NCDHR/DWC Informed Consent Study

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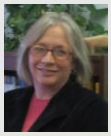

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What is "Informed Consent?" (IC)

- A legal and ethical concept and procedure
- Before being involved in:
  - Research
  - Surgery
  - Many other medical procedures
- You must fully understand
  - Risks
  - Benefits
  - Alternative choices
  - How to complain, who's involved, funding, etc., etc.

What is the Problem?

- Informed consent usually involves reading (and signing) an English "consent document," which is often very hard to understand (even for people who are good readers)
- Signing an informed consent document you don't fully understand could be risky
- Many researchers, doctors, etc., believe that signing the paper is "good enough"

What Has Been Tried?

- Informed consent documents are sometimes translated into other written languages (e.g., Spanish) but may still be to hard to understand
- Translating informed consent documents into ASL (either "live" or on film) has been done
- NCDHR has been trying a "dialogic" approach to informed consent, based on DWC work

What is the Dialogic Approach?

- Based on the belief that Deaf ASL-users learn best when information happens through discussion
- We analyze the "source" document for the "learning points" it contains
- Then we create a "story" about that topic, with Deaf characters having a conversation about it
- The conversation eventually includes all the learning points in the source material
- DWC has made many films using this approach

Why We Need "Proof"

- While we believe in the dialogic approach, we should "prove" that it really is a better way - with a carefully structured experiment
- If the experiment proves we are right, that might influence other researchers and maybe medical professionals, too, to get informed consent from Deaf people in better ways

A Special Funding Opportunity

- I thought about/designed this experiment for years but never found funding for it
- Last summer, a funding opportunity suddenly arose, focused on "research ethics" (rare!)
- Funding linked to "Clinical and Translational Science Institute" (NCDHR's home department)
- DWC/NCDHR rushed to apply for the funding
- National Institute on Deafness and other Communication Disorders gave the money!!!

Study Design (1)

- Comparing three methods of informed consent:
  - Written English document
  - "Straight" ASL translation (one signer on screen)
  - Dialogic translation (2 or more people in a "story")
- Using real IC documents from URMC research
  - 3 "minimal risk" study documents
  - 3 "greater than minimal risk" study documents

Study Design (2)

- 144 Deaf subjects needed
- Each person experiences all three types of IC
- Will check for IQ, English fluency influences
- Our "outcome measures" are:
  - How well you understood the key IC information
  - Your interest in joining the (pretend) research study
  - Your feelings of trust in the researchers and study

Our Deaf Community's Role(s)

- 144 Deaf subjects needed (adult ASL users)
- One sign model for 6 "straight ASL" consent films
- Other Deaf actors for 6 dialogic films
- Interviewers (esp. DWC staff funded on grant)

Timeline

- Almost 4 years
- Year 1
  - Choose IC documents, translate, film "straight ASL"
  - Analyze IC documents for learning points
  - Create dialogic stories/script
  - Film dialogic IC situations
  - Recruit 144 participants (ongoing in years 2 & 3)
- Years 2 – 3: do the experiment with 144 people
- Years 3 – 4: analyze data, lectures, articles

Questions, Discussion?

More Information

- Robert_Pollard@urmc.rochester.edu
- www.urmc.rochester.edu/dwc
- Pollard, R. Q, Dean, R. K., O'Hearn, A. M. & Haynes, S. L. (2009). Adapting health education material for deaf audiences. *Rehabilitation Psychology, 54*(2), 232-238.