

Recruitment and Consent of Vulnerable Populations

Bettina F. Drake, PhD, MPH

Professor - Division of Public Health Sciences
Associate Director - Siteman Cancer Center

National Academies of Sciences, Engineering, Medicine

Improving Consent and Response in Longitudinal Studies of Aging

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SCHOOL OF MEDICINE

Who Should We Recruit?

- All participants
 - Race
 - Rural/Urban
 - MUA
 - Others?

Why?

- Generalizability of results
 - Develop appropriate interventions/treatments for community/patient population
- Address disparities across race/ethnicity and SES

Consent Models for Biospecimen Research

- Biobanks are essential resources for cancer research
- Consent for secondary use of biospecimens is a critical ethical and policy issue
 - Policy discussions ongoing at the federal level
- Little empirical research has examined actual donors' preferences for different models of informed consent
- Lack of data from groups underrepresented in research
 - Racial and ethnic minorities
 - Those with limited health literacy

Barriers and Strategies to Improve Participation in Tissue Research among African-American Men

Objective: To understand barriers and strategies to improve participation in biorepositories through focus groups among African American men. The goal is to improve recruitment in a prostate cancer cohort.

Characteristics N=70	%
Age (mean)	57
Employed	
yes	46%
Education	
Some college or technical degree	66%
Marital Status	
Married	58%
Insurance	
Private	62%
Medicare/Medicaid	25%
Uninsured	13%
Participated in a Health Research	
Yes	28%
Participated in Tissues Research	
Yes	8%

• Themes & Quotes

– Strategies to increase participation

In response recruitment in a doctor's office:

"I don't think so. I don't like it because I got other things on my mind. I might be in pain or something...Ask me to come back another time."

I think it should be brought up in high school, whatever. You know, health classes"

– Mistrust

"They will take it and use it for their own personal gain"

"The privacy issue is very important....I think that's the main thing the privacy, you know what I'm sayin' of the person"

– Willingness to Participate

"Education is the key....since I've read this there is no problem now. Maybe if (they) make it clear to people that tissue involves hair, nails and things like that, here."

"Anything that can further research to help somebody else in my family, I am all for it."

"I have no objections (to participating).... As long as there is not a lot of suffering and pain involved, I'm gon' be honest about it"

Findings and Implementation

Main Findings

- Physician endorsement
- Increased awareness
- Potential to help a family member increases participation

Implementation

- Strategies identified from focus groups were implemented
 - Provided information to physicians about study so he/she could answer questions from patients
 - Provided additional details during recruitment
 - Approached a second time outside of initial clinic appointment
- Increased percentage of minorities from 7% to 12% in 1.5 years

Intentions to Participate by 3 Models of Consent – among Women

- Aims
 - To investigate preferences for models of informed consent for secondary research uses of biospecimens among a diverse sample of women.
 - Compare experimentally the effect of consent model on intentions to donate biospecimens to a biobank.

Consent Models

Approaches	Key points
Study-Specific	Researchers would <i>ask your permission before EACH future study</i> in which they would use your sample.
Broad	Researchers would <i>ask for your permission ONCE</i> to use your sample in multiple future studies.
Opt-Out	Researchers would tell you that your sample may be used in future studies but you <i>could say that you do not want your sample used.</i>
Notice	Researchers would <i>tell you that your sample may be used</i> in future studies.

Consent Model Preferences

Models	Most Preferred	Least Preferred
Notice	2	27
Opt-out	3	8
Broad	36	5
Study Specific	19	18
Other*	0	2
Total	60	60

*Other category includes participants that preferred multiple or none of the models and those that did not answer the question

Preferred Model by Race

Models	African American	%	Caucasian	%
Notice	1	3.2	1	3.4
Opt-out	1	3.2	2	6.9
Broad	17	54.8	19	65.5
Study Specific	12	38.7	7	24.1
Total	31	100.0	29	100.0

Notice model of informed consent

Perceived benefits of notice model

- Simple
- Efficient
- Requires little effort by participant

“It’s sort of simple and efficient and doesn’t take very much time.” White participant

“I think, I think it’s good once they take the blood and once you do that, then you ain’t gotta worry about nothing else. I think that’s a good thing.” Black participant

Perceived risks/concerns of notice model

- Not enough control over samples
- Not enough information
- Discourteous

“I think that this approach kind of makes me feel like I’ve lost control over my body you know and my samples.”

Black participant

“It’s not giving you enough information. It’s almost like a command.” Black participant

“Well again I, I think it’s, it almost seems discourteous to just. Say we’re going to do this. That would make me irritated.” White participant

“It isn't asking your permission. It's just telling you, "We're gonna use it." White participant

Broad model of informed consent

Perceived benefits of broad model

- Best balance of models
- More control over samples
- Less burden for researchers

“The client getting the full benefit of permission, asking, knowledge, and what-have-you, but the researcher's also being eliminated that pressure and time-consuming of coming or trying to find a method to contact a client or patient each and every time.” Black participant

“Makes me feel comfortable, like there's nothing being hidden; this is what we say we're doing, this, we've asked your permission to do it once and we're going to go forward.” Black participant

“In terms of asking for my permission once, to me that's like when you take the sample, you've asked for my permission once and you have it so just go on.” White participant

Perceived risks/concerns of broad model

- Not enough information about each individual future research study

“Well I guess it’s better than not asking at all. So I guess yeah, I mean I think it’s better so that at least you’re aware. But, but I guess still you aren’t you know, you’re not aware of what all is going on down the road.” White participant

Study-specific consent model

Perceived benefits of study specific model

- Provides information about all future studies
- More control over samples

“I think this is excellent. I think the—the fact of asking, the approach of asking, the—the fact of getting the buy-in from the person, uh, making them feel comfortable with each level of the procedure or each level of the study, um, all of that is wonderful. It—it—it eliminates, uh, anxiety. It eliminates, uh, frustration, not knowing the who, what, when, um, what it's for.”

Black participant

Perceived risks/concerns of study specific model

- Could slow down research
- Too much trouble – participant and researcher

“If you can’t get in touch with me or anything, you just got this sample and you can’t use it.” Black participant

“It’s too much trouble for me; it’s too much trouble for the researcher. It’s gonna cost the researchers money and it’s gonna cost me time that I really don’t need to know. I don’t really need to know every time somebody is gonna do a study and use my tissue. It’s not gold.” White participant

Experimental Aim

Demographics		
	N	%
Age (N=356)		
<45	78	21.91
45 – 54	103	28.93
55 – 64	135	37.92
65+	40	11.24
Race (N=358)		
White	157	43.85
Black	201	56.15
Education (N=354)		
HS degree/GED or lower	108	30.51
Some college or associates degree	122	34.46
College degree and above	124	35.03
Total Household Income (N=341)		
<\$20,000	161	47.21
\$20,000+	180	52.79
Prior Participation in Biobank (N=353)		
No/Don't know	314	88.95
Yes	39	11.05
Health Literacy (N=357)		
Limited	85	23.81
Adequate	272	76.19
	Mean	SD
Trust in Medical Research (N=358)	14.56	3.06
Decisional Conflict scale (N=353)	3.40	12.88

Intent to Donate to a Cancer Biobank (N=357)

	N	%
Notice		
Definitely not	24	6.72
Probably not	25	7.00
Probably	127	35.57
Definitely	181	50.70
Broad		
Definitely not	13	3.64
Probably not	21	5.88
Probably	138	38.66
Definitely	185	51.82
Study Specific		
Definitely not	12	3.36
Probably not	22	6.16
Probably	127	35.57
Definitely	196	54.90

Intention to donate to a biobank

Models predicting intention to donate to a cancer-related biobank with different models of consent

	Notice			Broad			Study Specific		
	OR	CI	p-value	OR	CI	p-value	OR	CI	p-value
BIVARIATE									
Black	0.785	0.516 – 1.195	0.2589	0.622	0.407 – 0.952	0.0287	0.712	0.466 – 1.087	0.1155
Adequate Health Literacy	1.654	1.007 – 2.715	0.0468	1.521	0.928 – 2.495	0.0964	1.798	1.095 – 2.950	0.0203
Previous Participation in Biobank	0.505	0.253 – 1.009	0.0532	0.723	0.366 – 1.430	0.3511	1.067	0.545 – 2.091	0.8491
Decisional Conflict	0.976	0.956 – 0.996	0.0177	0.979	0.960 – 0.998	0.0271	0.979	0.961 – 0.998	0.0272
Trust in Medical Research	1.127	1.050 – 1.210	0.0010	1.167	1.084 – 1.256	<0.0001	1.190	1.104 – 1.283	<0.0001
MULTIVARIABLE									
Black	0.960	0.593 – 1.556	0.8697	0.767	0.471 – 1.248	0.2857	0.967	0.592 – 1.579	0.8919
Adequate Health Literacy	1.420	0.806 – 2.500	0.2251	1.190	0.676 – 2.098	0.5464	1.437	0.811 – 2.546	0.2137
Previous Participation in Biobank	0.412	0.201 – 0.842	0.0151	0.581	0.286 – 1.180	0.1330	0.845	0.417 – 1.713	0.6409
Decisional Conflict	0.982	0.962 – 1.002	0.0827	0.984	0.966 – 1.003	0.1059	0.987	0.969 – 1.007	0.1951
Trust in Medical Research	1.128	1.043 – 1.219	0.0024	1.141	1.055 – 1.234	0.0010	1.187	1.095 – 1.287	<0.0001

Trust in Research and Control over Information

- How is trust in research associated with participants' wanting control over information in a biobank?
 - Black participants reported wanting more control than White participants ($p < .01$)
 - Individuals who have participated in medical research wanted less control than those who have not ($p < .01$)
 - Interaction analysis revealed that trust in research and doctors was significantly and negatively associated with level of control only among White participants (interaction effect: $p < .05$).

Thank You

Bettina F. Drake, PhD, MPH
drakeb@wustl.edu