A Surfeit of Surveys: Exempt Category 2

- *CRRO Clinical Research Seminar*
  10/13/2021

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Learning Objectives for Today

1. Does my study qualify for an Exempt 2 determination?

   Identifying Exempt 2 Research

2. Does my Exempt 2 study involve anonymous or identifiable collection of data?

   Identifying Anonymous vs. Identifiable Exempt 2 studies

3. What does the IRB need from me to make an Exempt 2 determination?

   Requirements for Exempt 2 submissions

4. How do I prepare my submission for review?

   Practical tips for preparing an application in INSPIR

Agenda

1. Recap: What is Human Subjects Research?
2. **Activity:** Is this Research? Does it involve Human Subjects?
3. Recap: What is Exempt Research?
4. What kind of studies fit into Exempt Category 2?
5. How does the Federal Code define Exempt Category 2?
6. Anonymous vs Identifiable category 2 studies
7. Restrictions on Exempt Category 2 studies
8. **Activity:** Which of these studies qualify for Exempt Category 2?
9. BUMC/BMC IRB requirements for studies seeking Exempt Category 2 determination
10. HIPAA and Exempt Category 2
11. Funding and Exempt Category 2
12. Step by step walkthrough of Exempt Category 2 application
13. **Conclusion:** Helpful Resources

What is Research?

"A systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge"[1]

What is a Human Subject?

"A living individual ***about whom*** an investigator conducting research:
(1) obtains data through intervention or interaction with the individual and uses, studies, or analyzes the information, *or*

(2) obtains uses, studies, analyzes, or generates identifiable private information."[2]

[1] 45 CFR 46.102 (l)
[2] 45 CFR 46.102 (e)(1)

Is it 'Research'?

- A MPH student is using a chart review method to look at the incidence of ear infections in pediatric clinic visits and ER visits in children who are housed in shelters during the winter. She will not access the chart herself but will receive a fully de-identified dataset with no identifiers/PHI directly from the CDW (Clinical Data Warehouse).

.....a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge?

Is it 'Research'?

A journalist writes an article chronicling a day in the life of a liver transplant patient at the time of the COVID epidemic. He plans to interview the patient, the patient's closest family and the patient's transplant surgeon.

.....a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge?

Is it 'Human Subjects Research'?

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*…….a living individual **about whom** an investigator conducting research:*
(1) obtains data through intervention or interaction with the individual and uses, studies, or analyzes the information, or

(2) obtains uses, studies, analyzes, or generates identifiable private information.”

Is it 'Human Subjects Research'?

- A student seeks approval to post an invitation for a survey online to examine the role of social media in body image. The survey is anonymous, and no identifiers will be collected.

*…….a living individual **about whom** an investigator conducting research:*
(1) obtains data through intervention or interaction with the individual and uses, studies, or analyzes the information, or

(2) obtains uses, studies, analyzes, or generates identifiable private information.”

What is *Exempt* Human Subjects Research?

- Research is termed "Exempt" when it constitutes research with human subjects AND meets the requirements of a defined low-risk category that is exempt from SOME (but not all) of the requirements governing human subjects research.

- To qualify as Exempt, the research must:
  - Pose no greater than minimal risk to the subjects; and
  - Fit into a defined Exempt category:
    - 8 Exempt categories defined by the Common Rule (Code of Federal Regulations Title 45 Part 46 – abbreviated 45 CFR 46) – regardless of the source of funding; *or*
    - 5 additional Exempt categories defined locally with our "Equivalent Protections" policies – only for research with no external funding.*

***We will not focus on these equivalent protections categories today.**

https://wwwapp.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=738

Exempt Research - Category 2

- Surveys
- Interviews (including cognitive interviews)
- Focus groups
- Educational tests (e.g., cognitive, diagnostic, aptitude, achievement)
- Observation of public behavior (i.e., behavior that occurs in a public place where there is no expectation of privacy and where no special permission is required to observe others such as a public street, or park.)*

**This category can involve ethical issues that may bump a study to expedited or full board, such as observational categories like "age", "race" or "sex".*

Exempt Research - Category 2 (cont.)

- In order to qualify for Exemption #2, one of the following must be true:

i. Data are collected **anonymously.** This means that no one, not even members of the study team, has the ability to link data with individual subjects at any time, directly or indirectly through the use of coding.

ii. The study **does not collect sensitive information about subjects that could place them at risk if inadvertently disclosed outside the research**. Sensitive information refers—but is not limited—to illegal activities, genetic or medical information, sexual behaviors, negative attitudes/opinions about one's employer or coworkers, etc. Risks include criminal liability, social stigmatization, etc.

iii. The study **collects identifiable information** about the subjects. In this case, the IRB will conduct a "limited" IRB review to ensure adequate provisions are in place to protect the subject privacy and the confidentiality of the data.

Anonymous vs. Identifiable Studies

- Exempt Category 2(i) - ***Anonymous***
  - Data does not contain any information that can identify an individual.
  - Data collected is **not** labeled with a study ID that is also used to label subject identifiers (name, email address, etc.) in a separate document (i.e., no mastercode).

- Exempt Category 2(iii) - ***Identifiable***
  - Data is linked to identifiers via Study ID (i.e., mastercode exists).
  - Data must be adequately protected against disclosure.
  - IRB will conduct a "limited IRB review" of the *privacy* and *confidentiality* protections to make this exemption determination.

If there is any doubt, the IRB will default to considering an exempt study identifiable – there is no additional burden on the investigator if this is the case.

Restrictions on Exempt 2 Studies

- No FDA regulated studies (Investigations of Drugs/Devices/Biologics)
- No prisoners
- No studies greater than minimal risk
- No collection of biospecimens
- Cannot involve children if investigators participate in the activity to be observed
- Cannot be linked to data that is collected via other methods, ie chart review

The IRB errs on the side of caution when research involves children, and, in most cases, will conduct expedited reviews of funded research with children.

Poll: Is the study Exempt under Category 2?

Is it Exempt 2?

Exemption Category	Study Example	Exempt Y/N?	Explanation
#2	Online survey of sexual behaviors; responses cannot be linked to respondents at any time, directly or indirectly.	Yes	Data are collected anonymously.
#2	Focus group about consumer products; participants' name, address, and phone number are collected.	Yes	Data are not sensitive.
#2	Survey about illegal activities; a code is used to link back to individual respondents.	Yes*	Data are sensitive (risk of criminal liability) and identifiable. *Limited IRB Review is required.
#2	Behavioral observation at a public park	Yes	Behavior occurs where no special permission is required to observe.
#2	Observation of attorneys and clients at a law practice.	No	Behavior occurs where there is a reasonable expectation of privacy
#2	Focus group conducted with children.	No	Use of exemption #2 with minors is limited to observation without interaction.
#2	Participants complete a questionnaire before and after a counseling intervention.	No	The study involves an intervention that is distinct from the data collection method.
#2	Study involves saliva collection and blood draw.	No	Collection of biospecimens is not allowed under exemption category #2
#2	Survey that links responses to respondents' financial information.	No	**Linking** of data with other personally identifiable information is not allowed under exemption #2. Informed consent is necessary when survey/interview data is linked to other sources
#2	A longitudinal survey with previously recruited participants that will link current survey responses to survey responses provided ten years ago.	No	**Linking** of current data with data provided in the past is not permissible. Informed consent is necessary when survey/interview data is linked to other sources.

Exempt 2 Research and Consent

The Common Rule requirement for a consent form does not apply to Exempt research. Local HRPP Policies and Procedures require that there still be a consent process for exempt studies that involve direct interaction with subjects. This should include:

- that this is a research study; and
- that participation is voluntary; and
- the purpose; and
- what the subjects are being asked to do; and
- confidentiality protections; and
- how long participation is expected to take; and
- a disclosure if the subject will be audio- or video-taped; and
- how to contact an investigator or research staff member for questions about the study.
- If no identifiable information is collected AND HIPAA is not involved, there is no requirement for a signature, and no requirement that this information be given in writing. The elements can be included as part of an on-line survey, as a written sheet that is given to participants, or it can be delivered orally.

Exempt Information Sheet Template can be found here: https://www.bumc.bu.edu/irb/files/2016/10/Exempt-Information-Sheet-Template.docx

Example of an EXEMPT INFORMATION SHEET

You are being asked to voluntarily participate in a research study. We are doing this study to understand what barriers new mothers like you experience when trying to breastfeed their infant. If you agree, we will ask you to join us for a focus group at the HAPPY MOM AND TOT resource center. The focus group will take about an hour to complete.

We will make an audio recording of the focus group. We will ask everyone in the focus group not to talk about the discussions outside the group. However, we can't promise that everyone will keep what you say confidential.

We will not record your name or any information that shows your identity. You will not be signing this form. We will destroy the audio recordings as soon as we have transcribed them.

If you have any questions, please contact Florence Nightingale at email, and phone number XXXXX

Exempt 2 Research and HIPAA

- Exempt studies involving gathering, using, and sharing Protected Health Information (PHI) must follow the requirements of the Health Information Portability and Accountability Act (HIPAA).

- It is a violation of HIPAA regulations to use or share a subject's PHI without the subject's signed authorization or a waiver of authorization from the IRB.

- Some exempt studies need access to BMC medical records to identify subjects who may fit the inclusion and exclusion criteria. This use of PHI requires a waiver from the IRB, regardless of whether you are accessing the records yourself or are obtaining them from the Clinical Data Warehouse. To request this Waiver, you need to complete the HIPAA section in INSPIR.

- Exempt studies that involve interaction with subjects during which PHI is collected need to have written HIPAA authorization obtained from the subjects.
  - Templated HIPAA language and signature lines should be added to the consent statement.

REMEMBER....

PHI (*Protected Health Information)*

=

Information about health status, provision of health care collected by a covered entity

+

linked to one of 18 HIPAA identifiers

Exempt 2 Research: What else?

In addition to your consent statement, the IRB needs to see the following documents/attachments:

- Survey questions, focus group and interview guides
- Demographic questionnaires
- Any materials that are subject facing
- Recruitment materials including initial or e-mail reminders

The process for approval of recruitment materials can be found here https://www.bumc.bu.edu/irb/files/2019/07/Research_Study_Recruitment_Promotion_Toolkit.pdf

The IRB does not need to see

- Separate protocols for exempt studies
- Translated consent forms and translator attestations
- Grant applications

After Exempt Determination

BMC/BUMC IRB requirements for exempt research: What comes next?

- Exempt determinations are given a status check-in date that is three years from the date of the initial determination.

- If during this period you make changes to your project that may affect the Exempt determination or HIPAA determination, then you will need to submit an amendment.* This includes changes to:
  - protections for privacy and confidentiality; or
  - funding; or
  - recruitment procedures; or
  - information provided for a waiver of HIPAA authorization
  - procedures related to the retention of data or samples for extra use

*If you are not sure whether you need to submit an amendment to an Exempt 2 study, contact the IRB.

After Exempt Determination – cont.

BMC/BUMC IRB requirements for exempt research: What comes next?

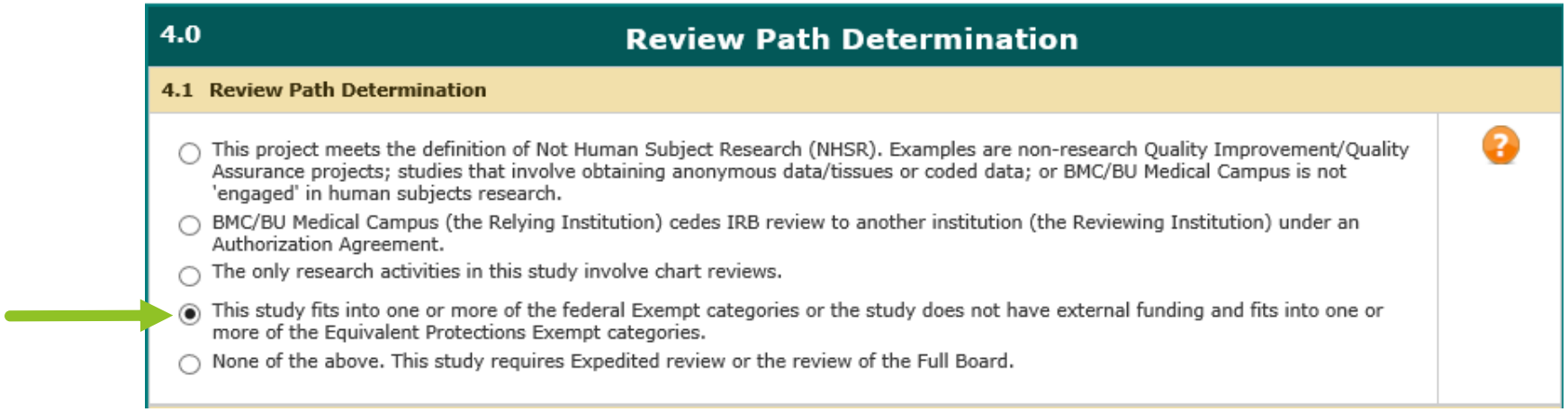
- Three years after the Exempt determination, you will receive a request to fill out a brief status check-in form that includes questions about the status of the study; and a request to detail the changes, if any, that have been made to the study since the time of initial review by the IRB.
  - You will indicate whether you wish to close the study or renew your Exempt determination for another three years.

- You are required to submit Internal Study Personnel Change forms in order to add new study personnel or remove personnel who are no longer working on the study.

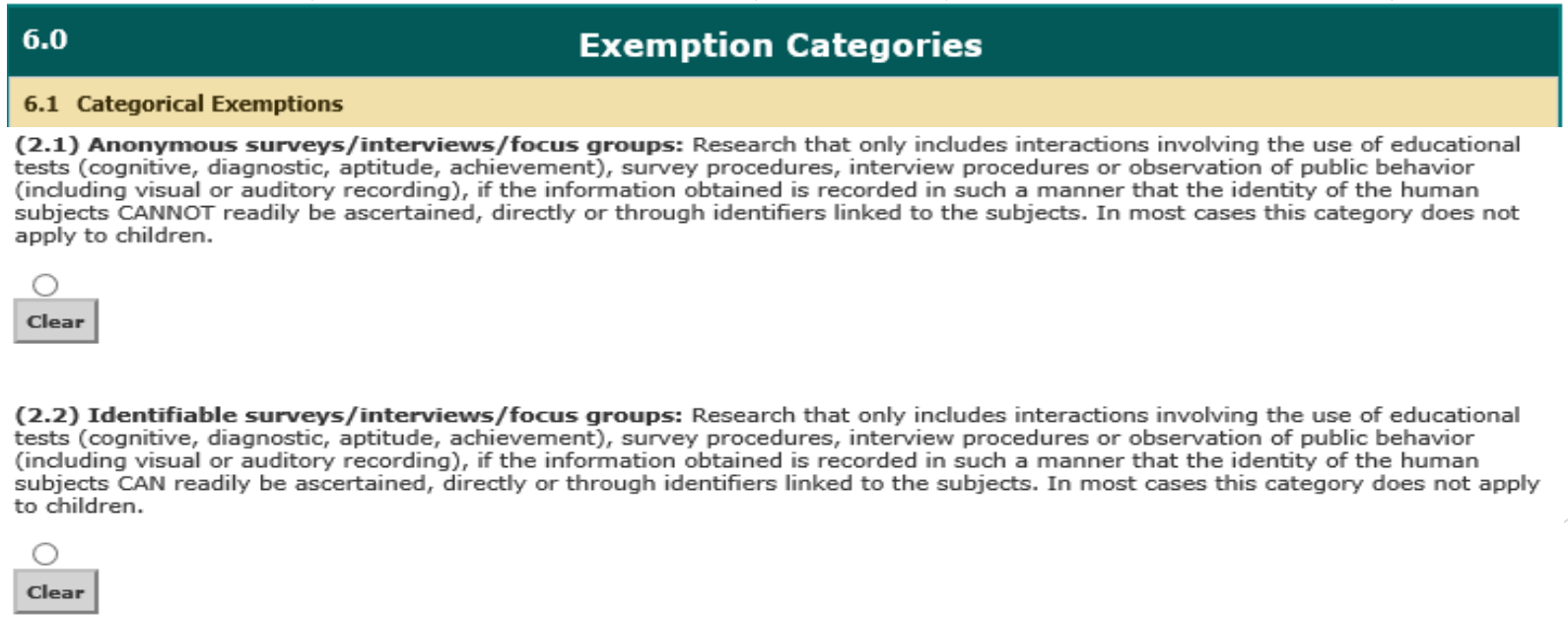
Human Subjects Training requirements for study staff continue to apply to your study during this three-year period

Exempt Research and INSPIR: How To Complete An Exempt 2 Application

Step 1: Selecting Review Path



Step 2: Select 2.1 (Anonymous Surveys) or 2.1 (Identifiable Surveys)



NOTE: IRB Analysts are responsible for making the determination about whether a project meets one of the Exempt criteria. Applicants indicate that they *think* that their project qualifies as Exempt in the Review Path Determination screen of the INSPIR application.

Step 3: Section 6.2 (Study Procedures)

6.2 Study Procedures

Provide a description of all the study procedures. Be sure to describe study methods, how you will select and access data (if applicable), and interventions or interactions with subjects (if applicable).

- For example:
  - Remote (BU/BMC Zoom) or in-person activities?
  - Paper or electronic surveys?
    - **NOTE:** BMC Investigators may only use BU REDCap. BU Investigators may use BU Qualtrics or BU REDcap. **NO* Google Forms*
  - Audio-recording?
    - **NOTE:** There are restrictions with using Zoom recording function for BMC Zoom.

Step 4: Section 6.4 (Prospective Recruitment and Consent)

6.4 Prospective Recruitment and Consent of Eligible Subjects

Describe plans for screening and recruiting potential subjects. Describe how you will obtain abbreviated consent (see Exempt Information Sheet Template) from subjects prior to participation. (Note that if your consent process includes obtaining an authorization for use of Protected Health Information, you must use the Use and Disclosure of Your Health Information language in the template. If the research is in Exempt category 3.1 or 3.2 and involves deceiving the subjects regarding the nature or purposes of the research, the abbreviated consent must include informing subjects that they will be unaware of or misled regarding the nature or purposes of the research.)

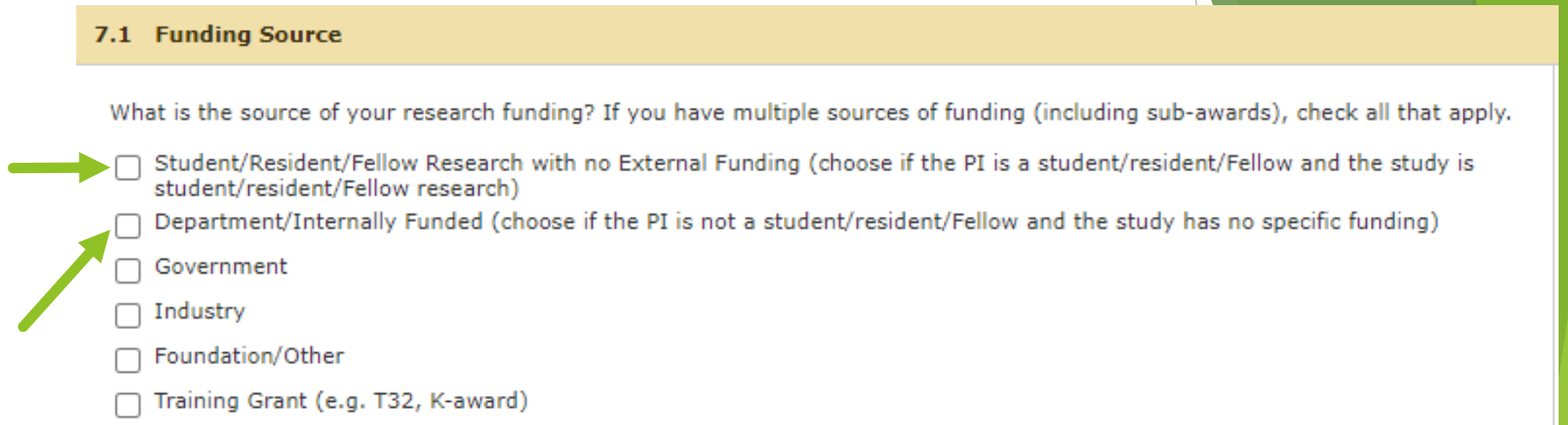
- How are you going to approach potential subjects for recruitment? Where are you obtaining email addresses?
- How are you going to present them with the Exempt Information Sheet? (e.g., include language in recruitment email, at the beginning of survey, read out-loud before interview, etc.)
- How are you obtaining HIPAA Authorization signatures, if required?

NOTE: BUMC/BMC espouses a warm hand-off approach: the first point of contact for the study should be a member of the subject's clinical team

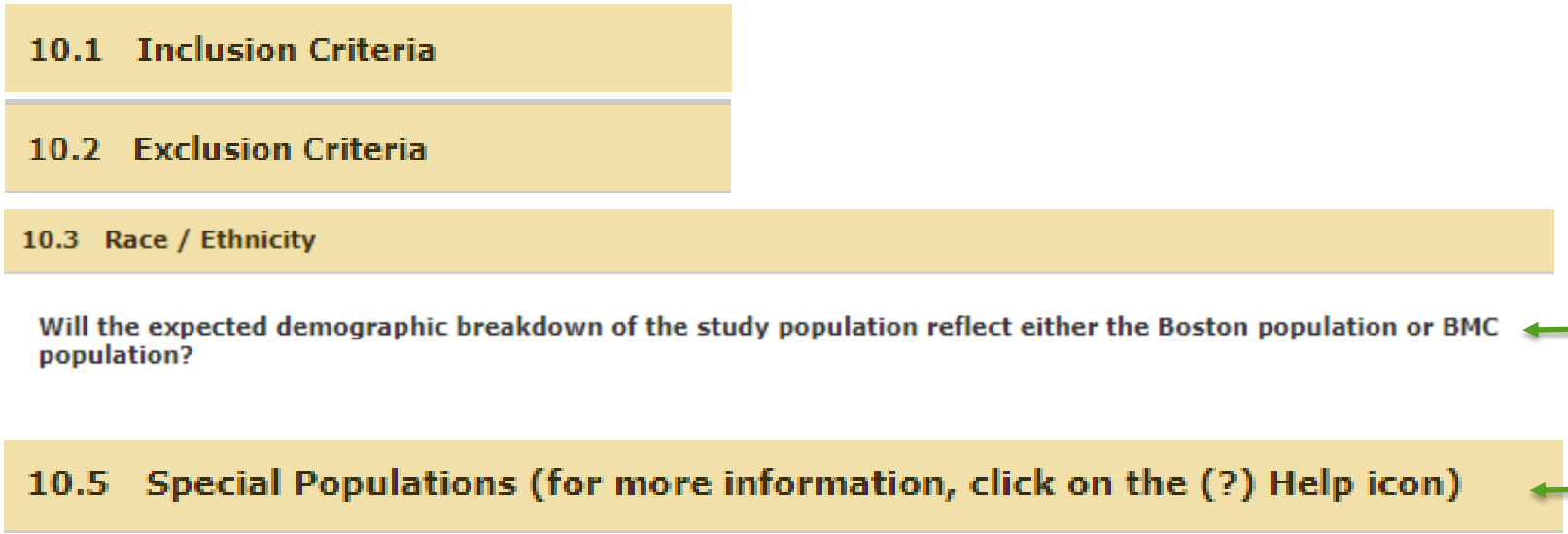
Step 5: Section 7.1 (Funding Details)

If no External Funding:
Only select "Student Funding" if PI is a student, Resident, or Fellow.

Otherwise, select Department/Internal.



Step 6: Section 10.0 (Subjects)

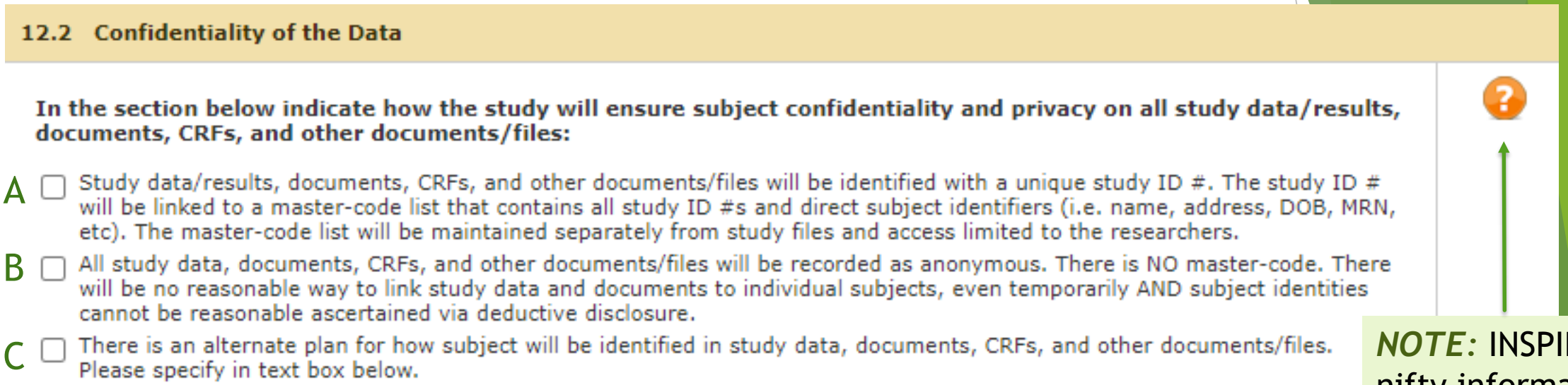


NOTE: Consider whether the demographic of your subject population matches that of the BMC patient/Boston population.

e.g., If subjects are medical students, the answer is NO.

NOTE: INSPIR Submission may require additional sign-off for special populations (e.g., medical or dental students, BMC Residents or Fellows)

Step 7: Section 12.2 (Confidentiality of the Data)



12.2 Confidentiality of the Data

In the section below indicate how the study will ensure subject confidentiality and privacy on all study data/results, documents, CRFs, and other documents/files:

A ☐ Study data/results, documents, CRFs, and other documents/files will be identified with a unique study ID #. The study ID # will be linked to a master-code list that contains all study ID #s and direct subject identifiers (i.e. name, address, DOB, MRN, etc). The master-code list will be maintained separately from study files and access limited to the researchers.

B ☐ All study data, documents, CRFs, and other documents/files will be recorded as anonymous. There is NO master-code. There will be no reasonable way to link study data and documents to individual subjects, even temporarily AND subject identities cannot be reasonable ascertained via deductive disclosure.

C ☐ There is an alternate plan for how subject will be identified in study data, documents, CRFs, and other documents/files. Please specify in text box below.

- **A** – Identifiable Surveys, etc. (i.e., mastercode exists)
  - Storage of mastercode vs. Study data set
  - What identifiers are included in the MC?
- **B** – Anonymous Surveys, etc. (i.e., no mastercode)
- **C** – OTHER (e.g., mix of anonymous and identifiable data collection)

NOTE: INSPIR has nifty information! Please check the '?' Icon for details on appropriate PHI storage, etc.

IMPORTANT: There is a specific way to set up REDCap/Qualtrics surveys such that the data collected is truly anonymous (instead of being linked to the respondents' email addresses).

- BU REDCap: Create survey using "Public Survey Link" function.
- BU Qualtrics: Set up survey using a "public" link AND check "Anonymize Response" under the Survey Options prior to publishing and disseminating the survey.

Step 7: Section 12.2 (Confidentiality of the Data) Cont.

Do you plan to share data with a third-party vendor or software application or program? Some examples include transcription services and smartphone apps. Note: sponsors are not considered third parties. Please contact the IRB @ medirb@bu.edu if you have questions about whether this applies to your study.

- (●) Yes
- ( ) No

NOTE: If manually transcribing audio recordings, please select 'NO' and mention manual transcription in textbox.

Approved Options:

BMC research: The already-approved options for BMC are listed in the (?) icon in the right-hand column of this section.

BU research: BU Information Technology has posted the following approved options for use:
https://www.bumc.bu.edu/it/infosec/researchcompliance/

Are you using one of these approved options?

- ( ) Yes
- ( ) No

- If using unapproved third-party vendor (such as transcription service), you will need to contact privacyofficer@bmc.org (BMC) or bumcinfosec@bu.edu (BU). They will need to review their privacy and security practices.
- IRB recommends you make this contact PROMPTLY as this process can require significant information gathering and analysis.

If Data is Identifiable....

12.3 Release of identifiable data.

Is identifiable data being released outside of BMC/BU Medical Campus? (e.g. to sponsors, because of mandated reporting, etc).

- (●) Yes
- ( ) No

If identifiable data is being transmitted outside of BMC/BU Medical Campus, please describe what information will be released and under what circumstances, to whom the information will be released, and how confidentiality will be maintained during data transmission. (e.g. encrypted email, encrypted flash drive, sponsor-provided data capture system).

Pertinent findings (related to the aims of the study) and incidental findings (unrelated to the aims of the study): Does the research (including screening) involve any test or procedure done for research purposes only that may yield findings that are of potential health or reproductive importance to the individual subjects (e.g., disease risk, abnormal lab values, imaging abnormalities, genetic results)?

- ( ) Yes
- (●) No
- ( ) Not Applicable - no additional research results will be collected for this study.

12.4 Destruction of Identifiers

If the data are identifiable and/or if a master-code exists, when and how will the data be de-identified or the master-code be destroyed?

Click here to access the text editor.

NOTE: If releasing data outside of BMC/BUMC Campus, a Data Use Agreement may be needed.

For More Info:
BMC: DUA.MTArequest@bmc.org
BU: segarra@bu.edu

NOTE:

1. Mastercode should be destroyed as soon as no longer needed.*
2. The study data should be retained for at least 7 years after completion of study per institutional retention policy.
3. Audio Recordings should be destroyed immediately after transcription.*
4. Identifying information in the transcripts should be redacted.

*unless study is federally funded.

Step 8: Section 13 (HIPAA Compliance) - Requesting Waiver of HIPAA Authorization for Recruitment

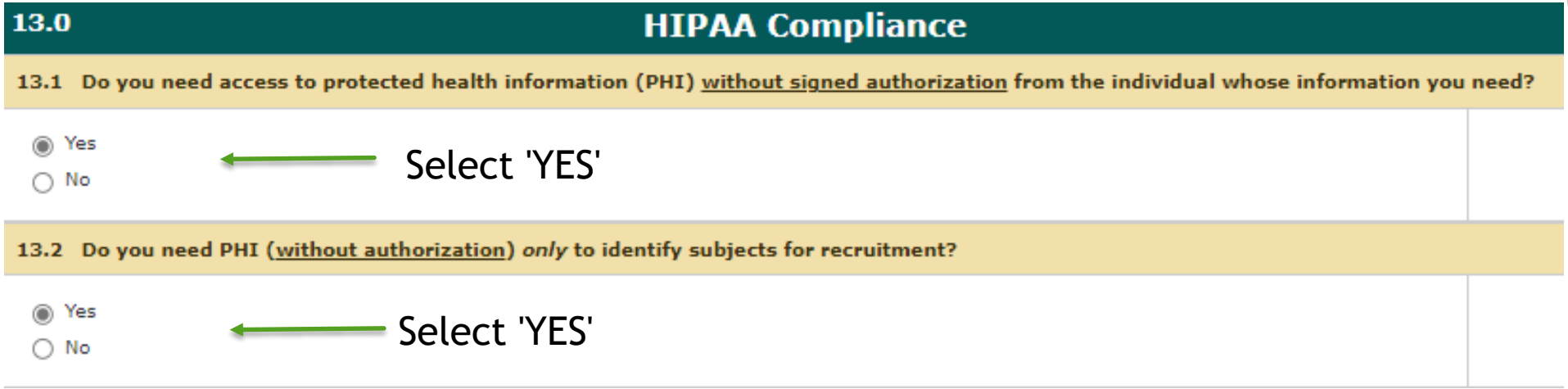
- Many research projects need to go into BMC medical records to identify subjects who may fit the inclusion and exclusion criteria.

- Use of PHI requires a waiver from the IRB, regardless of whether you are accessing the records yourself or are obtaining them from the Clinical Data Warehouse.

- INSPIR application has a HIPAA section where you can request this waiver.
  - ***IMPORTANT:*** Make sure that you accurately answer the questions about selection criteria, data fields, and date range; otherwise, your waiver will be invalid and you may be violating HIPAA regulations if you access PHI for which you have not received a waiver.

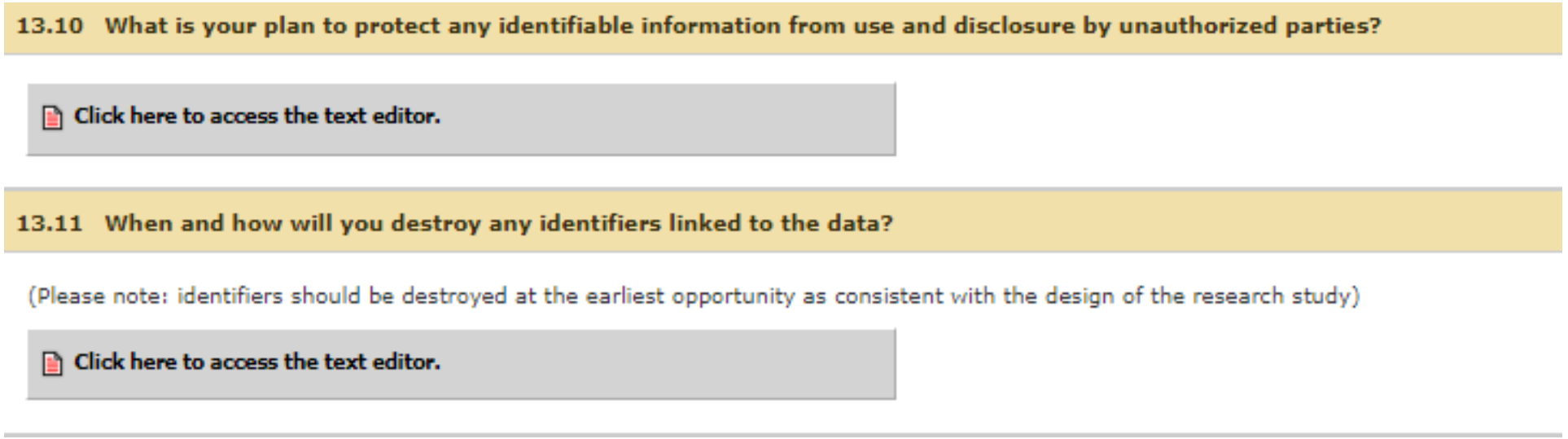
- HIPAA Waiver grants you access to only the medical records whose dates are within the approved date range, as noted in the Outcome Letter. If you'd like access outside of the date range, you must submit an amendment justifying why updating the date range is necessary.

Step 8: Section 13 (HIPAA Compliance) - cont.



- **Other HIPAA Sub-sections:**
  - 13.3 - The inclusion criteria of the potential subjects.
  - 13.4 - The dates of the records you wish to access.
  - 13.5 - List the variables that are needed from the medical record to identify whether subjects are eligible.
  - 13.4 - Who is accessing medical records? CDW, Study Team, or Both?
  - 13.7 - What HIPAA Identifiers do you need to access? (e.g., Name, MRN, contact information, Dates, etc.)
  - 13.8 & 13.9 - Study-specific justifications as to why you need the PHI and why research cannot be practicably conducted without obtaining signed authorization for PHI use.

Step 8: Section 13 (HIPAA Compliance) - cont.



- ***Section 13.10***
  - How will protect the identifiable information accessed from the medical record? (i.e., mastercode containing direct identifiers such as MRN, Name, Contact Information, etc. Stored in BMC Network Drive, BMC Box.com or BU Y Drive)
  - Who will have access to the identifiable information?

- ***Section 13.11***
  - How will you destroy the identifiers accessed from the medical record?

Step 9: Attach Relevant Documents

Please be sure to attach the following documents under "Other Study Documents":

1. Exempt Information Sheet(s)

2. Recruitment materials (including flyers, email drafts, opt-out letters, etc.)*

3. Interview/Focus-Group Guides

4. Surveys

*Recruitment materials such as flyers, social media posting, postcard, brochure, posters, or ads require review by the appropriate Communications Office.

Helpful Resources

- **CR Times, March 2019 Issue**
  https://wwwapp.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=738
- **OHRP Exempt Research Decision Chart #4**
  https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1
- **Code of Federal Regulations, 45 CFR 46.104(d)(2)**
  https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#p-46.104(d)(2)
- **Univ. Michigan Exempt 2 Tip Sheet**
  https://research-compliance.umich.edu/sites/default/files/resource-download/exemption_2_-_tips_and_examples.pdf
- **BUMC/BMC IRB Templates – Exempt Information Sheet**
  https://www.bumc.bu.edu/irb/inspir-ii/irb-templates/
- **Clinical Research Resource Office (CRRO)**
  https://www.bumc.bu.edu/crro/

PRO TIP:
The IRB is ***THE*** BEST HELP AVAILABLE! Contact us at medirb@bu.edu