OHSU

Recruitment Planning for Protocol and Grant Development:

A Practical Foundation for Clinical Trial Success

DATE: MAY 23, 2019 PRESENTED BY: KITT SWARTZ, M.P.H. & MEREDITH ZAUFLIK, M.P.A., OCTRI

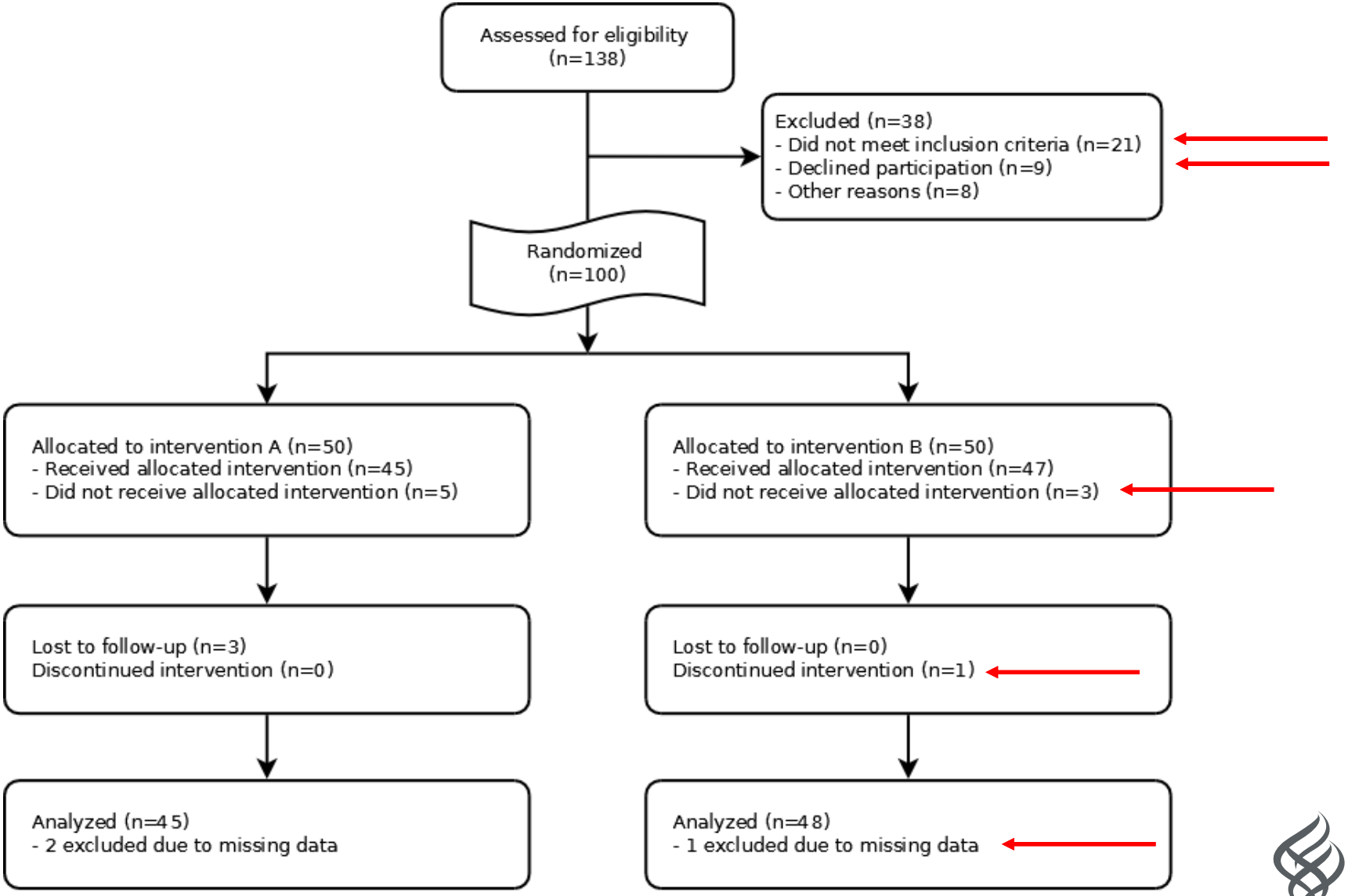
Agenda

- Where to start
- Developing a Recruitment Plan: Key NIH Considerations for Your Proposal
- What if I Have a Multi-Site Study?
- Questions & Answers
- Summary & Announcements

OHSU

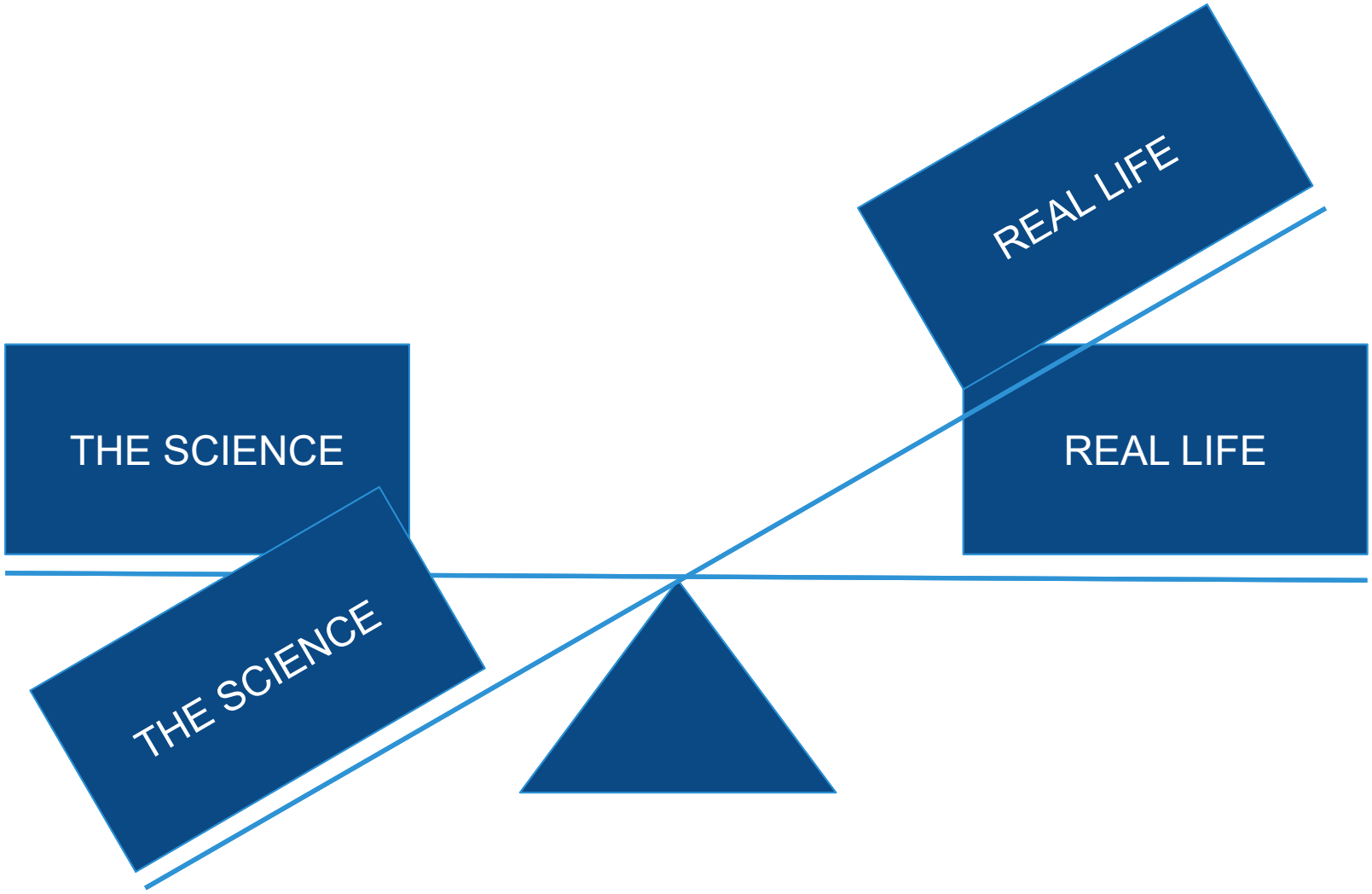
Do they exist?

How many do you need?



OHSU

How your Inclusion Criteria Impacts Recruitment



Do you really need it?

- Think about each inclusion/exclusion criteria – is it necessary?
- How can you lower the barriers?
- Timing, duration, acceptability of procedures
- Scope and appetite control! (ex: survey duration)
- This exercise will inform your proposal recruitment plan and other parts (budget, timeline, staff)

OHSU

Form E – Recruitment & Retention Plan

- **Who must complete one?**
  - Almost everyone. The attachment is required unless you selected 'Exemption 4' and no other exemptions on the '1.3 Exemption Number' question

- **Wait, did you say attachment?**
  - Yes, many sections in Form E are now required to be submitted as separate PDF attachments
  - See NIH's Format Attachments page for additional information and formatting requirements

- **What does this entail?**
  - Plan content must include how you will recruit and retain participants in your study

OHSU

R&R Plan Content

What I should include in my R&R plan?

- How many participants?
- Who are they?
- Recruitment location?
- Recruitment methods?
- Duration of recruitment?
- Feasibility?
- Oversampling?
- Retention plans?

OHSU

What are some of the methods?

Recruitment

- Patient population
- Electronic Health Records
- Pre-existing repositories
- Hospital and clinic space
- Community healthcare partners
- Flyers
- Letter and email campaigns
- Websites/online
- Social Media
- Media (TV, radio, newspapers)
- Public transportation
- Online registries
- Disease specific associations
- Advocacy and support groups
- Community outreach and engagement

Retention

- Birthday cards
- Holiday cards
- Appointment reminders
- Study newsletter
- Payment schedule

OHSU

Other Considerations

Participant Population

- Is your staff experienced to work with this population?
- Do you have an adequate amount of staff?
- How much time will you need to recruit this population?
- Is the study site accessible and appropriate for this population?
- What size budget will you need to recruit this population?

Recruitment Location(s)

- Will you need special permission to recruit from this location?

OHSU

NIH Inclusion Policies

- **Inclusion of Women & Minorities**
  - Ensure the inclusion of women and minority groups in research
  - That individuals are included in clinical research in a manner that is appropriate to the scientific question under study

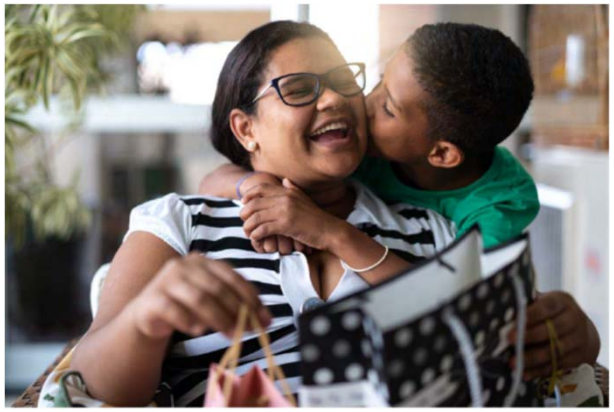
- **Inclusion of Children *(Now included in 'Lifespan')***
  - Ensure the inclusion of children in research

- **Inclusion Across the Lifespan**
  - Ensure the inclusion of individuals of all ages in research
  - Older age groups cannot be excluded from research unless for ethical or scientific reasons

OHSU

Inclusion Policy Requirements

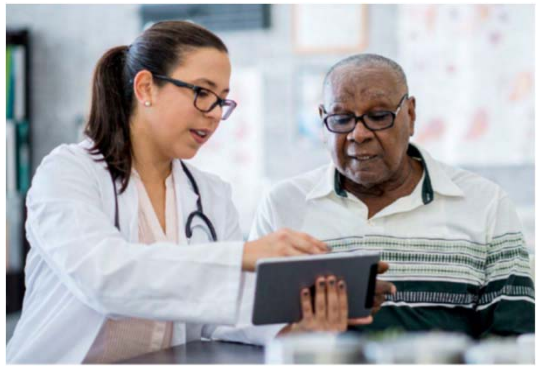
- ✓ Described the planned distribution of subjects by sex/gender, race, ethnicity and age
- ✓ Described the rationale for selection of each in terms of the scientific objectives and proposed study design
- ✓ Provided reasoning for exclusion of any group or sub-group
- ✓ Described proposed outreach programs for recruiting each
- ✓ Described expertise of the investigative team for working with individuals



OHSU

Requirements Continued…

- ✓ Described appropriateness of the available facilities to accommodate individuals
- ✓ Existing dataset or resource
- ✓ Described inclusion of a sufficient number to contribute to a meaningful analysis
  - ✓ For Phase III, also need to describe plan to test for differences in effect amongst groups
- ✓ Has appropriate attachments
- ✓ Addressed CFR 46, Subpart D in the Protection of Human Subjects attachment *(Children Only)*



OHSU

Acceptable Exclusion Based on Age

- Disease does not occur in the excluded age group or topic is not relevant
- Knowledge being sought is already available in the excluded age range
- A separate age-specific study is warranted
- The study will collect or analyze data on pre-enrolled study participants
- There are laws or regulations barring the inclusion of the age group
- The study poses an unacceptable risk to the age group

OHSU

Other Form E Considerations

- Facilities & Resources Form
  - What support do you have for Recruitment & Retention?

- Budget
  - Did you include enough for both recruitment and retention methods?

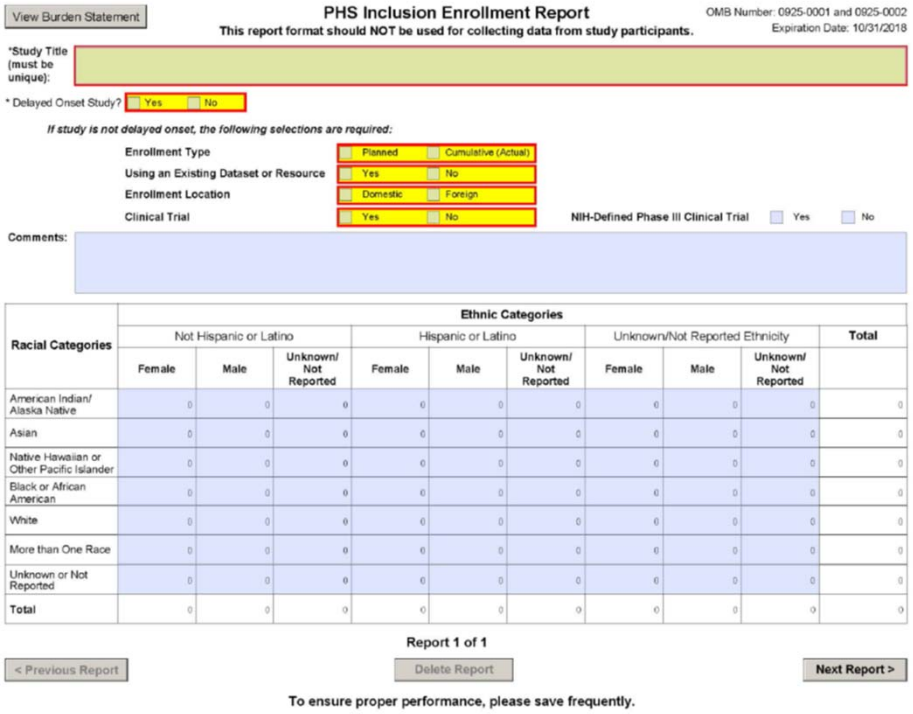
- Overall writing
  - Realistic?
  - Organized?
  - Clear and concise?
  - Did you follow the terms, layout, and other specifications laid out by the NIH?

OHSU

Reporting Requirements

Must report to NIH the enrollment by:

- Age
- Race
- Ethnicity
- Gender



View Burden Statement

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 10/31/2018

*Study Title (must be unique):

* Delayed Onset Study? Yes No

If study is not delayed onset, the following selections are required:

Enrollment Type: Planned / Cumulative (Actual)
Using an Existing Dataset or Resource: Yes / No
Enrollment Location: Domestic / Foreign
Clinical Trial: Yes / No
NIH-Defined Phase III Clinical Trial: Yes / No

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

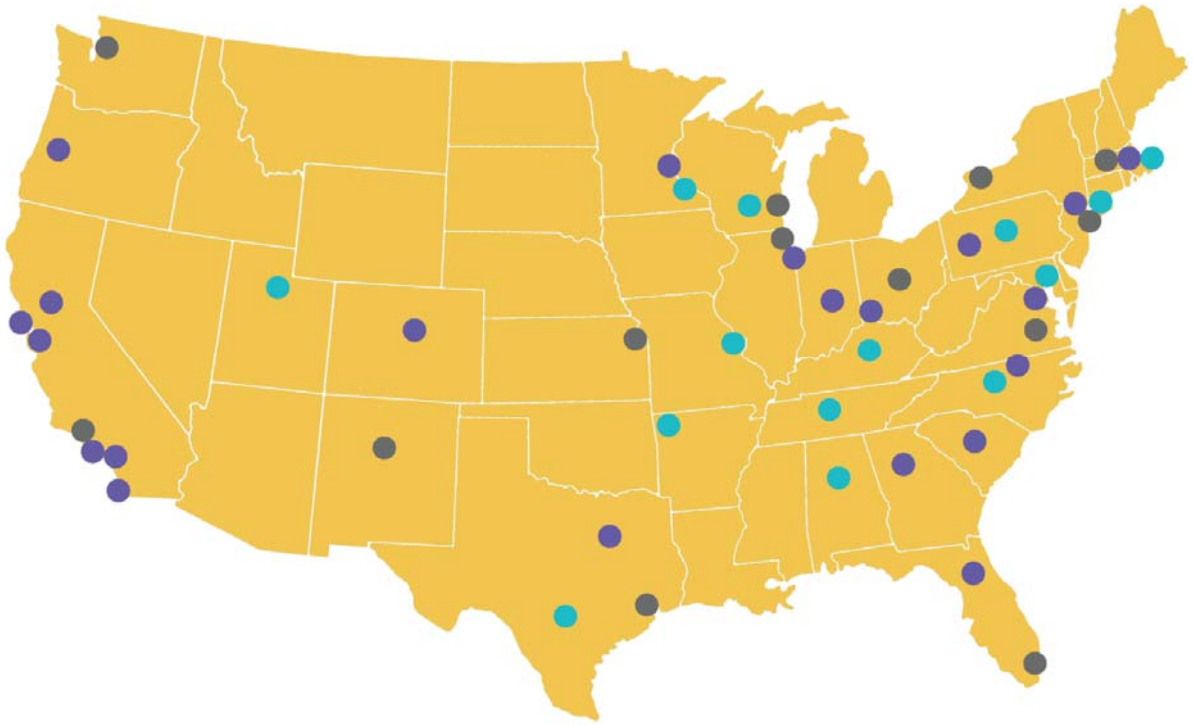
Report 1 of 1

< Previous Report | Delete Report | Next Report >

To ensure proper performance, please save frequently.

For more information and the form, please visit PHS IER Guide or the PHS IER Form

OHSU



What If I Have a Multi-Site Study?

OHSU

Examples - continued

- Study: Blood samples for new lab assay

- Inclusion Criteria – healthy participant
- Exclusion Criteria
  - **Evidence** of infection
  - **On medication**
  - Medical conditions that may compromise the quality of the cells
  - **Disorders that may cause problems for the subject**

- Too Broad!
  - Scientifically - Could enroll people who are pretty sick
  - Practically – How would you define/document these patients?

OHSU

Examples - continued

- Study: The relationship between hormone levels and PMS Symptoms

- Inclusion Criteria
  - Women between 18-30 years old
  - PMS Symptoms every cycle for at least a year
  - **Normal pap smear within last year**
  - Regular Menstrual cycles **>26 and <32** days
- Exclusion Criteria
  - Hysterectomy
  - **Hormonal contraceptives in last 3 months**
  - History of smoking
  - History of psychiatric disorder
  - History of alcohol/drug abuse
  - Use of medications that could affect mood or sleeping
  - **Abnormal screening blood tests (TSH, LFT, HGB)**
  - Pregnancy within last year or plan to get pregnant during study
  - Use of **medications**/alternative treatments for PMS within last 60 days
  - History of insomnia
  - History of migraines

- Too Narrow!
  - Scientifically – Will this be generalizable?
  - Practically – The exclusion criteria are so broad many will not be eligible.

OHSU

Examples - continued

- Study: Mindfulness to increase nursing among new mothers

- Inclusion Criteria
  - Women between 18-30 years old with first pregnancy
  - Enroll within 3 days of giving birth with a singleton pregnancy
  - Intends to breastfeed

- Exclusion Criteria
  - Clinically documented anxiety or depression
  - Actively practices mindfulness techniques at the time of enrollment.

- Study activities:
  - Must attend mindfulness or sham training (at a medical facility) within 1 week of birth
  - Must practices mindfulness a minimum of 3 times daily
  - Must record all mindfulness sessions
  - Must record time and duration of nursing sessions
  - Required to journal every evening about thoughts and feelings

- Timing too tight!
  - Scientifically – Will this be generalizable?
  - Practically – can you find and enroll new mothers in this study?

Questions & Answers

OCTRI Resources

- OCTRI Clinical Research Development Team (CRDT)
  - Please visit their website or email octri@ohsu.edu
- Human Investigators Program (HIP)
  - Please visit their website or email hip@ohsu.edu
- Research Forum
  - Please visit their website to learn more
- For recruitment questions, additional resources, and to request a recruitment consultation
  - Please email octrirecruitment@ohsu.edu
- Not sure who to direct your question to?
  - Please email the OCTRI Navigator at octri@ohsu.edu

OHSU

Additional Resources

NIH: Comparing Popular Research Grants
https://www.niaid.nih.gov/grants-contracts/research-project-grants

General Application Guide for NIH and Other PHS Agencies
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#top

NIH: How to Apply – Application Guide
https://grants.nih.gov/grants/how-to-apply-application-guide.html

NIH: How to Apply - Write Your Application
https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm#Your%20Research%20Plan

NIH: Sample Applications
https://www.niaid.nih.gov/grants-contracts/sample-applications

OHSU

Thank You

OREGON CLINICAL
& TRANSLATIONAL
Research Institute

OHSU