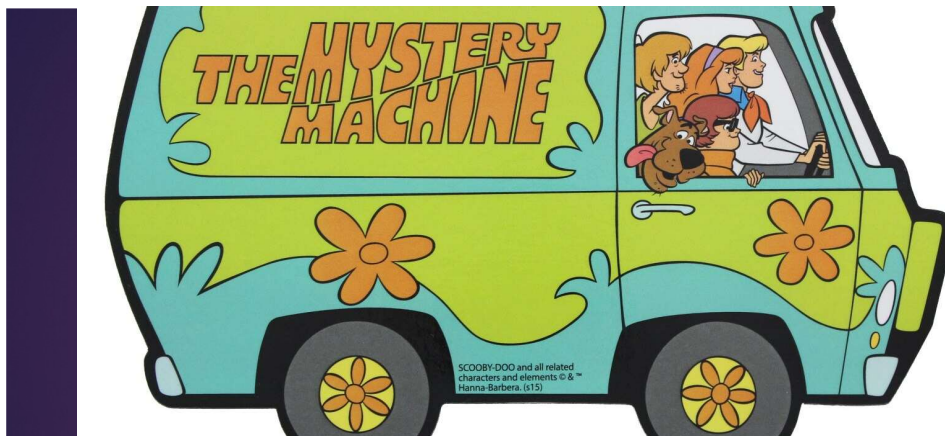




Scooby Doo and Recruitment Too!

SOLVING THE MYSTERIES OF RECRUITING IN THE CLINICAL ENVIRONMENT

1

Activity dependent degeneration explains hub vulnerability in Alzheimer's disease.
de Haan W, Mott K, van Straaten EC, Scheltens P, Stam CJ.
PLoS Comput Biol. 2012;8(8):e1002582. doi: 10.1371/journal.pcbi.1002582. Epub 2012 Aug 16.

Age-related decline in differentiated neural responses to rare target versus frequent standard stimuli.
Mott KK, Alperin BR, Holcomb PJ, Daffner KR.
Brain Res. 2014 Oct 31;1587:97-111. doi: 10.1016/j.brainres.2014.08.057. Epub 2014 Aug 27.

The impact of executive capacity and age on mechanisms underlying multidimensional feature selection.
Mott KK, Alperin BR, Fox AM, Holcomb PJ, Daffner KR.
Neuropsychologia. 2015 Apr;70:30-42. doi: 10.1016/j.neuropsychologia.2015.02.003. Epub 2015 Feb 3.

Interprofessional education in the clinical learning environment: a mixed-methods evaluation of a longitudinal experience in the primary care setting.
Mott KK, Zawacki S, White S, Youssef-Nyarkoon L, Mostow C, Furlong J, Mott KK, Kumar A, Winter MR, Becklein F, Jack B.
J Interprof Care. 2022 Nov-Dec;36(6):845-855. doi: 10.1080/13561820.2022.2025768. Epub 2022 Feb 2.
PMID: 35109762 Free article.



Katherine Mott, BA
Senior IRB Analyst

15 years in research

9 of those at BUMC

3 of those at the
BUMC/BMC IRB

2

Overview/Learning Objectives:

Define HIPAA waiver and demonstrate an understanding of how to obtain one for recruitment purposes

Differentiate between clinical and research use of patient data

Identify potential privacy and confidentiality concerns in your recruitment strategy

Describe the appropriate ways to approach a patient about a research study while they are in the clinic

Develop an approvable opt-out letter using the IRB's template

3



4

What's the point?



5

Let's dive in!



6

Medical Record Pre-Screening



Reviewing the medical record to identify potentially eligible patients to recruit



Accessing Protected Health Information (PHI) without consent



Different from screening, which requires direct interaction with potential participants

Clinical Data Warehouse for Research

<https://www.bumc.bu.edu/camed/research-impact/cores/clinical-research-data-warehouse/>

7

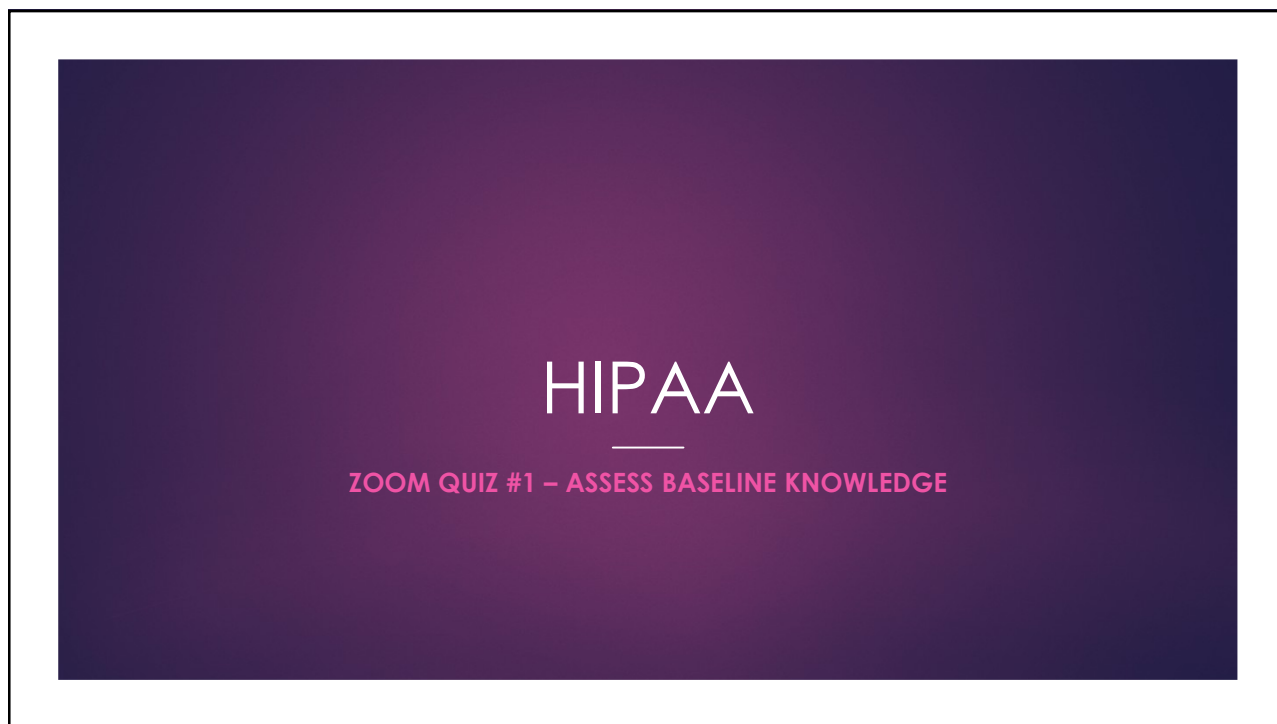
HIPAA Authorization ≠ Informed Consent

HIPAA authorization
= permission to
ACCESS and USE
health information.

Informed consent =
permission to BE IN
THE STUDY.

You need both
(unless you have a
HIPAA waiver for
pre-screening)

8



9



10



Separating Research and Clinical Care: Two Hats

11

But it's all in
my head!

- ▶ "I know this patient would be a good fit for the study"
- ▶ "I have some appointments coming up with patients who may be eligible"
- ▶ "I'm only recruiting my own patients"



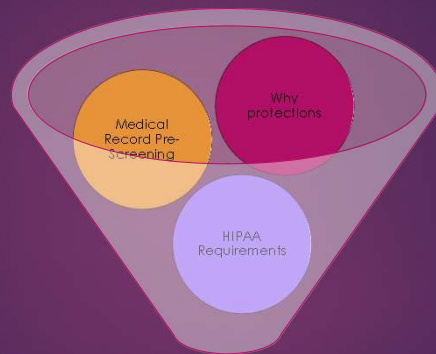
12

HIPAA

ZOOM QUIZ #2 – ASSESS POST KNOWLEDGE

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Basic Principles → Recruitment Strategies



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Approvable Recruitment Strategies in the Clinical Environment



Flyers



In-clinic approach



Clinician Referral



Opt-out letter and phone call



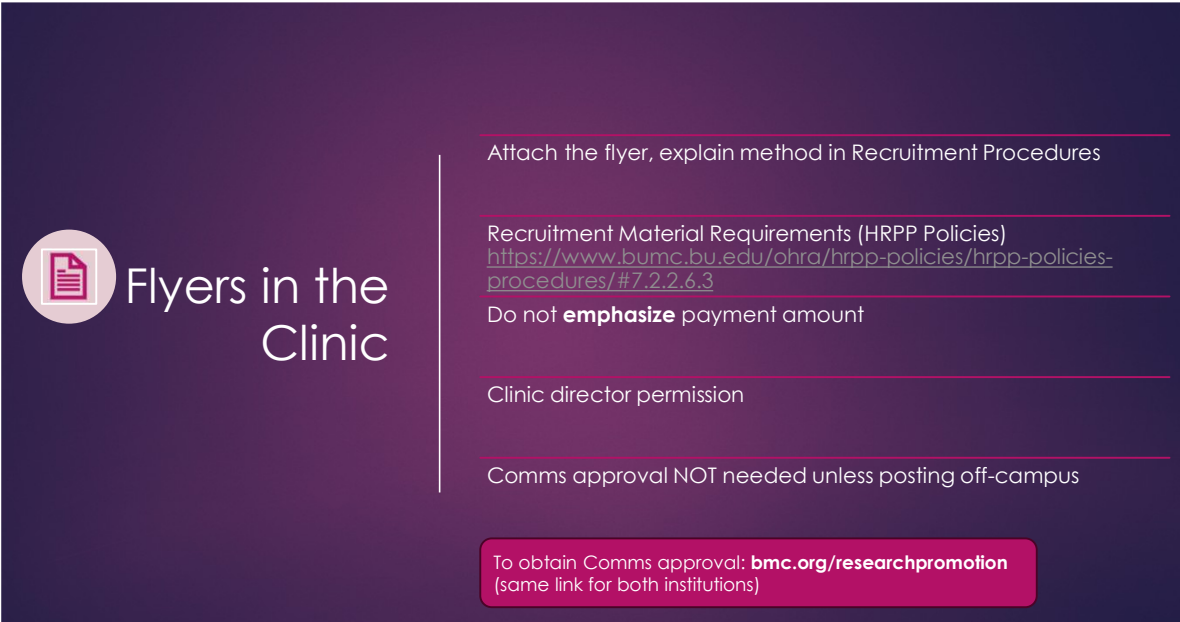
15

Example Study

- ▶ Dr. Scooby treats patients with eczema
- ▶ He wants to study how eczema outbreaks affect people's mood
- ▶ Participants will take a survey every week, reporting on their mood and symptoms, for 6 months
- ▶ Velma Dinkley is a patient of Dr. Scooby's who has eczema



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 Flyers in the Clinic

- Attach the flyer, explain method in Recruitment Procedures
- Recruitment Material Requirements (HRPP Policies)
<https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#7.2.2.6.3>
- Do not **emphasize** payment amount
- Clinic director permission
- Comms approval NOT needed unless posting off-campus

To obtain Comms approval: [bmc.org/researchpromotion](https://www.bumc.bu.edu/researchpromotion)
(same link for both institutions)

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Recruitment Materials

ZOOM QUIZ #3

18

- ▶ Comms Approval is only required to post flyers outside of BUMC or BMC space
- ▶ Payment amounts can never be emphasized by using large, bold, underlined, or italicized font or by putting this information first in the ad before the study purpose, procedures, and time commitment

Zoom quiz 3 – Recruitment Materials

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In-clinic approach

- ▶ Warm hand-off post-appointment
- OR
- ▶ Waiting Room pre- or post-appointment



20



In-clinic approach

- ▶ Warm hand-off post-appointment
OR
- ▶ Waiting Room pre- or post-appointment

What the IRB needs from you:

- ▶ Explain how you will preserve **privacy** and confidentiality
- ▶ Attach a Recruitment Script based on our template
- ▶ Request a HIPAA waiver



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Clinician Referral

Clinician

- Dr. Shaggy is a colleague of Dr. Scooby's. He identifies an eligible patient, Fred Jones, with an upcoming appointment
- Tells Fred about study

Patient

- If Fred is interested, Dr. Shaggy gives him the study contact info OR gets permission to share Fred's information with Dr. Scooby's study team

Study Team

- Contact is made between Dr. Scooby's study team and Fred Jones



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Clinician Referral

What the IRB needs from you:

- ▶ Explain the **direction of information flow**
- ▶ Attach a Recruitment Script based on our template
- ▶ Request a HIPAA waiver



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In Clinic Approach and Clinician Referral

ZOOM QUIZ #4

24

- ▶ The warm hand-off is performed by a provider known to the patient
- ▶ Referring clinicians who are on the study personnel can recruit and consent patients, otherwise they can only recruit

Zoom quiz 4 – In Clinic Approach and Clinician Referral

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Opt-out letter and phone call



Quick Facts:

Gives eligible patients a heads up that they will be called about the study

Sent through MyChart or Snail Mail

Do not reveal sensitive diagnoses

26



Opt-out letter and phone call

Quick Facts:

- Gives eligible patients a heads up that they will be called about the study
- Sent through MyChart or Snail Mail
- Do not reveal sensitive diagnoses

What the IRB needs from you:

- ▶ Attach an opt-out letter based on our template
- ▶ Attach a Recruitment Script based on our template
- ▶ Request a HIPAA waiver

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Opt-out letter and phone call

ZOOM QUIZ #5

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- ▶ Your submission will be sent back if you propose opt-out recruitment but do not include an opt-out letter and recruitment script

Zoom quiz 5 – Opt-out letter and phone call

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Approvable Recruitment Strategies in the Clinical Environment



Flyers



In-clinic
approach



Clinician
Referral



Opt-out letter
and phone call



30

Un-approvable Recruitment Strategies

- ▶ Cold-Calling
- ▶ Snowball sampling
 - ▶ Where participants give contact info of other potentially eligible people to the study team



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Your Impressions

- ▶ What is the IRB concerned about when it comes to recruitment strategies?
 - ▶ Enter your response in the Zoom chat

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Translating Strategy Into Your IRB Application

YOU'VE CHOSEN A RECRUITMENT
STRATEGY - NOW LET'S MAKE SURE
YOUR APPLICATION CLEARLY
DESCRIBES IT

33

Include in INSPIR application:

How will you obtain the information you need
to recruit?

Direction of information flow

Where and when recruitment takes place

Privacy protections

Request for a HIPAA waiver (most likely)

Associated documents must be attached



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Example Study

- ▶ Dr. Scooby treats patients with eczema
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- ▶ Participants will take a survey every week, reporting on their mood and symptoms, for 6 months
- ▶ Velma Dinkley is a patient of Dr. Scooby's who has eczema



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Developing an opt-out letter

[IRB Templates | Institutional Review Board](https://www.bumc.bu.edu/irb/inspir-ii/irb-templates/)

<https://www.bumc.bu.edu/irb/inspir-ii/irb-templates/>

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Recap:

Developing a recruitment strategy for research in the clinical environment can be complicated

There are a lot of interacting rules – federal research and HIPAA regulations, institutional policies, clinic practices

Ultimately, these rules are trying to help all of you carry out your research in a way that's sustainable

**But if Scooby Doo can do it, you can too.
Zoinks!**

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How to get questions answered in future

 [CR Times article on recruitment](#)

 [Mary-Tara's recent presentation](#)

 Email medirb@bu.edu

 [CRRO Consultation](#)

 [Institutional policies](#)

 [INSPIR Instructions](#)



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The IRB wishes you a Happy Halloween!

