



# CHART REVIEW FAQ'S: A GUIDE FOR SUBMISSION TO THE BUMC IRB

Senior IRB Analyst Matthew Ogrodnik  
[maogrodn@bu.edu](mailto:maogrodn@bu.edu), 617-414-1316

# REVIEW PATH DETERMINATION

- There are two review paths for chart review studies:
- Exempt, Category 4 vs. Expedited, Category 5:
  1. To code vs. not to code
  2. Retrospective vs. 'prospective' data



# EXAMPLE OF A MASTER-CODE

MRN	Unique Study ID	Unique Study ID	Age	Sex	Date of Admission	SBP	DBP
300222	1	1	25m		1/2/2014	128	92
205223	2	2	78m		12/16/2012	145	98
334561	3	3	31f		3/7/2014	131	82
256897	4	4	57m		3/15/2013	142	91
345112	5	5	64f		8/8/2014	167	97



## RETROSPECTIVE VS. PROSPECTIVE EXAMPLES

- Retrospective: We will analyze data from subjects admitted to the ER from 1/1/2014 to 1/14/2015.
- Retrospective and Prospective: We plan to administer a new medication to patients admitted to the ER with Andromeda Strain. We will analyze pre-implementation data from patients admitted to the ER from 1/1/2014 to 1/14/2015. **Following a year of implementation, we analyze post-implementation data from 1/15/2015 to 1/1/2016.**
- To qualify as retrospective, the data must be in existence **at the time of initial IRB submission.**



# REVIEW PATH DETERMINATION

First, we will discuss Exempt, Category 4 determinations:

Exempt Criteria 45 CFR 46.101(b)(4):

- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.



## EXEMPT CRITERIA 45 CFR 46.101(B)(4)

- Thus, for a study to qualify as exempt, all data must be in existence at the time of initial IRB submission **(Retrospective only)**.
- Furthermore, the data abstracted from the charts can never be linked to direct identifiers (such as name/MRN). **(Not Coded)**.

It is preferable to conduct chart review studies that qualify as Exempt, Category 4, as confidentiality is protected to a greater degree. Also:

1. INSPIR application for exempt studies is shorter
2. Continuing review is not required for exempt studies



## COMMON EXEMPT 4 STUDY DESIGN

- The research team obtains or creates a temporary list of identifiers (name/MRN), either from the Clinical Data Warehouse, or through a query of an existing database (such as a Departmental QI Database).
- The research team uses this list to enter the electronic medical records and abstract the data into a research dataset/spreadsheet.



## COMMON EXEMPT 4 STUDY DESIGN

- As the data for each subject is collected, the identifiers (name/MRN) are deleted from the temporary list, and not linked to the research dataset/spreadsheet.

Note: the # of different data sources (SCM, PACS, etc.) is not an issue, as long as research data is never linked to identifiers. Oftentimes, this means the data for a single subject must be collected in one sitting.





# SUBMISSION OF AN EXEMPT 4 STUDY IN INSPIR

## Section 11.1:

(4) Research involving the collection or study of **existing data** [at the time of this application], documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (if selected, check **all** that apply below):

- All data contained in the data set was in existence on the date this protocol was submitted to the IRB Office within INSPIR.

- At no point will a master code (link between a subject's identifiable data such as medical record number or name and the data set) be created even momentarily.

- The Subject ID will never be located along side of any identifiable data such as a name or medical record number.

- All data for each subject will be collected in one sitting and the medical record number will not be retained once the data is collected.

- Complete dates (month/day/year) will not be included in this data set for any data field. The data set may contain partial dates such as month/year.

- This study may contain some complete dates (month/day/year) in the data set but does not collect data from BUMC medical records or other sources of private health information.

Note: The last two boxes do not need to be checked, as a Limited Data Set may contain dates, and is still considered an 'Exempt' dataset



# SUBMISSION OF AN EXEMPT 4 STUDY IN INSPIR

- **11.2 Exempt Categories: Explain how the research fits into one or more of the categories that you have selected above:**
  - ❖ “This study will involve the analysis of data collected from the medical records of eligible subjects. All data will be in existence at the time of this IRB submission. No identifying information will be collected in the data set, nor will identifiers ever be linked to the data set.”
- **11.3 Study Procedures: a. Provide a detailed description of all the study procedures (e.g. interviews, anonymous internet surveys, anonymous medical record review, etc.). Be sure to describe study methods, any experimental interventions, estimated number and duration and types of subject contacts, phone calls, mailings, emails, etc.):**
  - ❖ “The study staff will perform an anonymous medical record review. Patients will be selected by searching ICD9 codes for patients who were admitted to the ER with a diagnosis of Andromeda Strain\*. This search will create a temporary list of identifiers of subjects who meet this criterion. The investigators will use this temporary list of subjects to review the medical records, and they will delete the names/MRNs one-by-one off the list as data is collected from each medical record into the research data spreadsheet. There will never be a master-code document that links the temporary list of identifiers with the research dataset.”
  - ❖ **\*Note: Please include WHO will be running the query – the research team, or the Clinical Data Warehouse, along with a justification. Please also include a brief justification regarding why the data needs to be abstracted by the study team, and why it cannot be provided by the CDW.**



# SUBMISSION OF AN EXEMPT 4 STUDY IN INSPIR II

- **Section 16.1 Confidentiality: Will research data include elements which will allow the subjects to be identified?**
- ❖ Check 'No'
- **Confidentiality of the Data: State what steps will be taken to maintain confidentiality of data and privacy (or anonymity) of subjects. Specify whether study data will be identified by specific subject identifiers (name, medical record numbers, etc.) or by study IDs that can be linked to subject identifiers via a master-code or key.**
- ❖ No identifying information will be present on any of the data collection sheets. The identifier for each eligible subject will be deleted once the data has been collected, and no master-code will exist that allows the research data to be linked with the identifiers.
- **Please check all that apply:**
- ❖ Check off: "Study data will be anonymous. All data will be RECORDED as anonymous. There will be no way to link data to individual subjects, even temporarily AND subjects' identities cannot be reasonably ascertained via deductive disclosure."



# HIPAA REGULATIONS AND EXEMPT STUDIES

One of the HIPAA forms common to most Exempt 4 studies is the Preparatory to Research

- HIPAA Preparatory to Research: This document is used query the medical records in order to create of the temporary list of identifiers.



# HIPAA PREPARATORY TO RESEARCH EXAMPLE

## DATA AND/OR RECORDS NEEDED FOR RESEARCH PROTOCOL

- Selection Criteria (e.g.; asthmatics seen is Asthma Clinic)

Patients admitted to the ER with a diagnosis of Andromeda Strain via an ICD9 code of 199.99

- Dates of required records: from 1/1/2014 to 1/14/2015 (\*cut-off can be up to date of initial IRB submission)
- Data fields required (list fields required from an electronic data base, or list fields to be recorded from the paper record by the researcher):

Name and Medical Record Number will be recorded as a temporary list in order to create list of potentially eligible subjects

(\*Note: do **NOT** list all variables that will be abstracted and analyzed to answer the research question)

- Anticipated sources of information (check all that apply)

Paper medical records

Electronic files X

Other \_\_\_\_\_



# HIPAA PREPARATORY TO RESEARCH

- The information obtained via a HIPAA Prep can only be given to investigators who are part of the covered entity. Please include a brief statement in the application that all investigators listed in section 3 (i.e. those that will have access to the data) are part of the covered entity, and have privileges to access the necessary medical records.



# HIPAA REGULATIONS AND EXEMPT 4 STUDIES

HIPAA Limited Data Set form or HIPAA De-Identified Data form are used to represent the anonymous research data set/spreadsheet.

- Choice depends on data variables:
- ❖ HIPAA De-Identified Data form does not include any of the 18 HIPAA identifiers
- ❖ HIPAA Limited Data Set is permitted to include:
  - dates such as admission, discharge, service, DOB, DOD;
  - city, state, five digit or more zip code; and
  - ages in years, months or days or hours (including age > 89 years old).



# HIPAA LIMITED DATA SET EXAMPLE

## DATA AND/OR RECORDS NEEDED FOR RESEARCH PROTOCOL

- Selection Criteria (e.g.; asthmatics seen is Asthma Clinic)

Patients admitted to the ER with a diagnosis of Andromeda Strain via an ICD9 code of 199.99, and whose eligibility has been confirmed by the study staff

- Dates of required records: from 1/1/2014 to 1/13/2015
- Data fields required (list fields required from an electronic data base, or list fields to be recorded from the paper record by the researcher):

Age, Sex, Date of Admission, BP @ Admission, HbA1C, Andromeda Strain Levels @ Admission, Medication(s) Administered, Date of Discharge, AS Levels @ Discharge

**OR**

Please refer to the attached spreadsheet entitled “Research Data Collection Spreadsheet”

- Anticipated sources of information (check all that apply)

Paper medical records

Electronic files

X

Other \_\_\_\_\_





# EXEMPT 4 CHART REVIEW SUMMARY

- Exempt 4 Studies:
  1. Involve retrospective data only
  2. Are not linked to direct identifiers
- Benefits of an exempt design:
  1. Greater confidentiality protection for patients
  2. INSPIR application is shorter
  3. No continuing review is required
- If possible, consider study designs that qualify as exempt. For example, for pre- and post-implementation studies, submit as two separate studies (one now, and one when post-implementation data is retrospective)
- Now, on to Expedited Studies....



# REVIEW PATH DETERMINATION

- There are two review paths for chart review studies:
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  1. To code vs. not to code
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# CHART REVIEW: EXPEDITED CATEGORY 5

- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
- Key Information to Include in Submission:
- **Procedures:** Who will identify eligible subjects, and how will research data be collected?
- ❖ **Confidentiality:** Explain the system used to code the data.
- ❖ **Waiver of Informed Consent** is required (if you are collecting data on minors, Waiver of Assent/Parental Consent is required)
- ❖ **HIPAA Waiver of Authorization** is required



# EXPEDITED CATEGORY 5: PROCEDURES FOR DATA COLLECTION

It is imperative that the application clearly states:

- HOW eligible subjects will be identified;
- WHO will identify the eligible subjects;

AND

- WHO will collect the research data.
- Will you use the Clinical Data Warehouse, or do it yourself?



# EXPEDITED CATEGORY 5: PROCEDURES FOR DATA COLLECTION

## 1. Depending on design, Clinical Data Warehouse can:

- Provide the list of eligible subjects only (identifiers), and the PI creates the master-code and abstracts the data.
- Provide the list of eligible subjects and some of the research data (as 2 documents - a master-code and coded research dataset).
- Provide all of the coded research data and the master-code, if the research team needs the master-code for validation purposes.



# EXPEDITED CATEGORY 5: PROCEDURES FOR DATA COLLECTION

OR:

2. Research team creates the list of eligible subjects and abstracts all of the data

- If Option #2, please provide justification for why you need to identify eligible subjects and perform all of the data abstraction without using the CDW.
- Example: “The eligible subjects will be identified by running a query of the Radiology Information database which maintains a complete record of all patients who present with Brain AVM. The PI and co-investigator Matthew Ogrodnik will perform the data abstraction, because the imaging results need to be reviewed to confirm the diagnosis.”



## EXPEDITED CATEGORY 5

- Key Information to Include:
- **Procedures:** Who will identify eligible subjects, and how will data be collected?
- ❖ **Confidentiality:** Explain the system used to code the data.
- ❖ **Waiver of Informed Consent** is required (if you are collecting data on minors, Waiver of Assent/Parental Consent is required)
- ❖ **HIPAA Waiver of Authorization** is required



# EXPEDITED CATEGORY 5: CONFIDENTIALITY PROTECTION

Regardless of the manner in which the data is collected, the INSPIR application must contain a justification for creating and utilizing a master-code.

For example, some justifications that the IRB may accept, depending on the type of study:

- The list of required data variables is so extensive that the data on a single subject cannot be collected in one sitting.
- The data need to be collected from multiple sources (i.e. PACS, SCM, etc.) and cannot be collected in one sitting.





# EXPEDITED CATEGORY 5: CONFIDENTIALITY PROTECTION

- Some of the data does not exist yet and needs to be linked to retrospective data (as in the pre- and post-implementation examples).
- The CDW can provide some, but not all, of the research data, and thus the study team needs the master-code to fill in the missing information.
- The PI anticipates that other currently unknown or unidentified data variables might be of future interest, and thus would prefer to be able to add new data for each subject in the future if needed.
- **\*Include justification in Confidentiality section.**



## EXPEDITED CATEGORY 5

- Key Information to Include:
- **Procedures:** Who will identify eligible subjects, and how will data be collected?
- ❖ **Confidentiality:** Explain the system used to code the data.
- ❖ **Waiver of Informed Consent** is required (if you are collecting data on minors, **Waiver of Assent/Parental Consent** is required)
- ❖ **HIPAA Waiver of Authorization** is required



# WAIVER OF INFORMED CONSENT

- Expedited chart review studies require a Waiver of Informed Consent; this needs to be requested in the consent section of the application.

OHRP 46.116(d) Criteria (and possible examples):

(1) The research involves no more than minimal risk to the subjects;

- Example: “The only risk to subjects involves a breach of confidentiality, and adequate provisions are in place to protect against any potential breach.”

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

- “As explained above and in the Confidentiality section, there are adequate provisions in place to protect against any loss of confidentiality. This waiver will not adversely affect the rights and welfare of subjects.”



# WAIVER OF INFORMED CONSENT

- (3) The research could not practicably be carried out without the waiver or alteration; and
- “This is a chart review study, and we will not have any interaction with subjects. It would be impracticable to locate all subjects for the purposes of obtaining consent, as some may have moved, or may be deceased.”
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- “As discussed, we will not have any interaction with subjects.”



## EXPEDITED CATEGORY 5

- Key Information to Include:
- **Procedures:** Who will identify eligible subjects, and how will data be collected?
- ❖ **Confidentiality:** Explain the system used to code the data.
- ❖ **Waiver of Informed Consent** is required (if you are collecting data on minors, Waiver of Assent/Parental Consent is required)
- ❖ **HIPAA Waiver of Authorization** is required



# HIPAA WAIVER OF AUTHORIZATION

- For expedited studies in which the coded research data will be linked to the list of identifiers, the IRB (acting as the Privacy Board) must determine that the study qualifies for a HIPAA Waiver of Authorization.
- Currently, the HIPAA Waiver of Authorization form needs to be submitted as a separate attachment.



# HIPAA WAIVER OF AUTHORIZATION

1. In this study, how does the use or disclosure of protected health information involve **no more than minimal risk to privacy** of the subjects?
  - “The only risk to subjects is a breach of confidentiality, and adequate provisions are in place to protect against any potential loss of confidentiality.”
2. What is your plan to protect identifiable health information from improper use and disclosure?
  - “The research dataset will not contain names or medical record numbers. Instead, the data will be labeled by a unique study ID that will be linked to a separate master-code document. Only the [insert PI/staff] will have access to this master-code, and it will be stored on a secure password-protected drive.”



# HIPAA WAIVER OF AUTHORIZATION

3. What is your plan to destroy the identifiers? Include how and when.

- “The master-code that contains the identifiers will be destroyed once data collection is complete by deleting the document.”

4. Why is it not practical to obtain an authorization from subjects?

- “As all data is retrospective, it would be impracticable to locate subjects for the purposes of obtaining authorization.”

5. Can the research be done without the protected health information? If not, why not?

“This study seeks to determine if administering Fauximab over the last 2 years in the ER resulted in a better outcome at discharge for patients presenting with Andromeda Strain. The PHI is necessary to answer the study question.”





# HIPAA WAIVER OF AUTHORIZATION

Please complete the following to describe selection criteria for records required (e.g.; all asthmatics seen in the Asthma Clinic), the dates of the records required (e.g.; clinic visits from July 1, 1998 through December 31 2000), and data fields required for the research.

- Selection Criteria for records required

Patients admitted to the ER with a diagnosis of Andromeda Strain via an ICD9 code of 199.99

- Dates of required records: from 1/1/2013 to 1/1/2016
- Data fields required (list fields required from an electronic data base, or list fields to be recorded from the paper record by the researcher)

Age, Sex, BP, PTT, Creatinine, Medications Administered in ER, Medication History

OR

Please refer to the attached spreadsheet entitled “Research Data Collection Spreadsheet”

- Anticipated sources of information (check all that apply)

Paper medical records

Electronic files

X

Other \_\_\_\_\_



# SUMMARY: REVIEW PATH DETERMINATION

- There are two review paths for chart review studies:
- Exempt, Category 4 vs. Expedited, Category 5:
  1. To code vs. not to code
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# SUMMARY FOR EXEMPT 4

- Exempt Category 4: **Consistency** in stating that data:
  1. Is in existence at the time of initial IRB submission
  2. Identifiers will never be linked to the research data
  3. Explain if CDW or research team will identify eligible subjects, and why

## HIPAA:

1. Preparatory to Research is **ONLY** used to obtain temporary list of eligible subjects
2. Anonymous research dataset is represented by Limited Data Set or De-Identified Data Set



# SUMMARY FOR EXPEDITED CATEGORY 5

- Expedited Category 5:

1. Procedures: Who will be identifying eligible subjects AND who will be abstracting the research data:

- a) Clinical Data Warehouse; OR
- b) Study Staff (and if study staff, include a justification for not using the CDW)

2. Confidentiality: Justification for needing to code the data.

HIPAA:

Attach a Waiver of Authorization, and respond to all 5 questions



# QUESTIONS?

- Thank you! Please feel free to ask any questions about chart review studies, or IRB submissions in general.

