National Institute of Mental Health

Office of the Clinical Director
Human Subjects Protection Unit

Julie Brintnall-Karabelas, MSW, LCSW-C
Mary Ellen Cadman, RN, MSN, LCSW-C

March 11, 2015

National Institute of Mental Health

DISCLAIMER

The views presented are those of the Human Subjects Protection Unit (HSPU) and do not represent the position or policy of the National Institute of Mental Health, the National Institutes of Health, the Public Health Service, or the Department of Health and Human Services.

NIH National Institute of Mental Health

HSPU within the Clinical Center

National Institute of Mental Health

Origins of Human Subjects Protections

In the Past,

Jewish twins kept alive to be used in Josef Mengele's experiments. These children were liberated from Auschwitz in January 1945 by the Red Army.

Source: http://collections.ushmm.org/search/catalog/pa14532
http://en.wikipedia.org/wiki/Josef_Mengele#mediaviewer/File:Child_survivors_of_Auschwitz.jpeg

A physician draws blood from one of the Tuskegee test subjects.

Source: http://en.wikipedia.org/wiki/Tuskegee_syphilis_experiment

In the Present,

Intubated female infant born prematurely at 26 weeks and 6 days gestation.

http://www.flickr.com/photos/ceejayoz/3579010939/

OHRP determined that the informed consent document for this trial failed to adequately inform parents of the reasonably foreseeable risks and discomforts of research participation (US DHHS, OHRP, March 2013).

"In Support of SUPPORT-A View from the NIH," Drs. Hudson, Guttmacher and Collins, respectfully disagreed with OHRP's conclusions raising a larger issue of ***"how risks should be conveyed in the informed-consent process when research is comparing interventions that are all considered to be the standard of care."*** (NEJM, 2013).

"Informed consent is a process, not just a form."

-Office for Human Research Protections (OHRP)
http://www.hhs.gov/ohrp

4,303 *and…Counting!*

- For over a decade, the Human Subjects Protection Unit has monitored the quality of thousands of informed consent discussions.

- During this time, the Clinical Research Advocates have observed a wide-range of communication styles between investigators and subjects.

- This prompted the creation of a training program on the informed consent process.

National Institute of Mental Health

The Perfect Marriage: Informed Consent and Education

Communication is key!

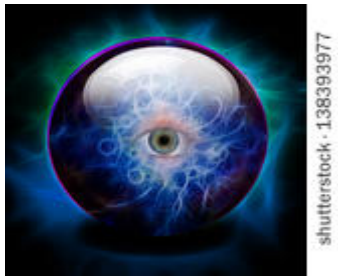
National Institute of Mental Health

854 *and…Counting!*

- The program consists of a video and didactic presentation to train investigators to conduct informed consent discussions.
- More than 800 researchers who are responsible for obtaining informed consent have participated in this training.
- Thus far, attendees have shown an increase in content knowledge regarding informed consent after the training.

National Institute of Mental Health

In the future…



- As discussed in our recent article, *" A Training Program for Improving the Informed Consent Discussion Between Clinical Researchers and Their Subjects,"* in the Journal of Empirical Research on Human Research Ethics, programs like this are feasible and can be utilized in a variety of settings.

- Modifications to the training can be made as necessary.

- The video, and pre- and post-tests, may be of particular use to educators and serve as a foundation for trainings regarding the essential elements of informed consent.

- *Cadman, ME, Murphy JH, Brintnall-Karabelas, J, Squires, C., Whorton, K. and Pao, M. A Training Program for Improving the Informed Consent Discussion Between Clinical Researchers and Their Subjects. Journal of Empirical Research on Human Research Ethics, 2014, Vol. 9 (4) 71-75.*

National Institute of Mental Health

Evaluation of the Informed Consent Process

NIMH-IRP, Office of the Clinical Director, Human Subjects Protection Unit

Trainee Name _____ **Institute**_____ _____

PROFESSIONALISM			
Introduces self and department/institute affiliation	Unacceptable	Acceptable	N/A
Ensures **privacy** during interview	Unacceptable	Acceptable	N/A
Promotes subject **comfort** during interview	Unacceptable	Acceptable	N/A
Utilizes **non -coercive** style of questioning	Unacceptable	Acceptable	N/A
Limits number of research staff present if appropriate	Unacceptable	Acceptable	N/A
Allows involvement of significant other if subject desires	Unacceptable	Acceptable	N/A
INTERPERSONAL AND COMMUNICATION SKILLS			
Presentation style :			
Utilizes a **conversational** manner	Unacceptable	Acceptable	N/A
Avoids **reading** content verbatim	Unacceptable	Acceptable	N/A
Attentive and **empathic**	Unacceptable	Acceptable	N/A
Elicits **questions** effectively	Unacceptable	Acceptable	N/A
Allows sufficient time for **discussion**	Unacceptable	Acceptable	N/A
Body and Verbal Language:			
Maintains **eye contact**	Unacceptable	Acceptable	N/A
Utilizes **language** appropriate to subject's education level	Unacceptable	Acceptable	N/A

National Institute of Mental Health

Evaluation of the Informed Consent Process

NIMH-IRP, Office of the Clinical Director, Human Subjects Protection Unit

• **INFORMED CONSENT PROCESS***			
• Process includes:			
• A statement that the study involves **research**	Unacceptable	Acceptable	N/A
• A statement that participation is **voluntary**	Unacceptable	Acceptable	N/A
• An explanation of the **purposes** of the research	Unacceptable	Acceptable	N/A
• The expected **duration** of the subject's participation	Unacceptable	Acceptable	N/A
• A description of the **procedures** to be followed	Unacceptable	Acceptable	N/A
• Identification of procedures that are **experimental**	Unacceptable	Acceptable	N/A
• A description of **risks or discomforts**	Unacceptable	Acceptable	N/A
• A description of any **benefits** to the subject or to others	Unacceptable	Acceptable	N/A
• A disclosure of appropriate **alternative** procedures or courses of treatment	Unacceptable	Acceptable	N/A
• A description of how **confidentiality** of records will be maintained	Unacceptable	Acceptable	N/A
• An explanation about **compensation**	Unacceptable	Acceptable	N/A
• An explanation about available medical treatments for a **research related injury**	Unacceptable	Acceptable	N/A
• Whom to **contact** for questions about the research, research subject's rights, or research-related injury	Unacceptable	Acceptable	N/A

• **Trainee signature** _____ **Observer signature**_____

*Source: U. S. Government Health and Human Services. (2010). Part 46: Protection of human subjects. In *Code of Federal Regulations: Title45-Public Welfare.* Department of Health and Human Services. Retrieved from: http://www.hhs.gov/ohrp/policy/consentckls.html

National Institute of Mental Health

"Elements of a Successful Informed Consent"

A Training for Investigators and Research Staff

Thank you!

https://www.youtube.com/watch?v=l26hdCD9g2I

National Institute of Mental Health

References

Cadman, ME, Murphy JH, Brintnall-Karabelas, J, Squires, C., Whorton, K. and Pao, M. A Training Program for Improving the Informed Consent Discussion Between Clinical Researchers and Their Subjects. Journal of Empirical Research on Human Research Ethics, 2014, Vol. 9 (4) 71-75.

Hudson, K.L., Guttmacher, A.E. and Collins, F.S. (2013). In Support of SUPPORT-A View from the NIH. *The New England Journal of Medicine,* 368: 2349-2351.

U.S. Department of Health and Human Services, Office for Human Research Protections. Retrieved from: http://www.hhs.gov/ohrp/detrm_letrs/YR13/mar13a.pdf (Retrieved September 16, 2013)

U. S. Government Health and Human Services. (2010). Part 46: Protection of human subjects. In *Code of Federal Regulations: Title45-Public Welfare.* Department of Health and Human Services. Retrieved from: http://www.hhs.gov/ohrp/policy/consentckls.html

http://collections.ushmm.org/search/catalog/pa14532 (Retrieved: January 23, 2015)

http://en.wikipedia.org/wiki/Josef_Mengele#mediaviewer/File:Child_survivors_of_Auschwitz.jpeg (Retrieved: January 23, 2015)

http://en.wikipedia.org/wiki/Tuskegee_syphilis_experiment (Retrieved: January 23, 2015)

http://www.flickr.com/photos/ceejayoz/3579010939/ (Retrieved: January 26, 2015)

http://www.hhs.gov/ohrp (Retrieved: September 13, 2013)

https://www.youtube.com/watch?v=l26hdCD9g2I (Retrieved: March 3, 2015)