

# SCREENING-DOOBY-DOO: UNMASKING SCREENING BEST PRACTICES

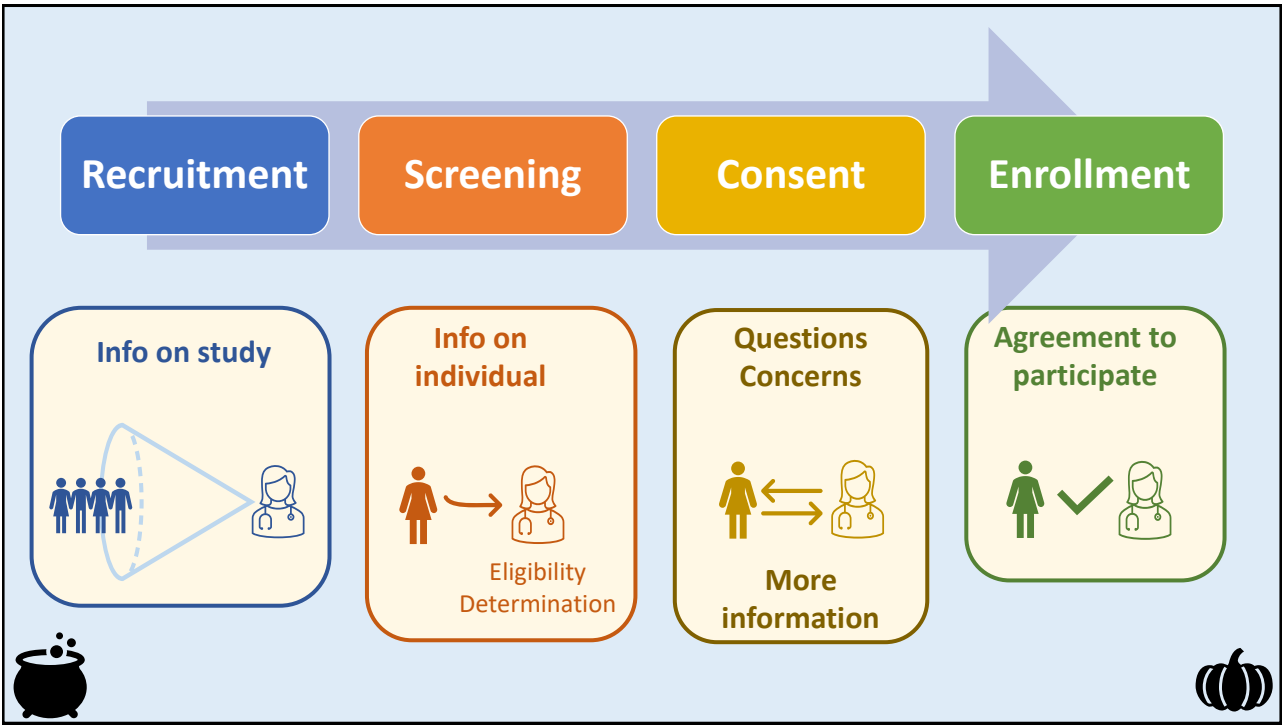


***This screening mystery IS starting to come together...***

## LEARNING OBJECTIVES

- Understand the purpose of screening and how it relates to recruitment and enrollment
- Learn where to find relevant screening tools, resources, and HRPP Policies
- Review consent for screening – using the Brief Screening Agreement vs. the Full Screening Consent – and how this differs from consent to enrollment
- Explore HIPAA implications when collecting and/or retaining Protected Health Information for screening purposes
- Identify common pitfalls in completing the screening section of the application
- Engage with real world examples to apply screening best practices





# WHAT IS SCREENING TO THE IRB?



- 1 Interaction...
  - Surveys
  - Finger Stick
  - Phone Call
  - "Chat"
- 2 (OR) Identifiable use of...
  - Existing Samples
  - EMR Data
- 3 (AND) in order to determine eligibility

# IS THIS CONSIDERED SCREENING??



Pharmacists' experiences with pre-travel health consultations

Link emailed to large listserv that takes you to anonymous online survey

US-based pharmacists who have given these consultations before



BMC patient perceptions of decision-making in their uterine fibroid care

Patients who come to a special UF clinic, with or without a history of pregnancy

QR code on flyers in waiting room for patients to complete an anonymous online survey on availability to be interviewed

# Gang Way for Ethics!



- ⊗ Respect for privacy
- ⊗ Lack of pressure
- ⊗ Unbiased presentation of the study
- ⊗ Avoiding therapeutic misconception
- ⊗ Voluntariness of Enrollment
- ⊗ Eligibility Determination

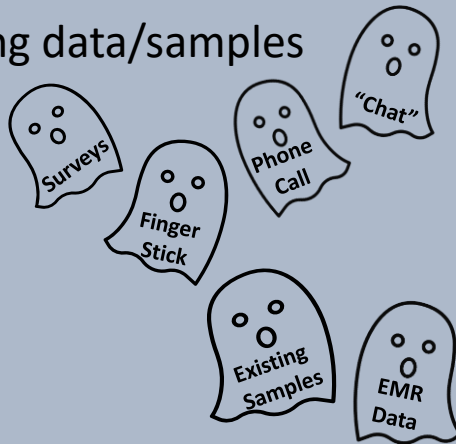
<https://ib.uci.edu/recruitment>

## THE MANY FLAVORS OF SCREENING

① Using existing data/samples

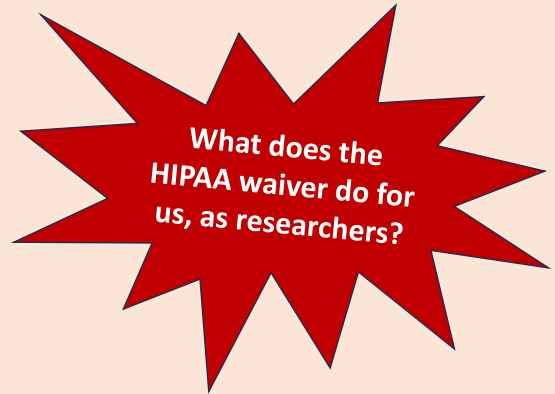
② Interacting

③ Intervening



# HIPAA WAIVERS FOR PRE-SCREENING

## Audience Weigh-In



# JEEPERS!!

It's spelled HIPAA...



Not Hippa



Portrait of Hippa included with her permission

# MYSTERIES OF THE HIPAA WAIVER FOR PRE-SCREENING



ENTIRELY and ONLY refers to the **exact data needed to determine eligibility** (aka SCREEN THE PERSON)



Use of patient data for **research purposes** as opposed to clinical care purposes



Don't be a Scruppy-Doo, read all application instructions slowly and carefully



[Bit.ly/HIPAAPrescreen](https://bit.ly/HIPAAPrescreen)

## INTERACTION: A CHECKLIST

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- Know who you're approaching
- Appropriate setting or secure platform
- Friendly smile
- Screening script
- Screening questions
- Screening agreement/consent

# SCREENING THROUGH INTERACTION OR INTERVENTION AT BUMC



Brief Screening Agreement (BSA)



Short and sweet!



Full Screening Consent (FSC)



Which of these, if any, have you used in your own research?



[BSA Template](#)

[FSC Template](#)

## THE REGULATIONS ARE STANDING RIGHT BEHIND ME... AREN'T THEY?

An IRB may approve an investigator obtaining information or biospecimens for the sole purpose of screening, recruiting, or determining the eligibility of prospective subjects without completing THE FULL, MULTI-PAGE INFORMED CONSENT PROCESS, so long as it fits into one or both of these:

- The investigator obtains information through interaction (oral or written) with the prospective subject or legally authorized representative, or
- The investigator obtains identifiable private information or identifiable biospecimens by accessing already existing records or stored identifiable biospecimens.



See the real regulation here: [45 CFR 46.116\(g\)](#)

## WHEN YOU NEED MORE THAN WHAT'S IN THE BACK OF THE VAN...

### \*CLINICAL SCREENING PROCEDURES...

- Pregnancy Test
- Finger stick for glucose measurement
- 30 Second Walking Test

...always require the Full Screening Consent!

\*PRIOR to the main consent; in majority of cases, clinical procedures occur AFTER the main consent



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## WHO IS UNDER THE MASK?

In the next slide, we're going to be breaking down when you need a BSA vs FSC

In some instances, this will depend on whether you're a member of a covered entity (e.g. BMC).


Given the overlap between BU and BMC, the institutions have developed the Space Matrix to determine affiliation.

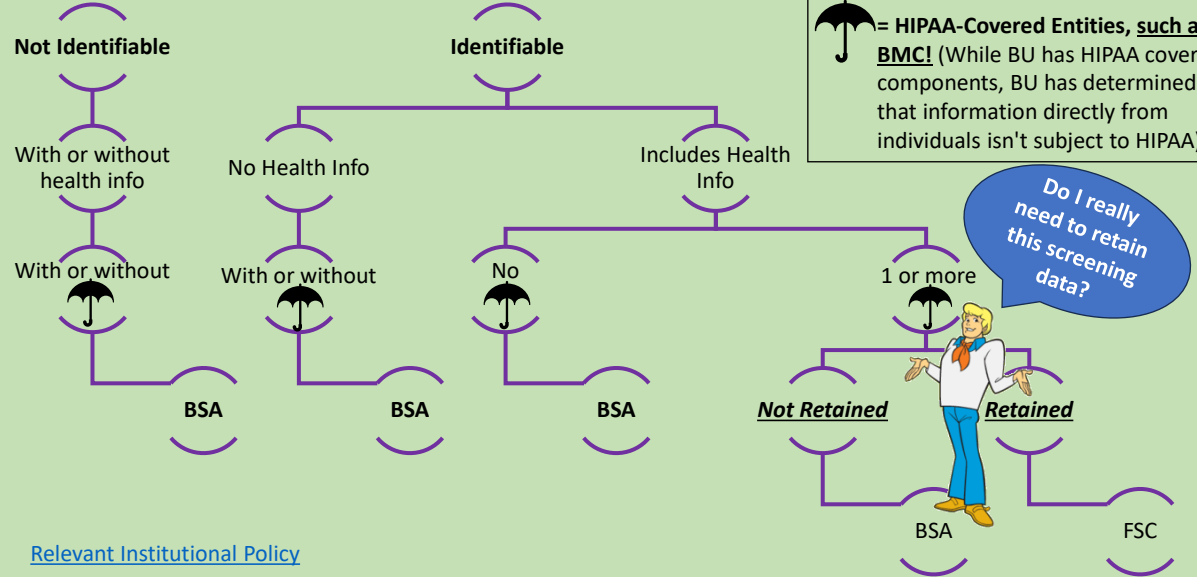
Check here to look up the PI – the PI's affiliation determines whether the study is either BU or BMC (you may be surprised!):

[https://wwwapp.bumc.bu.edu/PI\\_Home\\_Institution](https://wwwapp.bumc.bu.edu/PI_Home_Institution)



# TO MEDDLE, OR NOT TO MEDDLE...

 = HIPAA-Covered Entities, such as **BMC!** (While BU has HIPAA covered components, BU has determined that information directly from individuals isn't subject to HIPAA)



[Relevant Institutional Policy](#)

## RETAINING PHI FROM SCREENING DATA

1. Move directly to obtaining consent (with HIPAA auth.), or
2. Request (and justify) a waiver of HIPAA auth., or
3. Add HIPAA auth. language to screening consent, or
4. **DESTROY IT**



# NOW WHAT?

- Screen fails

Prevent re-approach

- Screen-ins

Characterize population that declined

- Enrolled

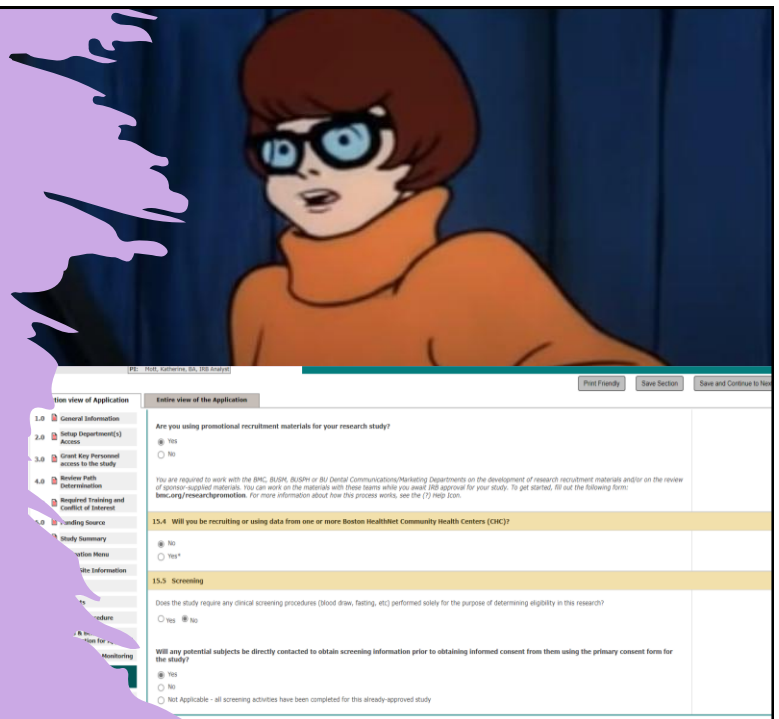
Incorporate into study data



## TOP APPLICATION ISSUES

### 1. Incorrect Answers

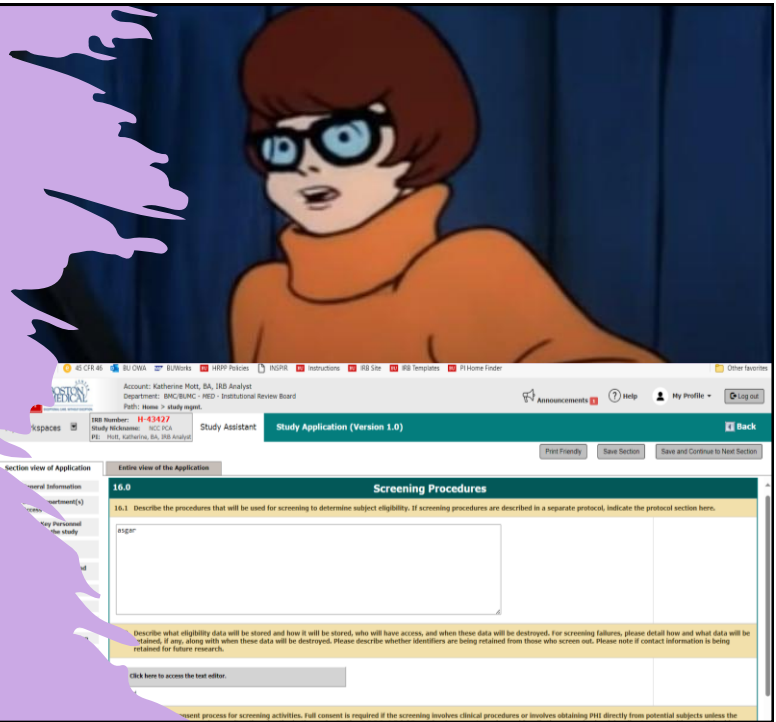
- If you're consenting and then having a screening visit, answer "NO"
- If you need to obtain **any** information directly from the subject before consent, answer "YES"



# TOP APPLICATION ISSUES

2. The screening section isn't filled out completely.

**WHO will do WHAT to WHOM, HOW, WHEN, and WHERE?**



## RUH-ROH!

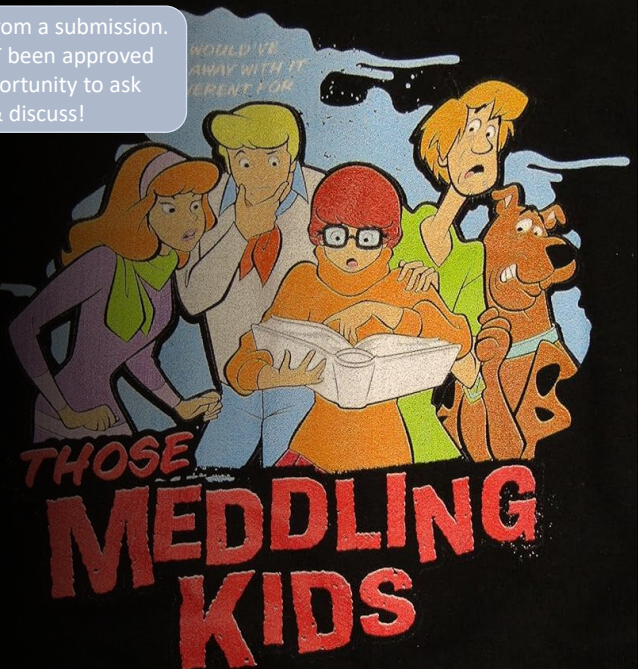
A BMC Investigator submits a study on behavioral health after giving birth:

Patients complete a screening survey that establishes when they delivered their baby in order to administer the survey at 6 weeks postpartum. Patients who gave birth >6 weeks ago are ineligible.

### Screening Questions:

1. Name
2. Date of birth (years):
3. Date of delivery:
4. Preferred Language:
5. If you are not currently eligible, would you like us to contact you in the future when you may become eligible?
  - a. If yes, please leave your email address, telephone number, and preferred contact method.

This is an example from a submission. This study has NOT been approved yet but great opportunity to ask questions & discuss!



# RESOURCES



- **HRPP Links**

- Policies on Screening: <https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#7.2.2.6.5>
- Policies on Consent for Screening: <https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#8.1.3.4>
- CR Times article on Screening (bit dated): <https://wwwapp.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=764> [You *might* just see an updated article on screening very soon]

- **IRB/CRRO Templates:**

- Brief Screening Agreement: <https://www.bumc.bu.edu/irb/files/2016/12/Brief-Screening-Agreement.docx>
- Full Screening Consent: <https://www.bumc.bu.edu/irb/files/2017/03/Screening-Questions-Full-Consent-Template.docx>
- Screening/Enrollment Log: [https://www.bumc.bu.edu/crro/files/2023/09/CRRO-Tool\\_Screening-and-Enrollment-Log\\_9122023.docx](https://www.bumc.bu.edu/crro/files/2023/09/CRRO-Tool_Screening-and-Enrollment-Log_9122023.docx)

## RUH-ROH, SOMEONE HELP!

There's a LOT to screening and many permutations... if your situation wasn't covered today and the resources just aren't enough – don't fret, just contact us!

- Main IRB: [medirb@bu.edu](mailto:medirb@bu.edu)
- Kat Mott: [kmott42@bu.edu](mailto:kmott42@bu.edu)
- Jamie Merrill: [jcm57@bu.edu](mailto:jcm57@bu.edu)
- Main CRRO: [crro@bu.edu](mailto:crro@bu.edu)

