Supplemental Material

Choosing a review pathway

Cede Reviews

- When BU/BMC is a site and another IRB does the review.
- Will become more common due to NIH's single IRB requirement.
- Generally, exempt studies are not ceded.
- 3 Options:
  1. Independent IRB: HIRB and WIRB
  2. Central IRBs (typically consortiums: NCI, Strokenet, PCORI, etc)
  3. "Other": Universities, Hospitals, Federal and State Research entities, Medical and Health Facilities, and Research Institutes which require a separate Authorization Agreement. BUMC/BMC can't be prime award and must be engaged in research. 'Other' IRB must have FWA.

Chart Review

- Use this pathway when your only research activity is a chart review of internal clinical records.
- If unfunded, chart review pathway is shorter than exempt.
- If externally funded, the application will change.
- Common Issues:
  - Specify: 1. WHO is extracting data, 2. HOW it will be extracted and 3. FROM WHAT SOURCE
  - Details about the abstraction: 1. temp list, delete as abstract, or 2. use a coding scheme
  - CDW involved? If not, why not?
  - Use specific date ranges in mm/dd/yyyy format
  - Confidentiality: State that -- Mastercode stored separate. All identifiable information will be transmitted, stored, analyzed, or otherwise exist only on HIPAA-compliant electronic systems that meet the standards for protection of PHI established by Boston Medical Center. Working dataset stored on password protected, encrypted computer.
  - **Fill out the HIPAA section!**

Chart Review: HIPAA section

(For future reference)

Q1: This should be YES since you are accessing medical records without authorization.
Q2: Please select "No" since you will need PHI for more than simply recruiting.
Q3: This should be your eligibility criteria - what will you be searching in EPIC to get what you want?
Q4: This should be the date range used in sections above.
Q5: Please state, "MRN (not stored with study data but needed for abstraction)" and then a listing of every data point including what you listed in Q7.
Q6: Complete as appropriate
Q7: Please state MRN and any of the other 17 identifiers (dates are commonly forgotten)
Q8: Research cannot be conducted without access to PHI as this is a retrospective study. The PHI are critical to identify, verify, and collect study images/data.
Q9: It is not practicable to obtain authorization from participants as this is a retrospective study and subjects are not nor will be at Boston Medical Center in the foreseeable future. Given the date range, contact information may be out of date, people may have moved, or passed away. Given the sample size, it would be impractical to obtain authorization from each subject.
Q10: All identifiable information will be transmitted, stored, analyzed, or otherwise exist only on HIPAA-compliant electronic systems that meet the standards for protection of PHI established by Boston Medical Center
Q11: If there is a mastercode, please note when it will be deleted. Otherwise state that MRN will only be used to access record and never stored.

Equivalent Protections: Who makes the rules?

1. **The federal government** has authority **IF**:
   a. Study has funding from the federal government via
      - Grant, or
      - Payment for BMC clinical services (billed to Medicare, etc…)
   b. Study requires oversight by FDA (drugs and devices)
   c. A promise to follow the federal rules
      - To OHRP (we did until 2/14/2011, we broke up on Valentine's Day)
      - To non-federal sponsor

- If the Feds have or could have oversight – we can only apply what is in the regulations

Equivalent Protections: Who makes the rules?

2. We do, **IF** federal government doesn't have authority

To be ethical, must provide "equivalent protections"

Research with appreciable risks

- ➢ federal rules needed

Low-risk research

- ➢ lesser requirements, still protect subjects

- If no Federal Oversight or any external funding –
- we have the **option** of applying different standards.

Equivalent Protections:

Applies

- Unfunded
- No drugs or device
- Benign intervention
- Minimal risk

Does not apply

- Funded
- FDA regulated
- Approved before 14-Feb-2011
- Uses BMC services
- Any Inter-institutional agreements

Non-Exempt Research: Expedited Review

Expedited review if study is **not greater than minimal risk** and fits into one of these categories:

1. Certain Drug or device studies (rarely used)
2. Blood collection (restrictions on amount collected and how often)
3. Prospective collection of biological samples by noninvasive means (Hair, nail clippings, saliva/urine samples)

Non-Exempt Research: Expedited Review

4. Data collected via noninvasive clinical procedures (MRI, ultrasound, moderate exercise)
5. Existing data or samples that have been collected, or data/samples collected solely for non-research purposes. (**Equivalent Protections Exempt Category 9**)
6. Collection of data from multimedia (voice, video, digital recordings).
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (**Equivalent Protections Exempt Category 7 and 12**)

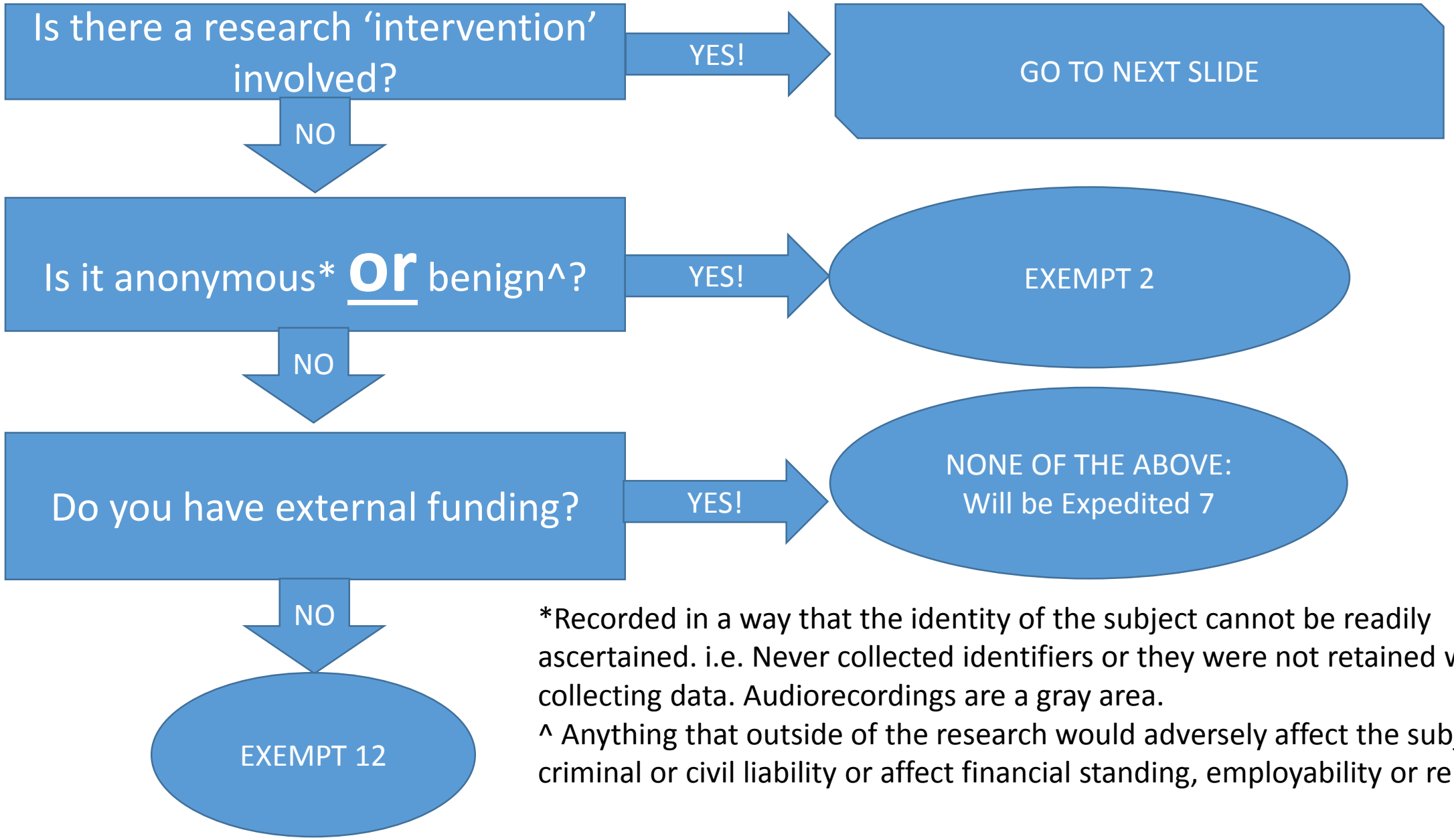
Equivalent Protections: Expedited Categories

Expedited review – minimal risk, not reviewed by full board

New categories for eligible submissions

10. Blood collection beyond federal expedited category
11. Minimally invasive tissue collection
12. Radiation ≤0.1 mSv (one chest x-ray)

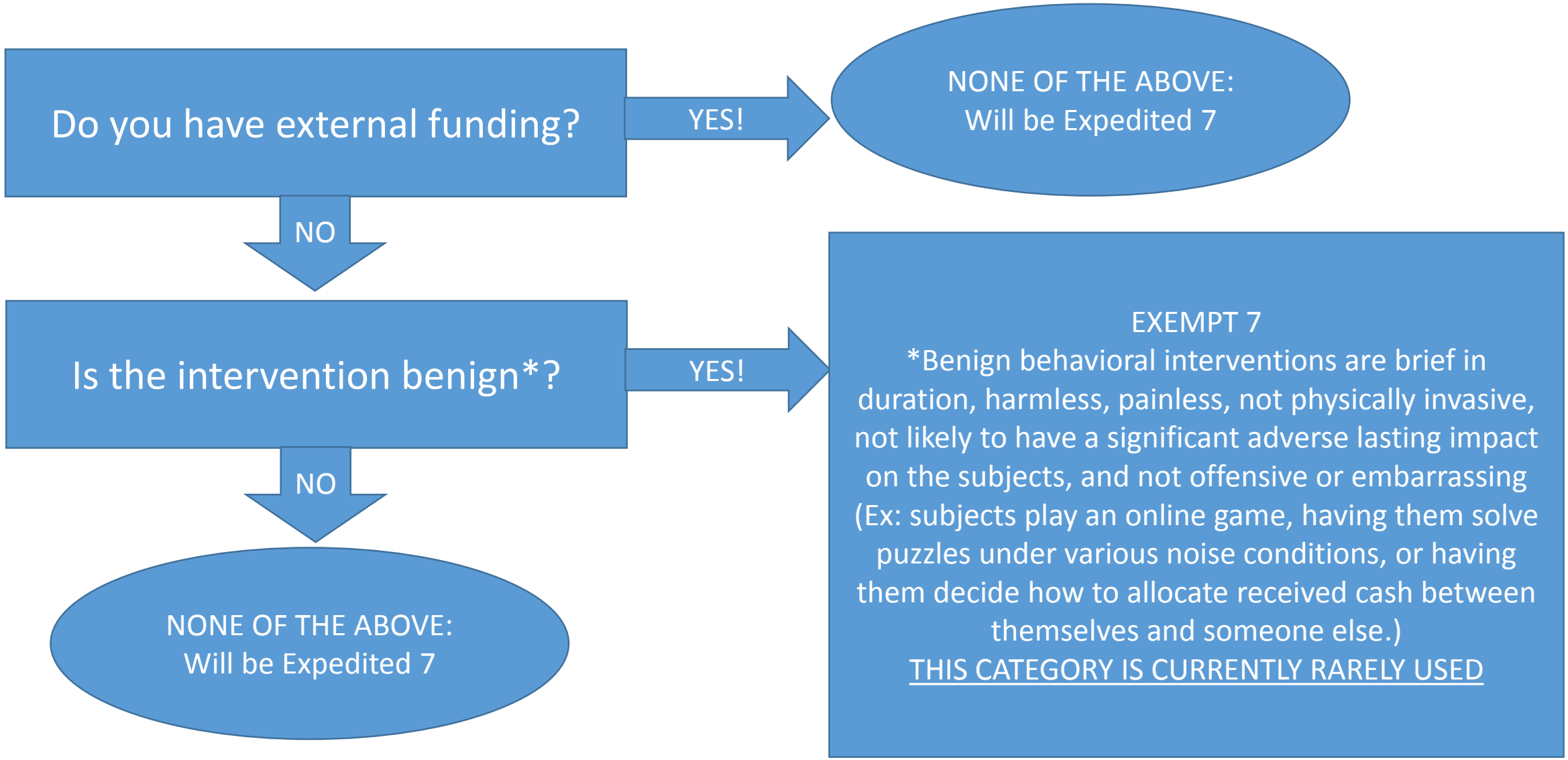
Interviews/Surveys/etc with adults



*Recorded in a way that the identity of the subject cannot be readily ascertained. i.e. Never collected identifiers or they were not retained when collecting data. Audiorecordings are a gray area.

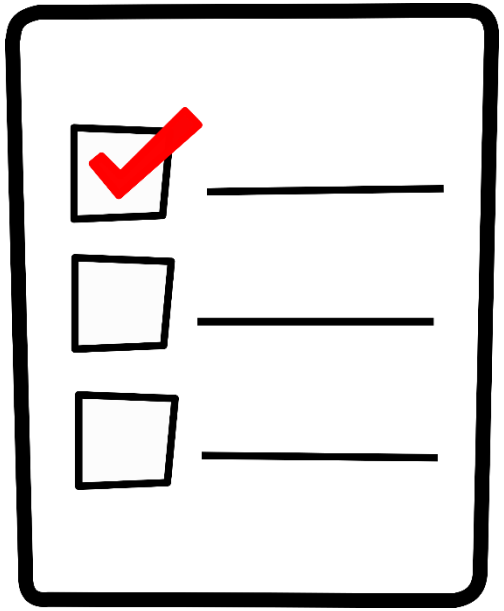
^ Anything that outside of the research would adversely affect the subject (e.g. criminal or civil liability or affect financial standing, employability or reputation.)

Research Interventions



Analysis of Existing Data/Samples

Recruitment/Screening



16.0 Screening Procedures

16.1 Describe the procedures that will be used for screening to determine subject eligibility. If screening procedures are described in a separate protocol, indicate the protocol section here.

You need to have sufficient detail in order assess your screening procedures.
Who is doing WHAT to WHOM, HOW, WHERE, and WHEN.

16.2 Describe what eligibility data will be stored and how it will be stored, who will have access, and when these data will be destroyed. For screening failures, please detail how and what data will be retained, if any, along with when these data will be destroyed. Please describe whether identifiers are being retained from those who screen out. Please note if contact information is being retained for future research.

Read and Answer this section, clause by clause.

16.3 Describe the screening consent process. Full consent for screening is required if either of the following is true:

- **identifiable sensitive information or PHI will be retained (retained as opposed to destroyed after being used to determine eligibility), or**
- **the screening involves clinical procedures**

A Brief Screening Agreement may be used for all other screening. For full consent form templates and the Brief Screening Agreement Template, click here.

Just like the main consent section: Who is doing the consent process; Where will the consent process take place; How long with participants have to decide to participate in the screening; etc.

Full screening consent

- Used when identifiable, potentially damaging information and/or PHI will be retained.
- Used when screening involves clinical procedures (i.e. blood pressure check, fasting, etc.) performed for the sole purpose of determining eligibility for the study.
- Options:
    - Verbal consent: Screening procedures only involve answering questions with adequate confidentiality protections, making the screening minimal risk; screening does not involve procedures normally requiring a signature.
    - Written consent: Greater than minimal risk procedures, clinical procedures, PHI.

Screening: Records w/o Authorization

[For future record]

You will need to say “Yes” to the HIPAA section.

- 3. Any patient presenting with XXXXX (from patient eligibility criteria)
- 4. Estimated start and end date of range of records needed in mm/dd/yyyy format.
- 5. All the datapoints you need to assess eligibility and to be able to approach the patient (date of appointment). Don’t forget the identifiers: MRN (to access chart), Name, and Dates
- 7. Identifiers: MRN, name, dates, contact info - as applicable
- 8. "Recruiting without already knowing that the potential subject is probably eligible would require an inordinate amount of time for study staff and ineligible subjects" or similar
- 9. “Approaching ineligible subjects would waste their time and be confusing; eligible and interested subjects will provide authorization during consent.” or similar
- 10. All identifiable information will be transmitted, stored, analyzed, or otherwise exist only on HIPAA-compliant electronic systems that meet the standards for protection of PHI.
- 11. “Identifiers will be destroyed as soon as eligibility has been determined for a potential subjects” or similar. NOTE: Often times need to keep identifiers through recruitment period to prevent rescreen. If you’re doing this, state it here with note that list of names/mrns destroyed.