ ] Biological samples

- [ ] Pathology results
- [ ] Radiology results
- [ ] Interviews, surveys or questionnaires
- [ ] Other, please describe below
- [ ] No PHI will be utilized

If other, please describe:

5.2 **If using data previously collected, enter the date range of data collected?**

Beginning Date:

01/01/2020

Ending Date:

12/31/2023

5.3 You will require access to PHI for the following reasons? (Choose all that apply)

- [ ] The identification of elilgible subjects
- [x] The conduct of the study

5.4 Do you need access to the entire medical record and/or health information database?

- (•) Yes
- ( ) No

If not, list the portions of the medical record and/or health information database your require access for recruitment:

5.5 It is assumed that all personnel currently associated on this study will request and/or use the collected PHI. Do you plan to use any other person to request or collect PHI?

- ( ) Yes
- (•) No

5.6 **Have all persons associated with this study completed UMC's approved CITI training courses?**

- (•) Yes
- ( ) No

5.7 PHI will be shared with the IRB and the Clinical Trials Office (CTO). Please identify any other person or groups with whom the PHI will be shared or disclosed:

- [ ] Other investigators
- [ ] Registries
- [ ] Study sponsor
- [ ] CRO
- [ ] Study monitor
- [ ] Laboratory
- [ ] Governmental Oversight Agencies
- [ ] Public Health Agencies

- [ ] IRB other than the UMC IRB
- [x] Other, please describe below

If other, please describe:

None

5.8 Provide the date and/or event by which you will no longer need to use the collected PHI:

Date:

Event:

Study Publication

6.0 HIPAA Part 1

6.1 Will you be collecting from the patient chart or requesting from UMC any of the following HIPAA identifiers?

- [x] Name or initials
- [ ] Geographic identifiers such as street address, zip code, etc.
- [x] All elements of dates such as DOB, admission date, etc. (except year)
- [ ] All elements of dates for persons over 89 years of age including year
- [ ] Telephone, fax, cell phone numbers
- [ ] Email, URL, IP addresses
- [ ] Social Security Number
- [x] Medical records numbers
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate or license numbers
- [ ] Vehicle identification number, serial number or license plate number
- [ ] Biometric identifiers
- [ ] Full face photographic images
- [ ] Any other unique identifying nymber, characteristic or code
- [ ] No HIPAA Identifiers will be utilized

6.2 Check the HIPAA Authorization Type you will be utilizing:

- (•) Not Applicable
- ( ) Stand-alone document
- ( ) Incorporated in the consent document(s) (Recommended)

6.3 Check the type of HIPAA Waiver you are requesting:

- (•) Complete HIPAA waiver for the entire study
- ( ) Partial HIPAA waiver for identifying potential subjects and determing eligibility
- ( ) No HIPAA waiver

6.4 When will the authorization expire?

12/31/2024

6.5 Identifiers will be destroyed upon completion of: (Choose all that apply)

- [ ] Identification of eligible subjects for recruitment
- [ ] Subject participation and end of any record-keeping requirements
- [ ] Conduct of protocol
- [x] Data analysis
- [ ] FDA approval and/or end of any record-keeping requirements
- [ ] Specimen processing
- [x] Other, please describe below

If other, please describe:

Study publication

7.0 HIPAA Part 2

7.1 Describe why the research cannot be practicably conducted without authorized access to PHI?

Patients will be identified for inclusion from Epic -- PHI is needed to access charts for collection of specific information related to the study as defined by the protocol.

7.2 Describe how the privacy of the PHI will be protected?

This study will be a retrospective review of data that is already collected for clinical purposes. Individual datasets will be entered into a de-identified, password-protected electronic spreadsheet (database). A separate identification key spreadsheet (password-protected) with medical record number (MRN) and dates linked to study ID# (random), will be maintained until completion of data collection. The de-identified database will be used for data analysis. The spreadsheet will be stored separately on a password protected share drive at UNLV (or UMCSN).

7.3

The investigator believes the use or disclosure of the PHI for the study represents no more than a minimal risk to the privacy of the subject because

Identifiers are protected against improper use or disclosure by the following means: (Choose all that apply)

- [ ] Research team members will sign Confidentiality Agreements
- [x] Information will not be disclosed unless it is scrubbed of all identifiers
- [ ] Only coded data will be disclosed, and agreement is in place where only covered entity will have coding list

7.4 If identifiers will NOT be destroyed, then explain why they must be retained (e.g., longitudinal study, specific federal requirements, etc.)

8.0 Conflict of Interest

8.1 Is any licensed UMC intellectual property used in this project?

○ Yes ◉ No

8.2 Does the PI/Project Director, any individual listed as Senior/Key Personnel on the grant/contract, and/or any individual identified by the PI/Project Director as having responsibility for and substantial independence in decision making for the design, conduct or reporting of this protocol (including spouse, same-sex domestic partner and/or dependent children, individually or in aggregate) have any of the following financial relationships with (a) the study sponsor; (b) a company whose products or services are used or studied in the research; and/or (c) the technology being studied. Select YES if any of the following apply:

- **Payments of $5,000 or more including salary; consulting fees; honoraria; and/or gifts received within the past 12 months or**

  anticipated for the next 12 months (excluding salary, grant support, and other payments for services received from UMC)

- **Equity or ownership interest (including stock options) valued at $5,000 or more as determined by reference to the entity's publicly**

  listed price (excluding mutual funds)

- **Any equity or ownership interest in an entity if the entity's value cannot be determined by reference to publicly listed prices (e.g.,**

  privately-held companies, such as start-up companies)

- **A position as director, officer, partner, trustee, employee, or any other position of management**

- **Receipt of licensing fees or royalties from intellectual property rights (patent, copyright, trademark, trade secrets, etc.) that are more than $5,000 annually from an entity or for a technology related to an Investigator's teaching, research, administrative, or clinical duties**

  at UMC

- **Any compensation whose value could be affected by the outcome of the research.**

Member of the study team has conflict of interest:

○ Yes ◉ No

If yes, please provide the detailed rationale for how this conflict will be managed and how subjects will be made aware of the conflict: