



# Effective engagement with patients on data sharing for research

The eMERGE reconsent study

**New kinds of research, such as genome-scale, require large, diverse pools of samples and data**

**Thus much interest in re-using and pooling existing data sets for efficiency and reliability**

**Not much is known about what people think about this, especially in the case of data and samples that were already collected for a different purpose**

**The eMERGE Network funded to explore the feasibility of linking genome-wide association studies (GWAS) with electronic medical records, using existing research cohorts**

**All sites required to submit de-identified study data to dbGaP, a federally administered data repository**

**Out of 5 eMERGE sites only the Group Health IRB ruled that living participants in the original research cohort should be asked for their consent to submit their data to dbGaP**

**Fortunately, we recognized this as a chance to learn about what our members expect and would want...**



## Existing cohort study

### **Adult Changes in Thought (ACT) study**

- Longitudinal cohort study of aging and dementia
- Participants 65 or older with no dementia at time of enrollment;
- Currently 2000 participants ages 65-102; GH members for a median 30 years

**Informed consent document mailed to ACT participants with follow-up call within 2-3 weeks**



# Key re-consent study questions

**Will ACT study participants give consent for data sharing?**

**What are the reasons, values, and beliefs that drive their decisions about re-consent for data sharing?**

**Do they feel re-consent is needed?**

**What do they think about the process used to ask for consent for data sharing?**

# Results: Will ACT study participants give consent for data sharing?



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**86% (1159/1340) of participants re-consented**

**11% (152) refused**

**2% (29) were ineligible (blind, too ill, difficulty with spoken English)**



# Survey participants

**Sample: 400 cognitively intact ACT participants who re-consented by mail**

**91% (365) completed the interview**

- No difference in gender between respondents (58% female) and non-completers (51% female).
- Respondents were younger (mean age=83) than non-completers (mean age=87).

# Main reason for deciding to sign consent (open-ended)



## **#1 reason by far was a desire to help others, especially as one is aging**

*I'm too old to volunteer doing active stuff, but this is one thing I can do.*

*As I read the letter, that it wouldn't be any benefit to me, but it would help someone else down the line, I thought that is not a bad thing to do.*

*I think it's important for people to contribute. If everybody didn't want to, what would be the point?*



## Other main reasons

### **Like and trust GHC**

*It's having trust in Group Health for this being legitimate, and to help move things forward in the field of health.*

### **Appreciate ACT study**

*I have been involved in the ACT study and I thought it made sense to expand that and I respect Eric Larson [ACT PI].*

### **It was easy to do / why not?**

*...because they said nothing else would be required.*

*I don't really know what the benefit is to this particular study, to eMERGE. I decided it didn't require anything of me so why not?*

# How important or unimportant was each reason to you in making your decision?



	Very important	Somewhat important
<b>Research could improve patient care and prevent or treat illness</b>	<b>81%</b>	<b>17%</b>
<b>Research could help increase knowledge for our society</b>	<b>75%</b>	<b>21%</b>
<b>Research could help me or someone close to me in the future</b>	<b>61%</b>	<b>25%</b>
<b>GHC researchers are leading the study</b>	<b>58%</b>	<b>40%</b>
<b>ACT study researchers are leading the study</b>	<b>52%</b>	<b>43%</b>

# How important or unimportant was each reason to you in making your decision?



	<b>Very important</b>	<b>Somewhat important</b>
<b>Concern that your privacy could be invaded or that your identity might be revealed somehow</b>	<b>19%</b>	<b>14%</b>
<b>Concern about the kind of research this databank could be used for in the future</b>	<b>25%</b>	<b>27%</b>
<b>Concern that your information could be used by others for their own profit</b>	<b>21%</b>	<b>20%</b>
<b>Concern or confusion about the study itself / not sure what you would have to do for the study</b>	<b>11%</b>	<b>26%</b>

# Open-ended question about “other concerns”



## 27 individuals mentioned specific concerns

### Potential misuse of information

*Maybe that some unscrupulous person could get a hold of the research, you know for extreme experimentation- ala Hitler.*

*“I worry a bit about it being used for insurance underwriting purposes.*

### Potential for profit

*I wouldn't like to see it used for profit. I would like to see it used for research purposes. I'm concerned about the information getting to the drug companies.*

### Privacy concerns

*Somebody might get my information about me that should not have it.*

# Open-ended question about “other concerns”



## **Many had no concerns**

*I don't think there is anything they could use it for that would bother me.*

## **Or mentioned their trust in GH and/or UW**

*I would rely on whoever in Group Health is doing this to use the proper discretion.*

*I was concerned and I'm just trusting the UW to know what they are doing.*

## **The word “concern” may not have been specific enough. Others took it to mean “interests”**

*I would like them to go into the cancer field. I don't see a lot of research with ovarian cancer.*

# How acceptable would it have been if we had...



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	<b>Completely unacceptable</b>	<b>Somewhat unacceptable</b>
<b>...sent a letter that asked you contact us only if you did <u>not</u> want to agree to place your information in the databank? (opt-out)</b>	<b>19%</b>	<b>21%</b>
<b>...just let you know by letter that we had already sent your information to the databank? (notification only)</b>	<b>47%</b>	<b>20%</b>
<b>...added your research information to the national databank without telling you or asking for your permission?</b>	<b>54%</b>	<b>16%</b>

# How important was it that we did ask you for your permission ?



**Very important = 69%**

**Somewhat important = 21%**

**Comments included full range:**

*It is important always to ask a subject for permission.*

*I don't think I would be too upset if you had and didn't tell me, but I think it is nice that you let people know.*

*You are going through an awful lot of trouble for very little.*



# Summary and conclusions

**Even though respondents were willing to allow their data to be shared, the majority thought it was important that researchers asked for their active consent.**

**Drivers: belief in value of medical research; trust and appreciation for GH, the UW, the ACT study**

**High value on benefits of health research, trust and appreciation for GH, the UW, the ACT study AND personal autonomy**

**High rates of re-consent ≠ open-ended use of previously collected research data without future need for individual consent**

**Consenters endorsed 'reasons against' as well as 'reasons for' consenting to data sharing, although 'reasons for' outweighed concerns in importance.**

**ACT study participants are elderly, very altruistic and have extraordinary trust in GHC and the ACT study researchers, yet they still wanted to be asked for permission.**

**This strengthens the argument that re-consent may be appropriate in other situations.**

**Or does it?**

**Would younger cohorts be less or more inclined to feel the need to give active consent?**

- Further investigation of the opinions of other participant cohorts will better inform current data-sharing research policy and practice.

