IRB 101

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Disclaimer:

The application of the regulations is an art, not a science.

- If it was an exact science, we wouldn't need staff – just a long application.

Ethics and Belmont Principles – grey topics

Opinions, to some extent, may vary. Interpretations, to some extent, may vary. Application, to some extent, may vary.

This presentation is consistent with the regulations known to me and to the BUMC/BMC HRPP policies and procedures.

However, this is JAMIE and CLAIRE's presentation: not Matt's, Katie's, Lin's, Rob's, Emily's, Jackson's, Mary-Tara's or Karla's. We strive to be as consistent as possible but we have different experiences.

Your mileage may vary.

Outline

1. Key BUMC IRB resources
2. Choosing the Correct **Review Determination Pathway**
3. “Deep dive” into **Recruitment & Screening**
4. IRB “Pet peeves”

BUMC IRB Resources

BUMC IRB Webpage: http://www.bumc.bu.edu/irb/

- INSPIR II Instructions for Investigators: http://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/
- IRB Personnel Directory: http://www.bumc.bu.edu/irb/about-us/personnel/
- HRPP Policies & Procedures document: http://www.bumc.bu.edu/ohra/hrpp-policies/

Weekly IRB drop-in sessions: Tues & Wed: www.bumc.bu.edu/irb/drop-in-schedule/

INSPIR II portal: https://inspir.bu.edu/

BU Clinical Research Resources Office (CRRO): http://www.bumc.bu.edu/crro/

- Consultations: http://www.bumc.bu.edu/crro/research-and-regulatory-consultations/

BU vs. BMC vs. BUMC vs. INSPIR II

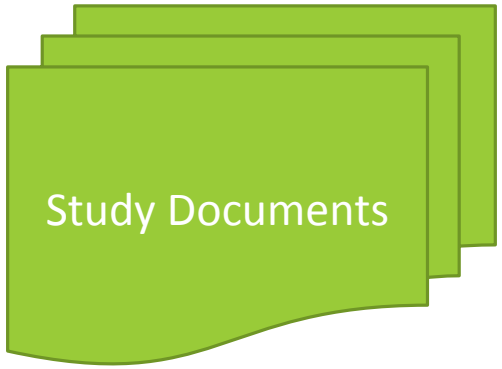
Boston University Medical Campus IRB

- Boston Medical Center — EXCEPTIONAL CARE. WITHOUT EXCEPTION.
- Boston University School of Medicine
- Boston University Henry M. Goldman School of Dental Medicine
- Boston University School of Public Health

INSPIR II = web portal for BUMC IRB applications

https://inspir.bu.edu/

IRB Submission “Packet”



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IRB INSPIR Application

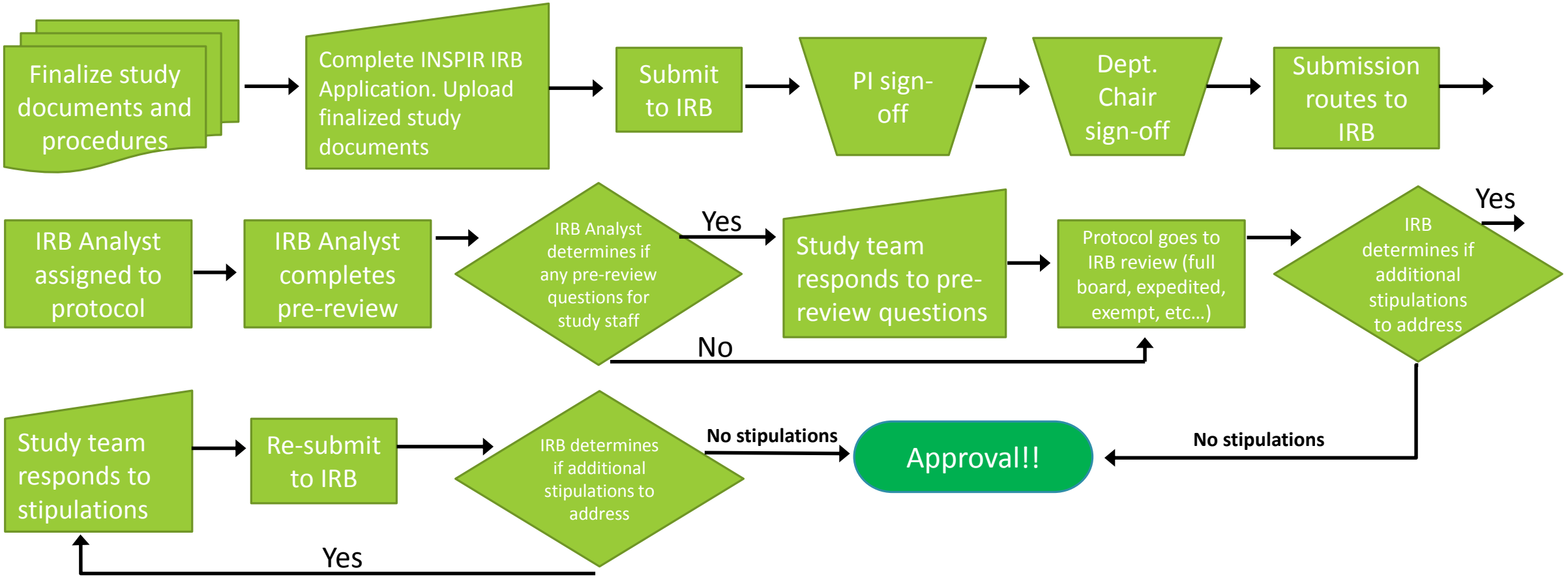
=

Complete IRB submission packet!

- Protocol (if required)
- Consent Form(s)
- Study Assessments/Data Collection Forms
- Recruitment Materials
- Investigator Brochure
- Etc…

- All study staff added
- All documents uploaded to INSPIR application

IRB Initial Submission Flowchart



Choosing the Correct Review Pathway

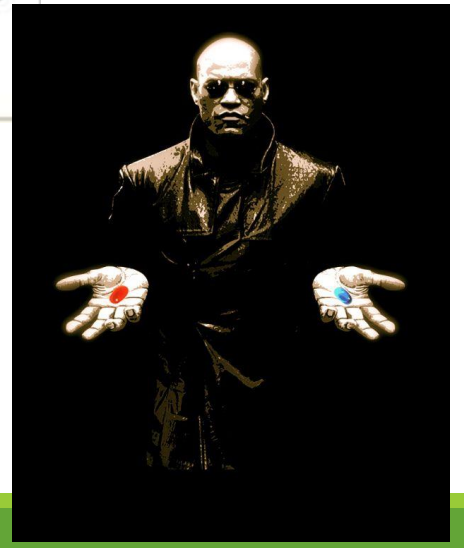
1. NOT HUMAN SUBJECTS RESEARCH (NSHR)
2. CEDE REVIEW
3. CHART REVIEW ONLY
4. EXEMPT/EQUIVALENT PROTECTIONS
5. EXPEDITED/FULL BOARD

How do I choose?

4.0 Review Path Determination

4.1 Review Path Determination

- ○ This project meets the definition of Not Human Subject Research (NHSR). Examples are non-research Quality Improvement/Quality Assurance projects; case reports or case series that include three patients or fewer; studies that involve obtaining anonymous data/tissues or coded data; or BMC/BU Medical Campus is not 'engaged' in human subjects research.
- ○ BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.
- ○ The only research activities in this study involve chart reviews.
- ○ This study fits into one or more of the federal Exempt categories or the study does not have external funding and fits into one or more of the Equivalent Protections Exempt categories.
- ◉ None of the above. This study requires Expedited review or the review of the Full Board.



Not Human Subjects Research (NSHR)

Not Human Subjects Research (NHSR)

Human subject: a living individual about whom an investigator conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

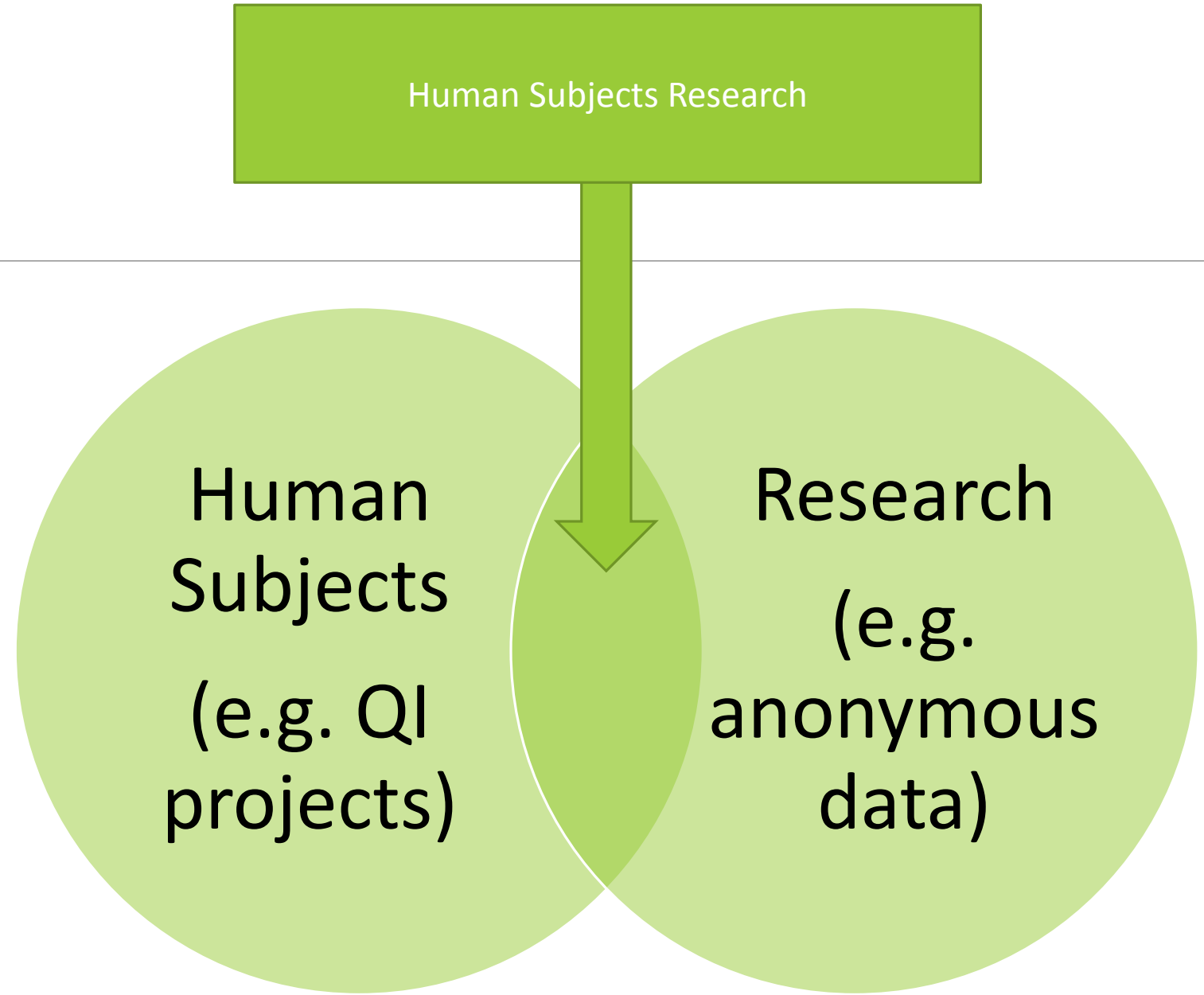
Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Not Human Subjects Research (NHSR)

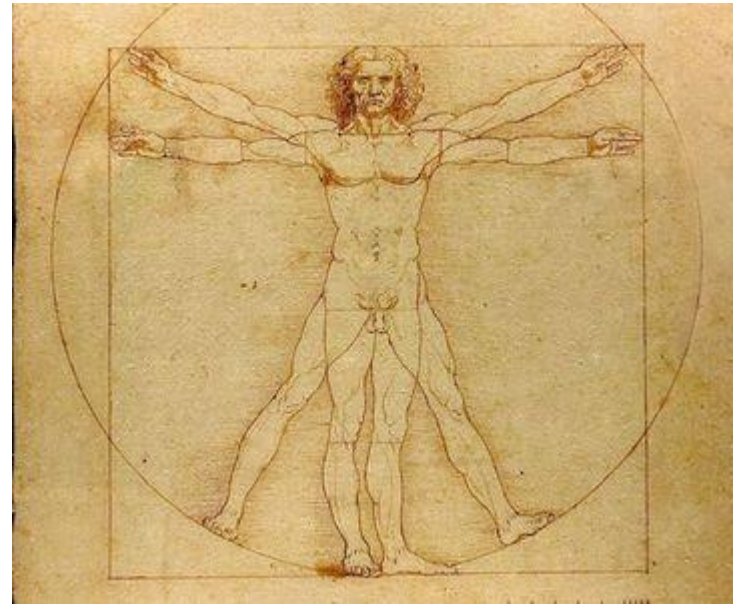
Common types of research with NO human subjects:

- Analysis of publicly available data (data is not 'private information')
- Analysis of anonymous datasets; for example, from CDW (data is not identifiable)
- Laboratory science with non-identifiable samples
- Someone is serving as a biostatistician; only analyzing coded data

*If you are confident that the research is NHSR, no IRB submission is needed (unless funder or releasing institution requires IRB determination)


Human Subjects Research
Human Subjects
(e.g. QI projects)
Research
(e.g. anonymous data)

Human Subjects Research



CEDE REVIEW

CHART REVIEWS

EXEMPT/EQUIVALENT PROTECTIONS

EXPEDITED/FULL BOARD REVIEW

4 Review Paths for Human Subjects Research

1. Cede Reviews – Contact Roz: 358-5329; roz@bu.edu
2. Chart Reviews only
3. Exempt Human Subjects Research
   - *Exempt* as per federal regulations 45 CFR 46.101(b), or;
   - *Equivalent Protections* for Research without Federal Oversight (BU/BMC-specific)
4. None of the above (i.e. Non-Exempt HSR)
   - *Expedited* (Not greater than minimal risk), or
   - *Full Board*

Chart Review

Use this pathway when your only research activity is a chart review of internal clinical records.

The IRB review is tricky because it depends on both the funding source and how you're abstracting your data. However, we have a 'smart form' that will adapt to make sure we're getting all the necessary information to make the right determinations.

While you can submit chart reviews under different pathways (exempt 9 or 'none of the above'), using the Chart Review pathway will be the shortest and least amount of work for you.

Levels of IRB Review

Full Board

- Greater than 'minimal risk'
- Not covered in other categories
- Ex: Drug, device, surgical interventions, invasive sampling or very sensitive SB interventions

Expedited

- Not greater than 'minimal risk'
- Reviewed by 'expeditors'
- Fits into one of 7 statutory* or new equiv. protections categories
- Ex: Non-invasive sample collection; Research on Existing Records; SB interventions

Exempt

- Fits into 6 statutory* or new equiv. protections categories
- Ex: Anonymous surveys; most chart reviews

*Defined by federal regulation (45 CFR 46)

Exempt Human Subjects Research:
Under Federal Regulations (45 CFR 46.101(b))

There are 6 federal exempt categories; generally, only 3 apply to research at BU/BMC. These submission are reviewed by the IRB Staff.

(1) Educational Research (only applies to research on students)

(2) Surveys/Interviews (only applies when anonymous or benign)

(3) Retrospective Analysis (only applies to existing data where subjects cannot be identified through direct or indirect identifiers; e.g. anonymous chart reviews)

BUT WAIT… THERE'S MORE!

Equivalent Protections:

There are 6 additional exempt categories that can be used when certain criteria are met. These are categories 7-12 in INSPIR.

We have flexibility to use these non-federal categories because the federal government only has oversight in a few situations:

- -When the study is funded by the Feds or there could be Medicare payments
- -Study involves drugs or devices (FDA regulated)
- BUMC/BMC IRB is serving as IRB of record for another site
- The IRB promised that we'd apply the federal rules.

If there is any external funding, we don't apply equivalent protections since the contract may have language that notes that we'll use the federal rules. Rather than listing which sponsors allow or don't allow, we've decided to only employ the federal rules with any funded study.

Equivalent Protections for Research without Federal Oversight

New exempt categories

7. Benign behavioral interventions (check definition in policies)
8. Surveys/interviews with children (req parental permission)
9. Existing or future data **not** originally collected for research purposes
10. Existing data collected for research purposes (ICF consistent with proposed use)
11. Research involving Quality Improvement/Quality Assurance
12. Surveys/interviews that are sensitive and NOT anonymous with adequate confidentiality protections

Why do I want my research Exempt?

Lowest level of review

Shorter Application

Exempt information sheet instead of consent form

Amendments: Are only needed if:

- If the amendment change will affect the exempt determination (new exempt category or bump up to non-exempt review)
- If a completely new recruitment document/recruitment strategy
- Change in a HIPAA element
- If you receive new funding

3-year approval period (no annual review)

If phases of your study would be exempt – you can cut up your study!

NICE

“None of the above” - The Non-Exempt

Two options: Full Board or Expedited

For Both, IRB must determine that the 111 criteria are met

1. Risks minimized
2. Favorable Risk/Benefit Ratio
3. Equitable Selection
4. Consent process – may be waived, if applicable
5. Documentation of consent – may be waived, if applicable
6. Data safety monitoring, if appropriate
7. Adequate Confidentiality
8. Additional safeguards for vulnerable populations, if appropriate

Non-Exempt Research: Expedited Review

The IRB will elect Expedited review if study is **not greater than minimal risk** and every research activity can fit into one of 7 federal categories or 3 equivalent protections categories.

Not greater than minimal risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Expedited Review:

- Generally reviewed by an IRB staff member (who is also a Board member). Although, we often will ask for input from other Board members of Consultants.
- Processed on first-come, first serve. Often times faster than full board review – but not always!
- If submitted as expedited, but could be exempt, we'll review it as exempt without you changing the review pathway.

Non-Exempt Research: Full Board Review

- Research that is greater than minimal risk and/or does not qualify for exempt or expedited review, as defined by the categories, will be reviewed at the Full Board IRB meeting.
- Certain populations used in some study designs: children or prisoners.
- Experimental drug or device studies.
- Invasive sampling collection.

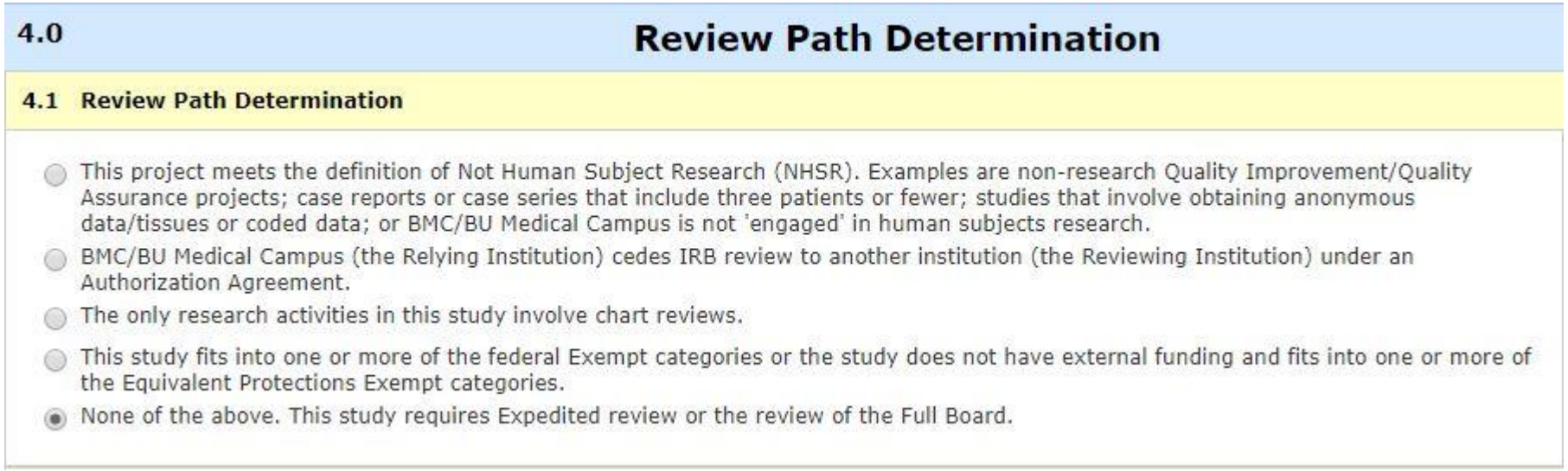
When to use “None of the above”:

If your study involves: Drugs, Devices, Biomedical interventions, ‘non-benign’ sociobehavioral interventions, prospective collection of bio-specimens, or the like → USE THE “NONE OF THE ABOVE” PATHWAY

If you’re unsure, the “None of the Above” pathway will capture all necessary information to make the appropriate determinations. If we can apply a lower standard of review, we will without you changing the pathway.

Take a swing:

An unfunded study is testing to see if sutures or staples lead to fewer infections. Subjects consented, randomized to either intervention, which are both standard of care.



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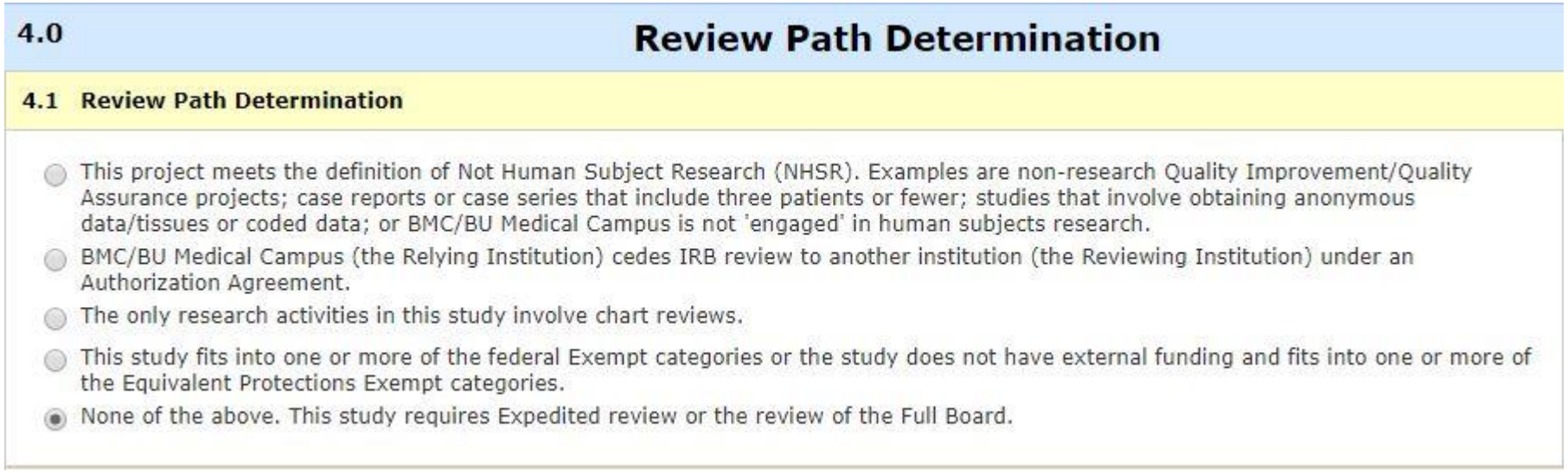
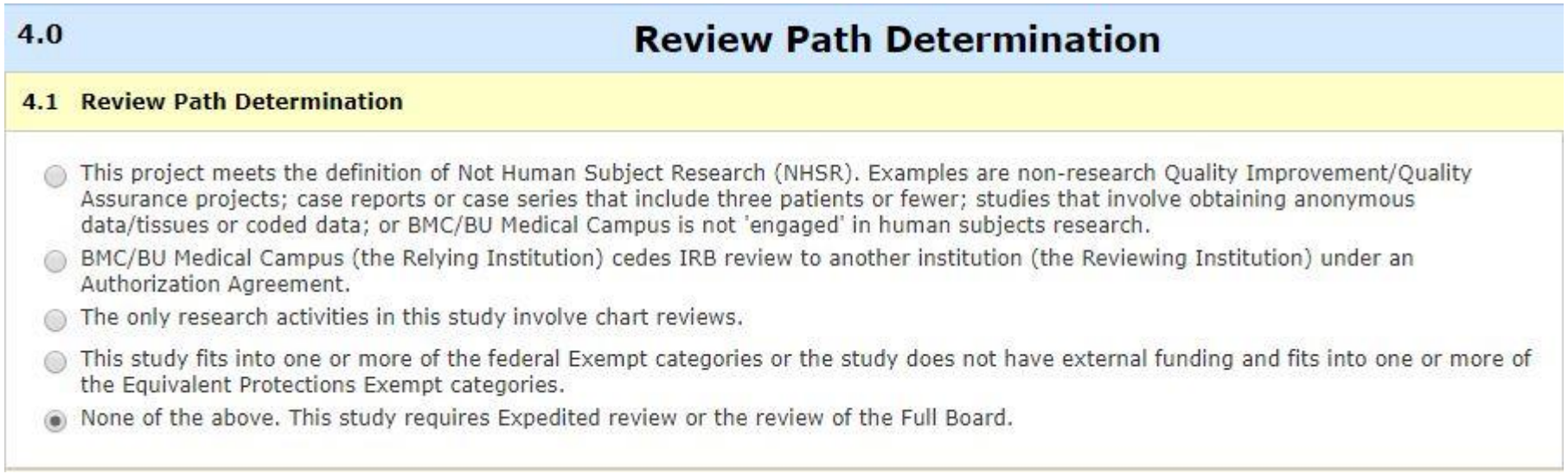


Take a swing:

An unfunded study wishes to ask formerly incarcerated individuals about their transitions back to the workplace. Recruitment via flyers. Data recorded anonymously with no audio recordings.



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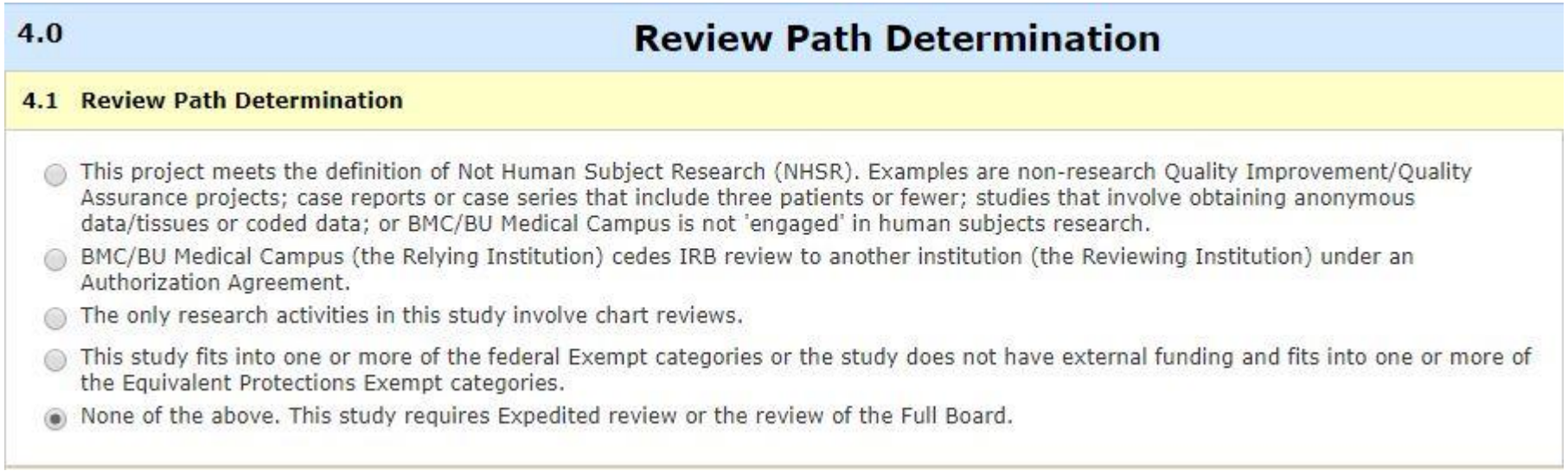
Take a swing:

A study with external funding wants to see if hospital departments where clinicians have similar political views yield better health outcomes for specific procedures. Will get a list of clinicians from BMC's website, will search for them on Twitter, will evaluate their public tweets for political leanings, and then will look up outcome data from public state-run database.



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Deep Dive:

RECRUITMENT & SCREENING

Recruitment

7.2.2.6.1 Recruitment Procedures Information

The submission information about recruitment procedures must include **a detailed description of how the research population will be identified, and how potential subjects will be contacted and provided information about the study**. The recruitment plan should draw subjects from a population selected to distribute the risks and benefits of the research in an **equitable** manner. The recruitment procedures should employ **adequate confidentiality protections** for potentially damaging information…

Recruitment: Common Issues

1. **Lacking sufficient detail to assess recruitment scheme.**
   - "We're going to recruit from our own patients in the XXX clinic".
     - Who is going to approach? PI or RA? Warm handoff?
     - How are you going to approach? In-person? Over-the-phone?
     - When is this approach – during scheduled clinical appointment?
     - Will you be using any scripts? Any flyers?
     - Where is the approach going to take place?
     - Are you going to approach everyone or only some?
       - How will you choose?
     - Will you be doing a pre-screen in the chart before approaching?

Recruitment: Common Issues

2. **Confusion over screening procedures [discussed later].**
   - Screening: interaction to determine eligibility **prior** to main consent
3. **Recruitment involves pre-screening in the medical record yet the HIPAA section is not filled out [discussed later].**
   - HIPAA section should ONLY list variables needed to determine eligibility
4. **Recruitment materials have compensation big & bolded or use the phrase "new treatment" w/o noting that it is investigational.**
   - All recruitment material needs to confirm to 7.2.2.6.3 of our policies
5. **Specifics for each cohort being recruited not provided.**
   - E.g. Healthy Control vs. Experimental; 'Some' will do a follow-up FG – which ones?

Recruitment: Ugh Moments

and how to fix them

Cold calls

- Opt-out letter

Approaches in the waiting room

- Clinic staff hands a flyer when checking in

Approaches by the study team in the clinic

- Warm handoff by known clinician

Recruiting the same day as a clinical procedure

- Sending recruitment material ahead of procedure with follow-up phone call

Snowball sampling where investigators is getting list of potentially eligible people's contact info

- Subjects hand flyers to potentially eligible people with investigators' info

Screening

15.5 Screening

Will any sensitive information or protected health information (PHI) collected during the screening without obtaining consent be retained that can be linked to the potential subjects OR does the study require any clinical screening procedures (blood draw, fasting, etc) performed solely for the purpose of determining eligibility in this research?

○ Yes ○ No

Will any potential subjects be directly contacted to obtain screening information?

○ Yes
○ No
○ Not Applicable - all screening activities have been completed for this already-approved study

Screening

Interaction w/ Subject

Chart Pre-screen

Brief Screening Agreement

Full Screening Consent

HIPAA Section Completed

Screening: Interaction

Any time you are obtaining private information about someone, you need some sort of consent process.

We have two screening interaction templates on our website:

- The Brief Screening Agreement (BSA)
- The Full Consent Screening form (FCS)

The choice of which one to use depends on what information you need and if you're going to retain this information as data.

If you're interacting with someone in order to determine eligibility, then you should select "Yes" in the second question. You will need to fill out the screening section.

Screening: Interaction

Type 	*Screening inclues questions that are potentially damaging and/or PHI)*	*Retention of data*	*Clinical Procedures (i.e. Blood pressure check, Fasting)*
Brief Screening Agreement	Maybe – if not linked	*-Name/Contact information retained, not linked to questions* *-all screening answers can be kept if unlinked*	Nope!
Full Screening Consent (FSC)	✓	✓	✓

Fast fact: HIPAA may come into play here. If retaining PHI in an identifiable way, will need signed Authorization.

Screening: Records w/o Authorization

When accessing PHI w/o authorization, the IRB must grant a HIPAA waiver and a waiver of informed consent. To do this, we need to assess:

1. Why you need PHI to conduct the research
2. Why it's impracticable to get HIPAA authorization from all participants
3. How you'll protect the PHI
4. When you'll destroy identifiers.

You should only be assessing the absolute minimum to make an eligibility determination. **This isn't a chart review.**

Recruitment & Screening

This is a challenging topic. Each scheme is study specific.

Opinions can vary widely on what's appropriate and what's not.

- My colleagues did a study surveying IRB chairs from dozens of institutions.
- Presented scenarios where respondents employed a Likert scale that assessed the likelihood of approval of the particular method at their institution.
- Major findings:
  - Vast variability.
  - Many 'It Depends…'
- We strive to be both internally consistent and historically consistent but "Past Determinations are not necessarily indicative of Future Determinations"

There are many permutations but if you thoughtfully read the INSPIR application and the help text, our 'Smart Form' will provide you with the sections you need to fill out and direct you to the materials you need to submit

Take a swing:

Do you have trouble sleeping at night?

Counting minutes on the clock instead of sheep?

Maybe we can help!

We're testing a new drug treatment called, Putchatosleep. (Risks include never waking up)

You could earn $3,000!!!!

Call Dr. Jones at xxx-xxx-xxxx

Take a swing:

A recruitment ad is posted asking for volunteers to call the study coordinator if they are over 18, are a smoker, and have tried a nicotine patch. A potential subject calls agrees that he meets the criteria. The coordinator doesn't record any research data but does take the caller's name and phone number and makes an appointment for the caller to come in to the clinic to enroll in the study.

Take a swing:

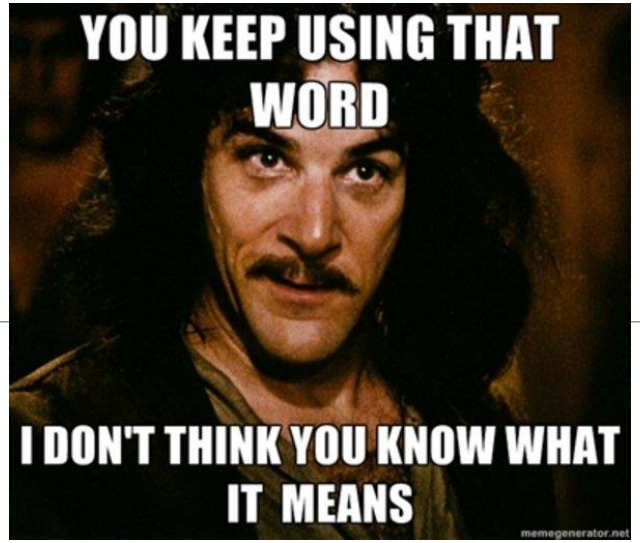
A PI is planning a clinical trial of a new medication for patients with hypertension. The screening interview, which takes about an hour**,** is done ensure each subject's eligibility before scheduling. Informational about illegal drug use is collected during the screening that must be linked to the subject so that the lengthy interview does not have to be repeated and the data can be used in the study if the subject is eligible; or so that the information can be retained in case an ineligible subject were to call again.

Take a swing:

PI wants to recruit subjects who are HIV positive to test out a non-FDA approved experimental drug. PI proposes doing a medical record pre-screen and then calling potential subjects – most are not their own patients.

Script states, “Hello, I’m a doctor at BMC. I know you have HIV. We’re testing out a new treatment. Would you like to know more?”

IRB Pet Peeves



WORDS MATTER: Coded ≠ De-identified ≠ Anonymous

- **Coded:** Identifiers have been removed (e.g., from data or specimens) and replaced with a code (words, numbers, etc) not derived from or related to the personal information. **BUT** identifiers are retained in a separate document that links with the code (mastercode, linking code, etc)
- **De-identified:** All direct personal identifiers are permanently removed (e.g., from data or specimens), no code or key exists to link the information or materials to their original source(s), and the remaining information cannot reasonably be used by anyone to identify the source(s). *Note: HIPAA covered data is de-identified when it does not contain any of the 18 identifiers specified by the HIPAA Privacy (or has been determined to be de-identified by a statistician in accordance with the Privacy Rule).*
- **Anonymous:** Identifiable (direct or indirect) information was not collected, or if collected, identifiers were not retained and cannot be retrieved.; Data/samples are *anonymous* if no one, not even the researcher, can connect the data to the individual who provided it.

IRB Pet Peeves

- Change request submissions that have numerous changes, but not every change is described in the Amendment Description section of the submission, *including* rationale for this change.
- Copy-and-pasting grant language into the IRB application - makes the review of the human subject research procedures and protections more difficult.
- Continuing reviews that are submitted at the last minute
- Lack of harmonization between IRB application information and attached study protocol
- Attaching updated document versions as new documents, instead of creating revisions to existing documents
- "Consent forms that require a PhD to understand what it means" ☺
- Using outdated templates (updated templates are listed here: http://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/)

IRB Pet Peeves

- Inappropriate boiler plate data analysis plans
- Providing answers that do not directly address the question asked in a section.
- Providing significantly more information than is required to answer an application question.
- Submitting exempt amendments that are not required

Thank you!

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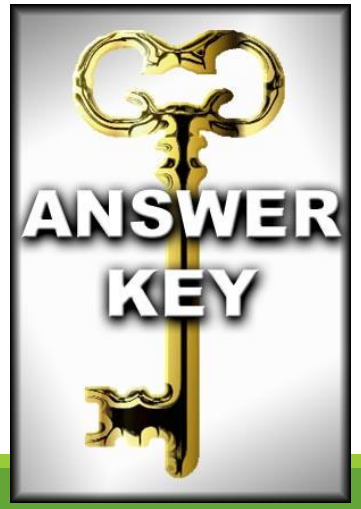
- 617-414-1911
- Claire.Oppenheim@bmc.org

Resources:
- https://www.bu.edu/crtimes/
- https://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/

Take a swing: Answer Key



Quick answer key:

Review path:

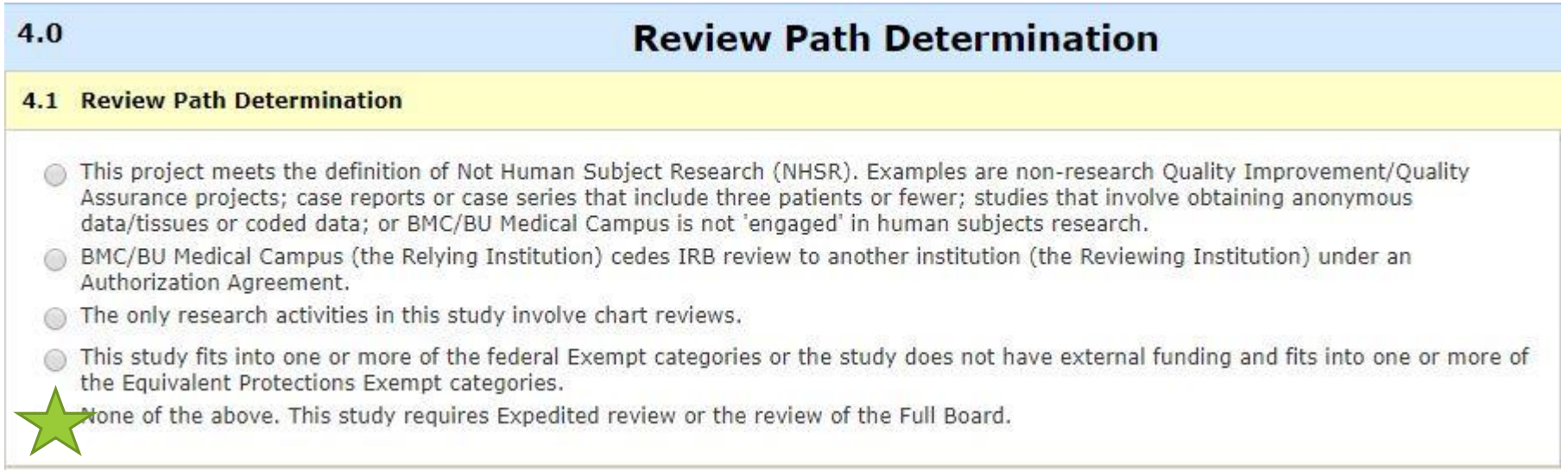
1. None of the above: Greater than min risk intervention
2. Chart Review: only procedure chart review w/ internal records
3. Exempt: Cat 2; survey where data is anonymous.
4. NHSR: All data is public w/ no interaction

Recruitment:

1. Flyer: does not conform to 7.2.2.6.3 of our policies
2. Subject calls: No research data obtained/recorded, no consent required
3. Screening drug trial: Sensitive data is retained, requires Full screening consent
4. HIV Cold call: Inappropriate recruitment procedure, deductive disclosure risks. Should use opt-out letter instead.

Take a swing:

An unfunded study is testing to see if sutures or staples lead to fewer infections. Subjects consented, randomized to either intervention, which are both standard of care.



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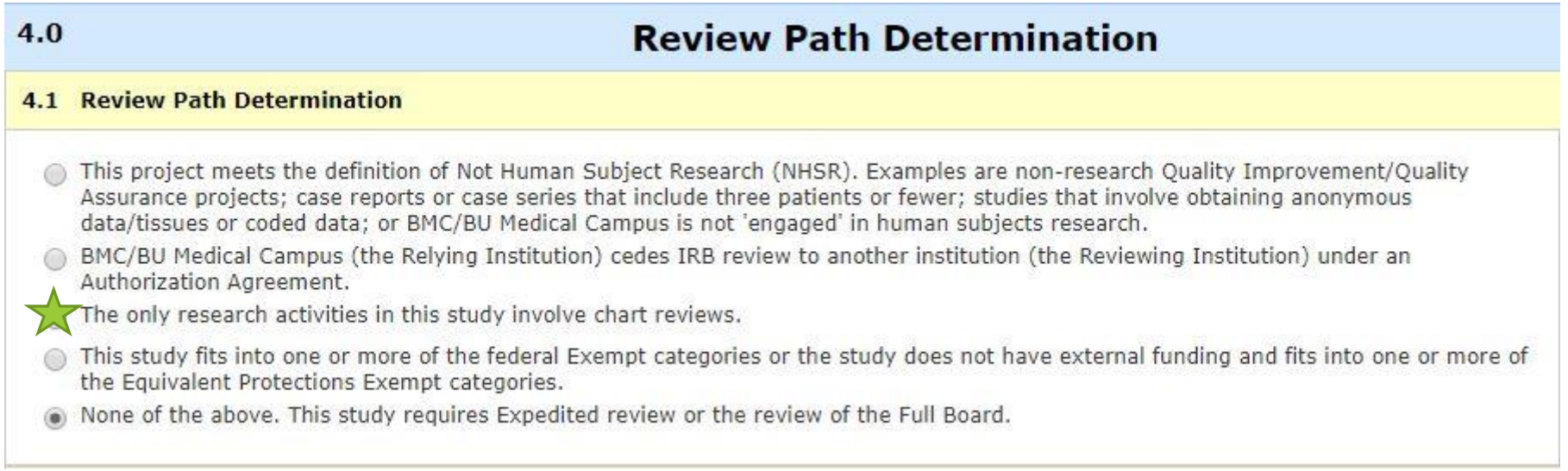
This study would require full board review since the intervention is greater than minimal risk. Randomization to an invasive procedure, which while it may be standard of care, the clinician Is not the one making a clinical decision in the best interests of the patient.

Take a swing:

An unfunded study is testing to see if sutures or staples lead to fewer infections. Investigators will look at BMC records from 2010-2015 and evaluate outcomes between those groups.



4.0 Review Path Determination

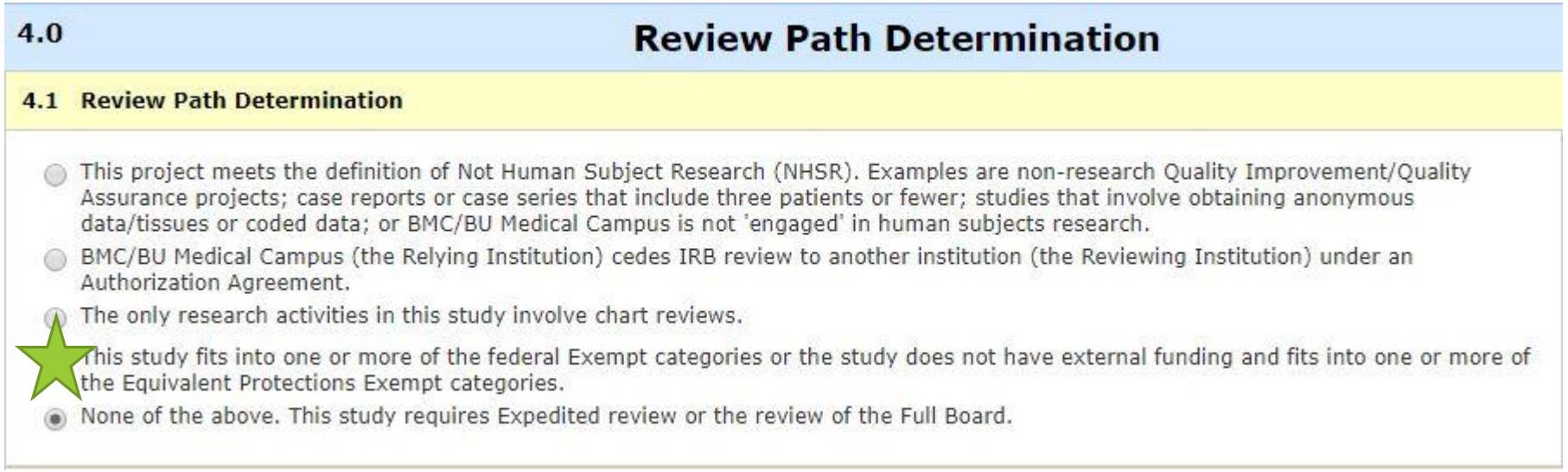
4.1 Review Path Determination

- ○ This project meets the definition of Not Human Subject Research (NHSR). Examples are non-research Quality Improvement/Quality Assurance projects; case reports or case series that include three patients or fewer; studies that involve obtaining anonymous data/tissues or coded data; or BMC/BU Medical Campus is not 'engaged' in human subjects research.
- ○ BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.
- ★ The only research activities in this study involve chart reviews.
- ○ This study fits into one or more of the federal Exempt categories or the study does not have external funding and fits into one or more of the Equivalent Protections Exempt categories.
- ◉ None of the above. This study requires Expedited review or the review of the Full Board.

This is a chart review: the only study procedure is reviewing of internal records. [It could also be submitted As ‘exempt’ category 9 since it is unfunded but the chart review path is easier!

Take a swing:

An unfunded study wishes to ask formerly incarcerated individuals about their transitions back to the workplace. Recruitment via flyers. Data recorded anonymously with no audio recordings.



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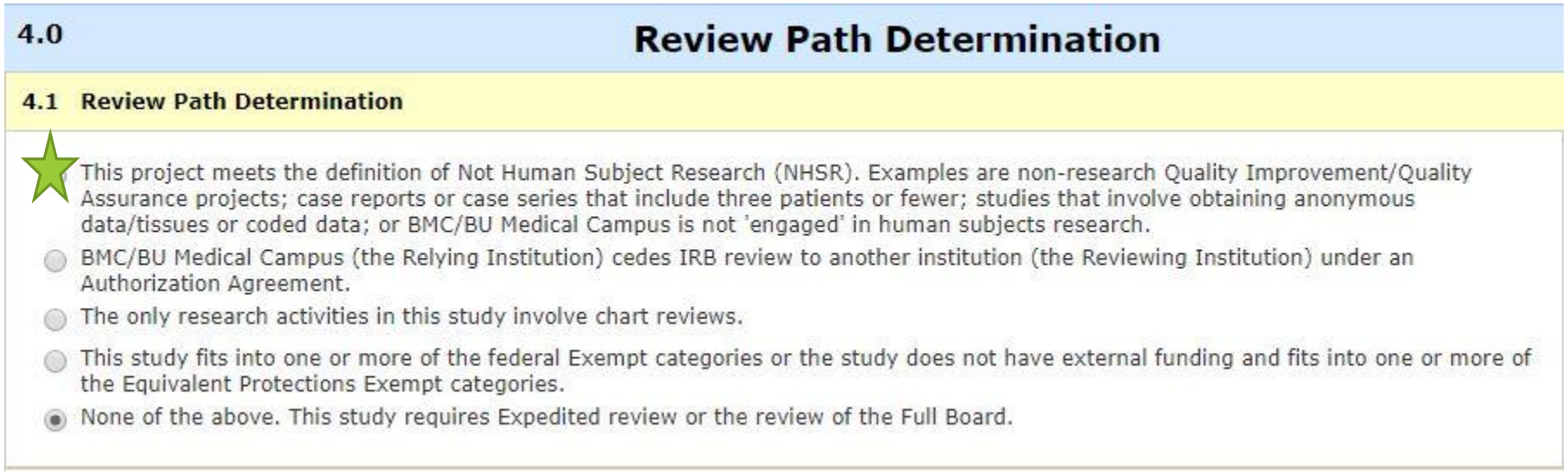
Exempt: This study would be exempt under category 2: while the data is likely to be ‘sensitive’ it is recorded entirely anonymously. [Note: While the data is anonymous, it’s not NHSR since there is ‘interaction’ with a subject

Take a swing:

A study with external funding wants to see if hospital departments where clinicians have similar political views yield better health outcomes for specific procedures. Will get a list of clinicians from BMC's website, will search for them on Twitter, will evaluate their public tweets for political leanings, and then will look up outcome data from public state-run database.



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This study would be not human subjects research since all the data is publicly available. To be NHSR: there can't be any interaction or private information. In this example, there's no interaction and all data is public and, thus, is not private

Issues include: bolded/big compensation; not statement that the drug is investigational; The risks are written in a smaller font; the flyer is incomplete since it's missing a true phone Number; there is not statement this this is a research study.

Take a swing:

Do you have trouble sleeping at night?

Counting minutes on the clock instead of sheep?

Maybe we can help!

We're testing a new drug treatment called, Putchatosleep. (Risks include never waking up)

You could earn $3,000!!!!

Call Dr. Jones at xxx-xxx-xxxx

Take a swing:

A recruitment ad is posted asking for volunteers to call the study coordinator if they are over 18, are a smoker, and have tried a nicotine patch. A potential subject calls agrees that he meets the criteria. The coordinator doesn't record any research data but does take the caller's name and phone number and makes an appointment for the caller to come in to the clinic to enroll in the study.

In short, this call is only to schedule a potential subject. There's not eligibility/screening questionnaire.
Since no 'research data' is being obtained/recorded, this example would not require any screening consent process.

Take a swing:

A PI is planning a clinical trial of a new medication for patients with hypertension. The screening interview, which takes about an hour**,** is done ensure each subject's eligibility before scheduling. Informational about illegal drug use is collected during the screening that must be linked to the subject so that the lengthy interview does not have to be repeated and the data can be used in the study if the subject is eligible; or so that the information can be retained in case an ineligible subject were to call again.

In this example, there is certainly screening activities to obtain information about the subject to determine eligibility. Thus a consent process is required. Since the data is both sensitive AND retained, we would require a full screening consent be used. [Note: If the PI is part of BMC, the data collected would be considered PHI and the screening consent would require HIPAA authorization language with a signature.]

Take a swing:

PI wants to recruit subjects who are HIV positive to test out a non-FDA approved experimental drug. PI proposes doing a medical record pre-screen and then calling potential subjects – most are not their own patients.

Script states, “Hello, I’m a doctor at BMC. I know you have HIV. We’re testing out a new treatment. Would you like to know more?”

This example includes a ‘cold call’ about a very sensitive topic. Generally speaking, this wouldn’t be allowed. We would prefer that a ‘vague’ opt-out letter from/referenced a known provider be sent first since given the population, HIV deductive disclosure is a risk. Outside of the cold call, this script should again be mindful of HIV status/disclosure and should include a statement this this is a research study.