Tool for submission of IRB applications that meet criteria for Exempt Category 4 (Version 2, 10/30/13)

For more information about completing your IRB application, please contact the Clinical Research Resources Office (CRRO) at 617-638-8876 and or check out the CRRO website: http://www.bumc.bu.edu/crro/.

1.0 General Information

1.1 *Please enter the full title of your study (Spell out acronyms):
Sample Exempt Category 4 submissions: the Retrospective Chart Review

1.2 *Please enter the Study Nickname you would like to use to reference the study:
Exempt 4

2.0 Add Department(s)

2.1 List of Departments associated with this study:

<table>
<thead>
<tr>
<th>Primary Dept?</th>
<th>Department Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>BU - MED - CLINICAL RESEARCH, OFFICE OF</td>
<td></td>
</tr>
</tbody>
</table>

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

3.1 *Please add a Principal Investigator for the study:
Joe Investigator, MD

Comment [BMA1]: Make sure Dept. is the department of the PI -- remove "default" medicine if PI is not from Medicine - If PI is from Medicine then you must list the Section as the primary department. You can list multiple departments as applicable.

Comment [SC2]: Make sure you and all your investigators who will be covered under the BUMC IRB have up to date Human Subjects Certification. You can check this link to see:
http://www.bumc.bu.edu/ocr/certification/ (see first link on this page)

If any of your investigators need to obtain their Human Subjects Certification, see this link for the process:
http://www.bumc.bu.edu/ocr/certification/#1

Don’t submit the protocol to the IRB until all investigators are up to date with certification and recertification requirements.
### Select if applicable

- Student
- Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Faculty Advisor must be supplied below.

### 3.2 If applicable, please select the Protocol Staff personnel:

#### A) Additional Investigators

- Candice Coi, MD

#### B) Research Support Staff

No Research Staff have been added.

### 3.3 *Please add a Study Contact:

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).

### 3.4 If applicable, please add a Faculty Advisor:

No Faculty Advisors have been added.

### 3.5 If applicable, please select the Designated Department Approval(s):

- Ima Theboss

**Important Notes:**

- **Comment [MSOffice3]:** Make sure to select if appropriate. If you select any of these three, you should add a faculty advisor in Section 3.4 below.
- **Comment [BMA4]:** Make sure PI and all investigators have completed their Personal Profile. Each profile must have: Degree, Specialty, Primary Number, Location, Affiliation, and Other Affiliation. (List section or center within the department in the Location or Other Affiliation)
  
  For a tutorial on how to do this, see: [http://www.bumc.bu.edu/irb/files/2011/03/Personal-Profile.pdf](http://www.bumc.bu.edu/irb/files/2011/03/Personal-Profile.pdf)
- **Comment [BMA5]:** Study contact is only for noting who will receive notifications via INSPIR. All investigators and study staff must also be listed in Section 3.2
- **Comment [MSOffice6]:** Add Study Contact as appropriate above.
- **Comment [SC7]:** If you are the PI and also a student/resident/fellow, you must have a faculty advisor; this person should be added here. This person must be full-time faculty.
- **Comment [BMA8]:** Dept. Chair of PI’s department must be listed here- if the PI is a Dept. Chair then protocol must be routed to Dean
  
  **All other special routing for signature must be listed in this section as well.**
3.6 If applicable, please select the Administrative Assistant(s)

No Administrative Assistants have been added.

Administrative Assistant Note

4.0 External non-BU/BMC Investigators

4.1 In this section, only list non-BU/BMC investigators (not a full-time or permanent part-time employee of BMC, BU, BPHC, etc.). Any BU/BMC personnel should be listed in the KSP section (3rd section)

List here all non-BU/BMC persons working on the protocol who will be engaged in the research on behalf of BU/BMC. This includes all persons who are conducting research under an Authorization Agreement (IAA) with BU/BMC IRB.

No External Personnel have been associated.

4.2 Does this study involve participation of non-BUMC investigators who are determined to be “not-engaged” in the research?

- Yes
- No

If you answered Yes above, indicate in the text box below; the names of the non-BUMC investigators, all study activities they will be performing, the names of their institutions, and why they are determined to be NOT-Engaged in the research (based on the OHRP engagement guidance).

4.3 Study Attachments

Click on the link below to attach any necessary documents related to external non-BU/BMC personnel.

No electronic document has been associated.

5.0 Investigator Information from INSPIR I

5.1 This section had been migrated from INSPIR I.

- If this is a new study, please skip this section (click Save and Continue).
- If this is a study that was migrated from INSPIR I, DO NOT ADD ANY MORE INVESTIGATORS IN THIS SECTION.
YOU CAN ONLY DELETE INVESTIGATORS HERE. All BU/BMC personnel should be listed in the KSP section (3rd section), and all non-BU/BMC investigators should be listed in the External non-BU/BMC Investigators section (4th section).

<table>
<thead>
<tr>
<th>KSP Info</th>
<th>Additional Personnel Info</th>
</tr>
</thead>
<tbody>
<tr>
<td>No records have been added</td>
<td></td>
</tr>
</tbody>
</table>

**6.0 Conflict of Interest**

**6.1 Conflict of Interest Disclosure**

By approving this protocol, as Principal Investigator, I am confirming that the appropriate individuals have filed a BU Project Specific Disclosure (PSD) with the appropriate office. I understand that this is a continuing obligation as new individuals join my research team in the future.

☑ Agree

Of the BU PSDs submitted, have any significant financial interests been disclosed?
☐ Yes ☐ No

If yes, please specify who has disclosed a COI.

**6.2 Conflict of Interest Disclosure imported from INSPIR I**

This question is read-only. It has been replaced by the statement listed above.

BU and BMC policy requires that all internal investigators, and some external investigators, complete a project specific Conflict of Interest Disclosure Form and submit it to the appropriate office (click on the Help icon for instructions). Do not submit these forms to the IRB. Do not attach these forms to this protocol.

Have all investigators and staff in this study submitted COI Forms?
☐ Yes ☐ No

**7.0 Funding Source**

**7.1 Funding Source**

What is the source of your research funding. If you have multiple sources of funding (including sub-awards), check
all that apply.
- Unfunded Student Research
- Dept/Internally Funded
- Government
- Industry
- Foundation/Other

7.2 Funding Details

For instructions on how to complete this section, click on the Help icon.
No Sponsors have been associated.

7.3 Grants Office

In the check boxes below, please indicate which grants office is handling your award/ sub-award.
- BU Office of Sponsored Programs (OSP-med)
- BMC Grants Administration (OGA)
- Charles River Campus Office of Sponsored Programs (OSP-CRC)
- Other

Funding Notifications:
- I have received a Notification of Award (NoA)
- I have received a Just In Time notice (JIT)
- I have received a fundable score for this study.

7.4 Study Attachments

Click on the Help icon for information on what you’re required to attach in this section.
No electronic document has been associated.

7.5 Funding Source Info from INSPIR

This table is read-only. It will only be populated if this study was migrated from INSPIR 1. If there are entries in this table, please use them to enter the funding information into the new Funding Source table above.

<table>
<thead>
<tr>
<th>Funding Type</th>
<th>Sponsor Name</th>
<th>Award #</th>
<th>PI of Award</th>
<th>Industry Protocol Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dept/Internally Funded</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comment [SC13]: Typically, though not always, funding for retrospective chart reviews is either departmentally funded or unfunded student research. If this is NOT student research do NOT select Unfunded Student Research.

If you are the student, and the research is not funded, check the first selection here. Make sure you list your faculty advisor/ mentor in Section 3.4.

If this project does have external funding, complete 7.1, 7.2, and 7.3 as applicable and attach your grant in Section 7.4. Must include the face page with the grant.

Comment [RM14]: If this study is externally funded then attach a copy of the grant (with facepage), the sponsor’s protocol, the contract with scope of work (for sub-awards), and/or a copy of the master’s thesis/doctoral dissertation prospectus if this research is for doctoral dissertation /master’s thesis.

Comment [BMA15]: Do NOT complete this section for new applications. The protocol will be returned to you if you do.
Here is where you should simply describe that you are proposing a retrospective chart review and are requesting an exemption under category 4. Explain simply why you are asking this research question. Then describe that all data/samples that will be reviewed/used will be existing at the time of submission and the data/samples will be anonymous with no way to link back to the subjects.

If you are receiving coded data from outside BU/BMC and there is an agreement in place that states you will never be granted access to direct identifiers or the master code, then your project still qualifies as exempt. If using BU/BMC medical records, full dates are generally not permitted in exempt protocols. You can use month/year for dates. If you need full dates and your

Comment [SC16]: Simple is good here. Is this a retrospective chart review of existing records with data that will be recorded anonymously? How many records will be reviewed? What is the purpose of the record review? What are you comparing? And why? You need enough info to "set the stage" but keep it brief and to the point and in lay language.

For a retrospective chart review you should try to emphasize two things throughout the application:

1) That all the data is existing prior to submission to the IRB (including the full date range is a good idea), and
2) That the data is recorded so that it is anonymous in your research data set. This includes any dates, if the data come from medical records at this institution. There should be no link back to the individual’s medical record or identifying information. This should be made clear in your application.

Comment [BMA17]: Anonymous means that there is no way that the data can be linked back to subjects either directly through identifiers in the dataset or via a mastercode. (Linked data should be referred to as “coded data” not anonymous data.) However, for a project to be exempt, there must be no way for the PI to link the research data back to the individual subject via a mastercode. For the PI and study team, the research dataset should contain anonymous data.
data is from the BMC medical records, then your protocol cannot be exempt.

8.2 Please skip this question for new studies - The following data was migrated from INSPIR I (if any). Eventually, the box below will go away. So please remove your answer from the box below and place it in the text editor (green button) above in section 8.1 by cutting and pasting it. The box below should be left blank.

9.0 Study Site Information

9.1 Select one:

- **Single site research** conducted by BUMC investigator(s) (skip question #2 below)
- **Multi-site research project** - BUMC is a research site but is NOT the main study site (Skip question #2 below)
- **Multi-site research** - BUMC is the main research site and/or BUMC investigator is the overall PI of the entire study or the FDA sponsor (must complete #2 below)

9.2 Provide details of all other research sites involved in this study.

<table>
<thead>
<tr>
<th>Institution &amp; PI Information</th>
<th>IRB approval for site</th>
</tr>
</thead>
<tbody>
<tr>
<td>No records have been added</td>
<td></td>
</tr>
</tbody>
</table>

9.3 Institution(s) where work will be performed in the U.S: (Please skip this question for new studies - The following data was migrated from INSPIR I (if any). Eventually, the box below will go away. So please remove your answer from the box below and place it in the corresponding table above in section 9.2 by cutting and pasting it. The box below should be left blank)

List below all other U.S. sites where study activities (e.g., recruitment, enrollment, testing procedures) will take place. For each institution that is engaged in the research (see DHHS 1/26/99 guidance memorandum on Engagement of Institutions in Research), provide their FWA number and confirm that IRB approval has been or will be obtained for each site engaged in the research. This does not include multi-center studies, unless the PI is the PI for all sites in this study.

Comment [MSOffice18]: If you are working with investigators from other institutions, you will click button 2 or 3 here and then answer the resulting questions the appear pertaining to the outside institutions/researchers.
### 9.4 Does this study involve Community Based Participatory Research?

- [ ] Yes
- [x] No

### 9.5 Indicate below if any recruitment, consenting, and/or study interventions/procedures/data collection will take place in any of the following places (check all that apply)

- [ ] Boston Healthnet Community Health Centers (click on ? icon for listing)
- [ ] MD offices or clinics (not part of BUMC campus)
- [ ] Subjects’ places of residence including nursing homes, assisted living facilities, etc.
- [ ] Community centers or other ‘community’ locations (homeless shelters, daycare, etc.)
- [ ] International sites
- [ ] Veterans Administration (VA)

### 9.6 Study Attachments

Here you can attach any study sites related documents. Attach IRB approval letters from other institutions (If you answered question #2).

No electronic document has been associated.

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### 10.0 Navigation Menu

Please note: Questions in the Navigation Menu section determine which subsequent sections will be displayed and which ones will be hidden. If later you make any change to the Navigation Menu section, you will need to click on the "Save and Continue to Next Section" button throughout the whole application to display any new required section or hide any sections that are no longer required.

### 10.1 Emergency Use

Is this application for an FDA approved EMERGENCY USE of an Investigational Drug or Device?

- [ ] Yes
- [ ] No

### 10.2 Individual Patient IND or Humanitarian Use Device

Is this application for an FDA approved Individual patient (single use) IND or Humanitarian Use Device?
10.3 Review Path Determination

☐ This project meets the regulatory definition of Not Human Subject Research (NHSR). Examples are Quality Assurance, Quality Improvement projects, or studies involving obtaining data/tissue.

☐ BUMC has delegated IRB review to another institution (BUMC is Institution B). (Please note: this relationship requires an Authorization Agreement.)

☐ According to the Engagement of Institutions in Research guidance by OHRP, neither BUMC (Boston University, Boston Medical Center) nor affiliated institutions/organizations for which the BUMC IRB has oversight responsibilities is "engaged" in human subjects research.

☐ This study fits into one or more of the Federal Exempt categories.

☐ None of the above. This study requires Expedited review or the review of the Full Board.

10.4 IRB Authorization Agreement (IAA) - BUMC is Institution A

Does this study have or require an IRB Authorization Agreement (IAA) where investigators from another institution will rely on BUMC IRB review? ***

☐ Yes ☐ No

**If this study has or will require an IRB Authorization Agreement (IAA) where BUMC investigators will rely on IRB review by another institution, do not check YES here, but instead, go to Exempt-BUMC is Institution B and check yes there.

***If the study is Exempt, then there should not be an IAA.

10.5 International Research

Are any BU/BMC investigators involved in any way in any research activities at any non-US (international) sites, including oversight of international research activities?

☐ Yes ☐ No

10.6 HIPAA Compliance

Is the PI a member of the covered entity and the study involves the collection of protected health information (PHI)? Is any investigator or member of the study staff, whether a member of the covered entity or not, using (i.e. accessing, recording) and/or disclosing PHI as part of this research? If your answer

Comment [MSOffice19]: It is important to complete this correctly. Once you select here, the application will ask you in Section 11 for more information in regards to the specific exemption. Also, the application will automatically shorten since certain sections of the full application do not apply to exempt research.

Comment [RM20]: An IAA is not applicable for exempt research.
to either question is YES then select Yes below.

<table>
<thead>
<tr>
<th></th>
<th>Yes - This study is subject to the HIPAA Privacy Rule</th>
<th>No - This study is HIPAA Exempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.7 Genetics</td>
<td>Does this research involve genetic testing, gene therapy, or collection of genetic information?</td>
<td>Yes</td>
</tr>
<tr>
<td>10.8 Biological Samples Collection</td>
<td>Does this study involve collecting, banking, and/or distributing biological samples?</td>
<td>Yes</td>
</tr>
<tr>
<td>10.9 Drugs/Biological Agents</td>
<td>Does this study involve administering drugs or biological agents?</td>
<td>Yes</td>
</tr>
<tr>
<td>10.10 Device</td>
<td>Does this study involve testing or use of a medical device?</td>
<td>Yes</td>
</tr>
<tr>
<td>10.11 Repositories</td>
<td>Will you be collecting data or samples that will be placed into a repository, or will you be establishing a repository (either as a new protocol or to be added to an existing protocol)? (Do not check yes if this protocol involves ONLY obtaining samples FROM a repository to conduct this research)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**11.0 Categorical Exemptions**

**11.1 Categorical Exemptions**

Under the Federal Regulations certain types of research studies can be designated as exempt if all of the study activities fit into one or more specific categories. In order to qualify as Exempt under a categorical exemption the study must meet the federal definition of **MINIMAL RISK** and fit into one or more of the federally defined **Exempt categories**.

***If this project involves research on prisoners (incarcerated subjects), pregnant women or fetuses,***

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**Comment [MSOffice21]:** This will apply to BU/BMC chart reviews. See: http://www.bumc.bu.edu/hipaa/

If you have no HIPAA identifiers in your dataset, complete the Deidentified data form. If you have limited identifiers, such as full dates, month/year or parts of addresses such as city and zip code you should complete a Limited Data Set form. If you are searching in the medical records for criteria to determine which charts to review, you will also need a Preparatory to Research form.

If your dataset will contain dates or specific ages greater than 89 this is NOT a de-identified data set because dates are HIPAA identifiers.

This HIPAA requirement pertains even to investigators who are not part of the "covered entity" (such as SPH investigators)—if you will be accessing medical records from a covered entity for research then HIPAA applies.

**Comment [BMA22]:** If the data you will be collecting will be put into a repository for future release to others for analysis then this study doesn’t qualify for Exempt review under Category 4. Will need to go back to question 10.3 and select the final option (Expedited/Full Board review).
surveying /interviewing minors/children, research on drugs/devices, then do not continue. Research involving focus groups, audio/videotaping of subjects, collection of identifiable data including coded data, in most cases will NOT qualify for Exempt review.

Please select the most appropriate exempt categories from the list below. ***Note there are restrictions on research involving prisoners, pregnant women, fetuses, and children.

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. In most cases this category does not apply to children.

☐

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐

(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.
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.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

11.2 Exempt Categories: Explain how the research fits into one or more of the categories that you have selected above.

You should explain here that this study

Comment [MSOffice23]: Select here for a retrospective chart review. Make sure to carefully review and select all of the checkboxes below that apply to your study.

Comment [MSOffice24]: It is good to reiterate these check-offs in your Procedures section. In describing your procedures, consider how you will ensure there is not link to the individual record, ever.

Comment [MSOffice25]: One of these last two MAY apply to your study as well. Note that full dates are appropriate in an Exempt category 4 application in certain cases. One must look at whether the dates, along with other study data, would allow the subjects to be “readily identifiable.” Sensitivity of the data will also come into play.

If the date is for a procedure or test that is not rare, then you can make the case that the date will not (in the context of other data) allow the subjects to be readily identifiable. If you are using complete dates it will be helpful to provide this justification in your Procedures section.
meets exempt category 4 because all the data is in existence at the time of submission (and it’s good to provide your beginning and ending date ranges here to underscore this point) and the data will be recorded, stored, and analyzed anonymously; there is no way to link the data back to the identities of the subjects so the data is anonymous to you.

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.)

You should explain here how you will be gaining access to the data; what is your actual procedure? Will you obtain the information from the Clinical Data Warehouse? Will you be going directly in to the medical record and searching for specific patients who meet your inclusion criteria? If so, are you collecting the data on a patient in one sitting? Make sure you include the date range and that the end date is NOT after your date of first submission to the IRB.

If you haven’t already, attach your data collection form listing all your variables. Make sure that form does not list include HIPAA identifiers such as full dates (unless the dataset is from records outside BMC).

b. Describe the anticipated duration of the study. * * * If this study involves record or chart review; indicate SPECIFICALLY the date ranges for the data to be collected. Note- Exempt category 4 only allows for retrospective review of EXISTING records. All data points must have already been

Comment [SC26]: Make sure to either list all your variables or attach a list of variables that you will extract from the medical record.

Comment [MSOffice27]: While you have already checked in Section 11.1 that you will not create a mastercode even momentarily, you will want to reiterate that here. For example, you can state that you will collect each data set for a given subject in one sitting and never combine the subject identifying information (such as name or medical record #) with the study data.

Comment [MBA28]: ***It is very important to explain how you will be obtaining data from medical records- especially if you are not obtaining data from the Clinical Data Warehouse but are directly reviewing medical records. As a rule, BMC does not allow those who do not have access to BMC medical records for clinical purposes to review patients’ medical records to collect research data. So the IRB must know exactly who is going to be looking at patients’ records- hard copies and or electronic records and the plans for them gaining access.

Comment [RM29]: It’s a good idea to check with the Clinical Data Warehouse to see if the services provided by Linda Rosen can benefit your study. See: http://www.bumc.bu.edu/ocr/clinical-research-clinical-warehouse-data-access/

If all the data will be obtained from the Clinical Data Warehouse and the investigators will not be accessing medical records to abstract the data then this study might qualify as NHSR (an even easier IRB application to complete!).

Comment [SC30]: Make sure to put the date range of your record review. Make sure these dates are consistent with the ranges you put on your HIPAA waiver form, attached to the protocol.
Explain how long it will take for you to complete your chart review. Also, make sure to supply information requested above; what is the date range of your medical record review?

### 11.4 Sample Size/Data Analysis

Provide an estimate of the anticipated number of subjects who will be enrolled or charts that will be reviewed. Provide a brief explanation as to the sample size.

Explain that you expect to review [insert number of] charts because [insert response here].

Also, describe how you will analyze the data. What kind of statistics will you be using to answer your research questions?

### 11.5 Recruitment

If this study involves recruitment activities, please describe plans for recruiting potential subjects. Describe any screening activities to determine eligibility. If this study involves record/chart review, describe how you will determine which records will be reviewed.

Since this is a retrospective chart review study, explain how you will identify which records to review. Use specific date ranges (month, day, year) to be clear. State who will be accessing the records and whether you will utilize the Clinical Data Warehouse to help with identifying eligible subject records and/or providing you with your dataset.

### 12.0 Purpose

#### 12.1 Background/Rationale/Purpose

Provide background information, study rationale, and purpose / study objective(s) and/or hypotheses for this study.

Comment [SC31]: Provide sufficient information to justify doing this study. For example, if you were looking at success rates of a certain procedure, take this opportunity to describe this procedure and the difference between the various types being studied. Answer the “so what” question….. Why is your research question important?
Here you should add a couple of paragraphs describing the issue; why you are proposing this research study, what you hope to learn, and why this study is important. Justify your research study - why should you be permitted to review people's records in order to answer this question? You should include references as applicable.

### 12.2 Background/Rationale/Purpose

The following data was migrated from INSPIR I (if any). Eventually, the box below will go away. So please remove your answer (if any) from the box below and place it in the above text editor (green button) by cutting and pasting it. The box below should be left blank.

### 13.0 Subjects

#### 13.1 Inclusion Criteria

Specify your inclusion criteria for each cohort.

<table>
<thead>
<tr>
<th>Inclusion criteria List</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Add info on what the criteria for inclusion in your data set are</td>
</tr>
</tbody>
</table>

The following data was migrated from INSPIR I (if any). Eventually, the box below will go away. So please remove your answer from the box below and place it in the above text editor (green button) by cutting and pasting it. The box below should be left blank.

#### 13.2 Exclusion Criteria

Specify your exclusion criteria for each cohort.

<table>
<thead>
<tr>
<th>Exclusion criteria List</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. List exclusions here, but note that your exclusions should not be opposite of inclusions. Of the subjects above, what would make someone ineligible? For example, use of certain medications.</td>
</tr>
</tbody>
</table>

The following data was migrated from INSPIR I (if any). Eventually, the box below will go away. So please remove your answer (if any) from the box below and place it in the above text editor (green button) by cutting and pasting it. The box below should be left blank.

Comment [SC32]: Make sure to include the date range of the records here as well.
### 13.3 Subjects (Please choose the appropriate categories for your subjects.)

#### Gender
- [ ] Both

#### Age
- [ ] Adolescent (15-17 years)
- [X] Adult (18-64 yrs)
- [ ] Child (7-15 years)
- [ ] Child < 7 years
- [ ] Fetus
- [ ] Geriatric (65+ yrs)
- [ ] Other/unknown (specify in the box below)

#### Race/Ethnicity:
- [X] All Ethnic Groups
- [ ] American Indian or Alaskan Native
- [ ] Asian or Pacific Islander
- [ ] Black (Not of Hispanic Origin)
- [ ] Hispanic
- [ ] Mixed Race or Ethnicity
- [ ] White (Not of Hispanic Origin)
- [ ] Other or Not Available (specify in the box below)

#### Languages:
Remember that informed consent forms and all other written documents must be given in a language understandable to the subject. List all languages in which you are planning to obtain informed consent. Once the English version of the consent form is approved in INSPIR, please submit an Amendment with applicable translated consent & attestation forms prior to use.

#### Languages
- No records have been added

Which if any of the following vulnerable populations will be recruited as subjects?

Comment [MSOffice33]: Select age categories that apply to your research.

Comment [MSOffice34]: Select Race/Ethnicity that applies to your research.

Comment [MSOffice35]: Languages and vulnerable populations do not apply to exempt category 4 submissions.

(However, as an FYI, it is important to note that research involving prisoners cannot be exempt; also certain exempt categories (#2, survey research) do not apply to children, but this does NOT pertain to retrospective chart reviews which CAN include children).
13.4 Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

The following data was migrated from INSPIRI (if any). Eventually, the box below will go away. So please remove your answer (if any) from the box below and place it in the above text editor (green button) by cutting and pasting it. The box below should be left blank.

14.0 Potential Risk/Discomforts

14.1 Lists the possibilities for risks of harm or discomfort to subjects as a result of their participation in the research.

Describe the risk of breach of confidentiality risk.

14.2 Provide a description of how risks will be minimized.

Describe that the dataset is anonymous to you and thus the risk of breach is extremely small.

14.3 Description of Risks or Discomforts - The
In order to approve a study the IRB must be able to determine that "Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk."

List the possibilities for risk or harm to the subjects as a result of their participation in the research. Be sure to include physical harms, discomforts, hazards, inconveniences, or the potential for legal or social harms (i.e. loss of confidentiality). Whenever possible, include for each:

1. Probability of occurrence
2. Magnitude
3. Duration

For each harm listed, indicate measures that will be taken to prevent or minimize the effects of all of the potential the hazards, discomforts or risks.

15.0 Potential Benefits

15.1 Describe potential benefit(s) to be gained by the individual subject as a result of participating in the research. (Payments to subjects should not be included in this section.)

Here you can explain that there is no direct benefit to the individual subjects, but you can briefly talk about what benefit may be gained by future patients and society.

The following data was migrated from INSPIR I (if any). Eventually, the box below will go away. So please remove your answer (if any) from the box below and place it in the appropriate sections listed above by cutting and pasting it. The box below should be left blank.
Will research data include elements which will allow the subjects to be identified?

☐ Yes ☐ 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.

Here you must reiterate that there is no mastercode linking the study data back to the subjects. You can say it is either de-identified or that you have a data set with limited identifiers (such as month/year). The recorded data will be anonymous to you as you will have no way of linking back to the person or medical record.

The following data was migrated from INSPIRI (if any). Eventually, the box below will go away. So please remove your answer (if any) from the box below and place it in the above text editor (green button) by cutting and pasting it. The box below should be left blank.

Please check all that apply:

☑ 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.

☐ Study data will be coded. All study documents will be identified by a unique study ID. The unique study ID will be linked to subject identifiers via a mastercode or key. Access to the mastercode/key will be limited to the researchers. The mastercode/key that links study data to identifiers will be stored separately from the study data and protected (locked, separate flash drive, etc.).

☐ Study data will contain certain identifiers such as dates including dates of birth, medical record numbers, etc. Data will not contain social security numbers.

☐ Study data will contain high-risk identifiers (e.g. social security numbers) or very sensitive information with subject identifiers such as HIV status, psych diagnosis, illegal drug use, etc.

☐ There is an alternate plan for how subjects will be...
Release of identifiable data.
Indicate who will be PROVIDED with identifiable research data (including “coded” data). Be sure to include study sponsors, students, outside institutions, etc. (Note: in most instances NIH and other study sponsors are not provided identifiable study data but they have access to study data on-site for monitoring and auditing purposes. The IRB and the other institutional officials also have access to study data for audit and quality assurance purposes. These do not have to be listed below) Include any release of study data into registries or research databases.

<table>
<thead>
<tr>
<th>Who gets data</th>
<th>Type of data</th>
</tr>
</thead>
<tbody>
<tr>
<td>No records have been added</td>
<td></td>
</tr>
</tbody>
</table>

Read-only migrated from INSPIR I.

Storage and destruction of study data
Where will research data be kept? How will such data be secured? How long will it be kept? How and when will it be destroyed?

- Note: Federal regulations require that study data be maintained by the investigator for a minimum of three years following the COMPLETION of the study. FDA regulations may require that study data be retained for significantly longer.

Here you should explain specifically where your data will be stored, who has access to it, and when it will be destroyed. You must keep your data for at least three years after the close of your study.

The following data was migrated from INSPIR I (if any). Eventually, the box below will go away. So please remove your answer (if any) from the box below and place it in the above text editor (green button) by cutting and pasting it. The box below should be left blank.

Comment [MSOffice42]: Since exempt data are not identifiable, this is not applicable to an exempt retrospective chart review.

Comment [MSOffice43]: Make sure to answer all the questions.
Certificate of Confidentiality
Will you obtain a Certificate of Confidentiality for this study?
(Note: If a CoC will be obtained then CoC language is required in the consent form. See IRB website for more information about CoCs.)
☐ Yes ☐ No

16.2 Study Attachments
Here you can attach the Certificate of Confidentiality (CoC) and any Confidentiality related documents.
No electronic document has been associated.

17.0 Cost/Payment

17.1 Cost
What costs / potential costs will subjects incur (include travel, parking, medication, etc.)? How will the cost of research visits / procedures be covered? Will the subject (or the subject’s insurance) be responsible for any research related costs? If yes, state specifically which items the subject (or the subject’s insurance) will be responsible for and the cost of each.

Explain that there will be no costs.

17.2 Payment / Course Credit

Payments
If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc.) of the payment. Describe any other reimbursement that will be provided to subjects, (i.e. travel, parking, public transportation, etc.). Explain specifically how and when these reimbursements for expenses will be paid. Specify your plan for reimbursement if a subject withdraws from the study.

Explain that there will be no payments.

Course Credit - If student subjects will receive course credit for their participation in this study. Explain below.
N/A
### 18.0 Study Attachments

**18.1 Attach here any remaining study documents other than the ones listed below.**

No electronic document has been associated.

**Comment [MSOffice44]:** Attachments that may be relevant to your submission may include:
- HIPAA form(s) (see http://www.bumc.bu.edu/hipaa/)
- If this study is externally funded then attach a copy of the grant (with facepage), the sponsor’s protocol, the contract with scope of work (for sub-awards).
- If you attach a HIPAA Limited Dataset form you will fill out but not attach a Data use agreement. This states that you will never receive a link back to the subject (in instance when you receive data from another institution that includes identifiers such as dates).

**Comment [BMA45]:** Do NOT attach human subjects training certificates for any internal or external investigators. These are not protocol specific documents. These need to be faxed to IRB – see www.bumc.edu/irb for more details.