# No Participants, No Trial

(Don't Plan for Everything, but Recruitment)

Presentation will begin at 12:00 PM (PT)













### What We Offer:

- Research Support Services: Members gain access the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.
- 2 Community Engagement: Members can connect with regional and community based practice networks
- 3 Education & Training: Members can access a variety of workforce development and mentoring programs and apply for formal training programs.
- Funding: Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.

# Contact our Director of Research Development



- Project Consultation
- Strategic Direction
- Resources and Networking

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### **Feedback**

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.

# No Participants, No Trial

(Don't Plan for Everything, but Recruitment)

# The presenter for today's educational program is:

#### **Michael Donahue**

University of Washington Clinical Trials Office Institute of Translational Health Sciences mgd@uw.edu



**UW** Medicine

\*I have no relevant financial relationship(s) in connection with this educational activity.

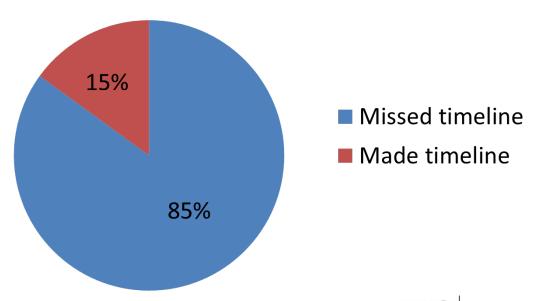


# **Learning Objectives:**

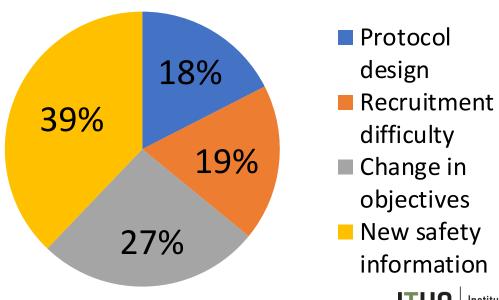
- Characterize the study population, anticipate barriers, and develop an effective recruitment plan
- Measure, evaluate, and modify recruitment strategies
- 3 Create participant recruitment materials that are eye-catching and bring participants and study teams together

### **Let's Start The Conversation**

# Percentage of clinical trials that fail to meet enrollment timelines



# Percentage of protocol amendments made to facilitate recruitment





# Pl's estimate of eligible participants

"I see 20 patients a month with this diagnosis"

20 patients is an exaggeration

Some won't meet eligibility criteria

Some are there for second opinion only

Some won't live locally

Some won't be interested



# **Assumptions**

- People are going to be as engaged in the study as we are
- Research Coordinator's responsibility

# Clinical research involves a specific set of skills



# Recruitment is a marketing activity!

# **Learning Objective 1:**

Characterize the study population, anticipate barriers, and develop an effective recruitment plan

#### **Recruitment Strategizing Worksheet**

	Define the characteristics of your population	Identify potential barriers to participation and retention			
	Where do they live, work, shop, and spend time?		Are there elements of the study design or inclusion/exclusion criteria that might be too limiting?		
	Are they likely to be employed? Retired? Do they have	_	Is it possible to revise some of the criteria?		
_	leisure time?		Does your site serve a large geographic area? Will there be a lot of travel time to study visits?		
	Where do they get information in general and health		How much flexibility do you have with scheduling study visits?		
_	information in particular?		Could people in your target population have transportation problems?		
	What is their level of health literacy and experience with		What is the burden of time and inconvenience? Is there anything you can do to make		
_	health care systems?		participation more convenient?		
	What would engage them with your study? What's in it for them? Why would they want to participate?		How might they feel about medical research?  Do they have family responsibilities: childcare or elder care?		
п	Are there different characteristics among different racial,		Would they have other medical conditions that might affect their participation (in addition to		
_	ethnic, and socioeconomic groups?	_	being excluded)?		
	What would engage them with your study? Why would		cong coolacty.		
	they want to participate?				
	Study start-up		Reaching your audience		
	Evaluate strategies from other studies		Identifying participants by screening upcoming clinic appointments.		
	How much do other studies pay? Where do you see studies		Is there a service that searches the electronic medical records to identify potential participants?		
_	advertised? Get feedback from participants.		Community outreach: advocacy organizations, senior centers, community centers, faith based		
	Are there other clinical team members (social worker,	_	organizations, support groups, and health fairs		
	physical therapists, etc.) who might have suggestions or		Direct (specific individuals) and targeted (large scale, based on demographic profiles) mailings.		
	refer participants? Establish a referral network early in the		Online advertisements: Craigslist, and listserves.		
_	process.		Study-specific website.		
	IRB recruitment materials basic tool kit  O Brochures (mail, leave in clinics or community		Local advertising: Newspaper (consider community and neighborhood papers), public transportation.		
	areas, etc.)		Health reporters and bloggers: Is there something particularly innovative about what you're		
	Flyers (for posting, could make into a poster or		doing?		
	print ad)		Social media: YouTube, Facebook.		
	Information statement: one paragraph		Radio		
	description, suitable for newsletters, websites,				
	Craigslist, etc.				
	<ul> <li>Approval for emailing participants information</li> </ul>				
	Budget: Create line items for compensation, parking, and				
	printing, targeted mailings; consider adding advertising				
	and graphic design costs.				
	Implementation		General guidance		
	Make a plan for rollout		Making participation as easy as possible will help with enrollment and retention.		
_	Staffing to take calls		Provide compensation or gratuity, and pay for parking costs. The compensation should be		
	Keep metrics: when each strategy was implemented, how		accessible to your population.		
	many contacted you, where did they see the material?		Plan to hit early and hit hard, and strategies are worth repeating. You will often reach people		



## Define the characteristics of your population

- What are their daily lives like?
- ☐ How do they get their information?
- ☐ Consider at different demographics levels
- ☐ Why would they want to be in your study?

# Study start up and implementation

- ☐ Review strategies from other studies
- ☐ IRB approval of recruitment materials
- ☐ Plan for rollout timeline
- □ Metrics

# Identify barriers

- □ Transportation
- ☐ Certain study procedures
- ☐ Burden: how much are we asking them to do?

# Reaching your audience

- Web postings
- ☐ Flyers
- ☐ Clinics
- ☐ Social media

# General guidance and resources

- Make participation as easy as possible
- ☐ Tips for rollout
- ☐ Links to resources



#### Recruitment Plan Template

+		Plan Date:						
1	Name of Study							
	Target N							
	Team Contributors							
	Initial Assessments / Environmental Scan							
	What access to the study population do you already have?							
	Is your team familiar with the study population or is this a new community?							
	At your institution or in our catchment area, are there competing projects that target the same population?							
	What is the public health or social value of the study?							
	Why would people want to participate?							
	Are there aspects (procedures, timing, etc.) of the study that may make it difficult to recruit or enroll?							
	What are the predicted barriers (location of clinic, access to population, etc.) to recruitment?							
	What is the anticipated	l screen failure rate?						

<b>√</b>	A	sse	SS	
	$\checkmark$	Pl	an	
		<b>√</b>	Bu	udget
			<b>√</b>	Do

ITHS Institute of Translational Health Sciences Accelerating research, improving Health.

Regulatory, Finance & Human Resources								
Recruitment Method		ted For		Modifications Required			Notes	
	Yes	No	Protocol	ICF	Other	None		

# **Learning Objective 2:**

Measure, evaluate, and modify recruitment strategies

# Recruitment Data 1 – Kids and MRI study

Sources of enrollment (n = 36)	Enrolled	% of enrollment
UW recruitment website	17	47
Seattle Childrens Hospital outreach	10	28
Local parent list serves	3	8
Other/unknown	4	11
Research Coordinator list serve	1	3
Principal Investigator outreach	1	3

# Recruitment Data 2 – Kids and MRI study

Sources of contacts (n = 116)	Contacts	Number enrolled	% *
UW recruitment website	79	17	22%
Seattle Childrens Hospital outreach	16	10	63%
Local parent list serve	7	3	43%
Other/unknown	7	4	57%
Research Coordinator list serve	3	1	33%
Principal Investigator outreach	4	1	25%

<sup>\*</sup>percentage is the number of subjects enrolled out of each source of contacts

### What to track?

- Number of contacts
- How did they hear about the study?
- Outcome: phone screen fail; they didn't follow up; how many enrolled?

# Value of tracking

- Quantifying what's working and what's not working
- Documents effort
- Identifies barriers modify protocol?

# **Learning Objective 3:**

Create recruitment materials that are eyecatching and bring participants and study teams together



### Before and After



### **Study Information**

#### What is Project EPIC?

Proje udy conducted through the Center for the Study of Health and KISK behaviors at the University of Washington in Seattle, WA. This study aims to explore health-related behaviors, including alcohol use and sexual behaviors. We are interested in recruiting young people between the ages of 18 and 20 with the long-term goal of studying health behaviors during the transition to adulthood. This is a national study conducted online.

#### Who can participate?

All men and women between the ages of 18 and 20 who currently reside in the United States are invited to participate.

#### Do I get paid?

Invited participants who complete the survey will be paid with their choice of a \$25 gift certificate, which will be emailed with two weeks of completion. Participants who complete each of the follow-up surveys (at 3-,6-,9-, and 12 month time points) will receive gift certificate payments of their choice of a select number of merchants, which will increased by \$5 at each time point (\$30, \$35, \$40 and \$45). Each time a participant completes a survey within 2 weeks of being invited, they will also be entered into a drawing for an Apple



UW researchers are studying 18-20 year olds' choices about drinking and having sex

Not Your Average Survey Get \$200 to fill out 5 surveys

# **Appeal to different audiences**









# What catches your attention?

# Tips for creating print material:

- Goal is to pique interest so people will want to know more
- Characterize the audience
- Image that resonate with the target audience

# Tips for creating print material:

- Content
  - Eye catching and easy to read from a distance
  - Tagline
  - Only list general eligibility
  - Concise text

# Tips for creating print material:

- Layout
  - Cluster information with text boxes
  - Use bulleted lists
  - Don't use more than two fonts, and sans serif fonts are easier to read
  - Use italics sparingly
  - Avoid long stretches of text in all caps

# Tips for web material:

- Much the same as print material
- Can link to eligibility survey
- Email contact click rather than call

# **Social Media:**

- 68% of adults on Facebook (2016 data); 24% on Twitter, 32% on Instagram
- Can target ads based on specific demographics
- Keywords
- Google ads: picks up on what people are searching for

## **Social Media:**

- Can link to a basic eligibility survey (keep to just a few key questions)
- Facebook
  - Provide tool for creating an ad; objective, audience, budget
  - Can track number of clicks to see how popular it
  - Site provides guidance
  - Links on recruitment worksheet used today

# Case History 1: Fetal MRI

Purpose	To learn more about the pattern of fetal brain growth and to develop better ways of evaluating abnormal brain development. It's hoped that fetal MRI can provide additional information about the internal brain structures that cannot be seen by ultrasound.
Study Procedures	One MRI
Benefits / Incentives	\$50 and an MRI image
Risks	Feelings of claustrophobia and discomfort from the loud noises
Inclusion Criteria	Pregnant women aged 18-45, between 18 and 36 weeks gestational age, carrying developmentally normal fetuses AND women carrying fetuses with suspected brain development abnormalities (by ultrasound)

#### To consider:

- Why would they want to participate?
- Availability -what would be barriers to participation?
- How would you do outreach?
- How would you target this specific population?



#### **Recruitment Strategizing Worksheet**

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_	leisure time?		Does your site serve a large geographic area? Will there be a lot of travel time to study visits?
	Where do they get information in general and health		How much flexibility do you have with scheduling study visits?
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_	health care systems?	_	participation more convenient?
	What would engage them with your study? What's in it for		How might they feel about medical research?
	them? Why would they want to participate?		Do they have family responsibilities: childcare or elder care?
	Are there different characteristics among different racial,		Would they have other medical conditions that might affect their participation (in addition to
	ethnic, and socioeconomic groups?		being excluded)?
	What would engage them with your study? Why would		
they want to participate? Study start-up			Reaching your audience
			Identifying participants by screening upcoming clinic appointments.
	How much do other studies pay? Where do you see studies		Is there a service that searches the electronic medical records to identify potential participants?
_	advertised? Get feedback from participants.		Community outreach: advocacy organizations, senior centers, community centers, faith based
П	Are there other clinical team members (social worker,	_	organizations, support groups, and health fairs
_	physical therapists, etc.) who might have suggestions or		Direct (specific individuals) and targeted (large scale, based on demographic profiles) mailings.
	refer participants? Establish a referral network early in the		Online advertisements: Craigslist, and listserves.
	process.		Study-specific website.
	IRB recruitment materials basic tool kit		Local advertising: Newspaper (consider community and neighborhood papers), public
	<ul> <li>Brochures (mail, leave in clinics or community</li> </ul>		transportation.
	areas, etc.)		Health reporters and bloggers: Is there something particularly innovative about what you're
	<ul> <li>Flyers (for posting, could make into a poster or</li> </ul>		doing?
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	many contacted you, where did they see the material?		Plan to hit early and hit hard, and strategies are worth repeating. You will often reach people



# Case History 2: Hypnosis and Pain Management

Purpose	Evaluate a hypnosis audio recording for chronic pain management with cancer survivors
Study Procedures	Randomization to one of two arms 1) relaxation audio recording or 2) hypnosis intervention. One in-person visit for consenting and baseline questionnaires. Daily paper diaries and follow-up questionnaires (by phone) at 2 and 4 weeks after randomization
Benefits/Incentives	\$50 for completing the questionnaires and an additional \$25 for transportation costs  Experience of stress and anxiety during the
Risks	intervention and questionnaires
<b>Inclusion Criteria</b>	Adults who have completed cancer treatment

#### To consider:

- Health experiences
- What would be barriers to participation?
- How would you do outreach?
- How would you target subpopulations?



# Take home messages:

- Consider multiple strategies there's no magic bullet
- Build into initial IRB application
- Track progress Pls like data

# Take home messages:

- Repeat messaging
- Recruitment is marketing!

## ParticipateInResearch.org

## **Connecting Volunteers with Researchers**

Volunteers contact you directly via the website

Less than 10 minutes to post

Free posting of studies



Available to WWAMI Region

23 medical categories for posting

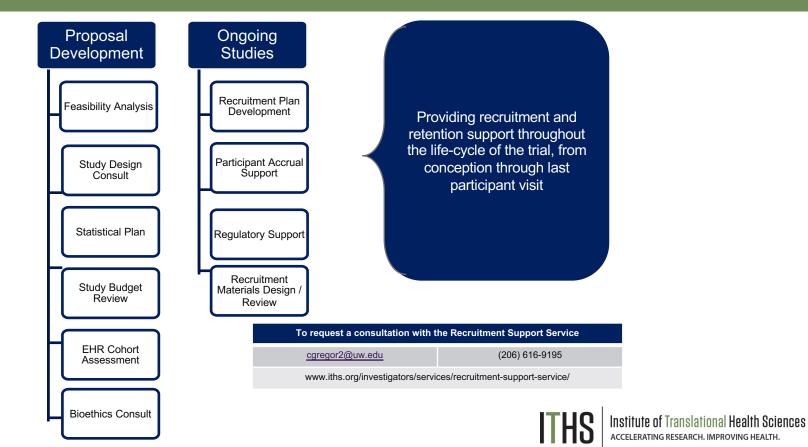
Tag your study with key search terms

- ✓ > 300 studies posted
- √ 70-90 studies currently active
- → 9.500 study team contacts (3 years)
- √ 130 average hits each day



## **Recruitment Support Service**

Strategic, project-specific recruitment consultations



## **Acknowledgments:**





This work is supported by the National Center For Advancing Translational Sciences of the National Institutes of Health under Award Number UL1 TR002319

## **Acknowledgments:**

Research participants, past present and future!







# Feedback Survey

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.