Recruitment Planning for Protocol and Grant Development:
A Practical Foundation for Clinical Trial Success
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
Do they exist?

THERE'S A NEEDLE IN HERE. WE HAVE TO FIND IT.
How many do you need?

Assessed for eligibility (n=138)

- Excluded (n=38)
  - Did not meet inclusion criteria (n=21)
  - Declined participation (n=9)
  - Other reasons (n=8)

Randomized (n=100)

Allocated to intervention A (n=50)
- Received allocated intervention (n=45)
- Did not receive allocated intervention (n=5)

Lost to follow-up (n=3)
Discontinued intervention (n=0)

Analyzed (n=45)
- 2 excluded due to missing data

Allocated to intervention B (n=50)
- Received allocated intervention (n=47)
- Did not receive allocated intervention (n=3)

Lost to follow-up (n=0)
Discontinued intervention (n=1)

Analyzed (n=48)
- 1 excluded due to missing data
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)
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
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?
What are some of the methods?

<table>
<thead>
<tr>
<th>Recruitment</th>
<th>Retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient population</td>
<td>Birthday cards</td>
</tr>
<tr>
<td>Electronic Health Records</td>
<td>Holiday cards</td>
</tr>
<tr>
<td>Pre-existing repositories</td>
<td>Appointment reminders</td>
</tr>
<tr>
<td>Hospital and clinic space</td>
<td>Study newsletter</td>
</tr>
<tr>
<td>Community healthcare partners</td>
<td>Payment schedule</td>
</tr>
<tr>
<td>Flyers</td>
<td></td>
</tr>
<tr>
<td>Letter and email campaigns</td>
<td></td>
</tr>
<tr>
<td>Websites/online</td>
<td></td>
</tr>
<tr>
<td>Social Media</td>
<td></td>
</tr>
<tr>
<td>Media (TV, radio, newspapers)</td>
<td></td>
</tr>
<tr>
<td>Public transportation</td>
<td></td>
</tr>
<tr>
<td>Online registries</td>
<td></td>
</tr>
<tr>
<td>Disease specific associations</td>
<td></td>
</tr>
<tr>
<td>Advocacy and support groups</td>
<td></td>
</tr>
<tr>
<td>Community outreach and engagement</td>
<td></td>
</tr>
</tbody>
</table>
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?
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
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
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)
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
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?
Reporting Requirements

Must report to NIH the enrollment by:

- Age
- Race
- Ethnicity
- Gender

For more information and the form, please visit PHS IER Guide or the PHS IER Form.
What If I Have a Multi-Site Study?
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?
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.
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
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

NIH: How to Apply – Application Guide

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
Thank You