

Ethical Challenges in Translating
Psychophysiology and Neuroscience
To
Technology for Intelligence and Counterintelligence


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The Talk will Consist of:

- } Introduction
 - } **Responsible Conduct of Research in Psychophysiology and Neuroscience -Based Technology**
 - } Ethics and Regulatory Compliance in Drugs and Devices – What can we learn?
 - } **Ethical and Cultural Challenges in Psychophysiology and Neuroscience-Based Technology**
 - } Suggested Regulatory Scheme
 - } Conclusions
- 

} The psychophysiology-based technologies:

} Polygraph,

- } Electrogastragram (EGG),
- } Radar Vital Signs Monitor (RVSM),
- } Facial Expressions,
- } Eye Blinks, Saccades, and Fixations,
- } Voice Stress Analysis (VSA),
- } Thermal Imaging,
- } Truth Serums/Narcoanalysis.

} The neuroscience-based technologies:

- } Electroencephalography (EEG),
- } Magnetoencephalography (MEG),
- } Positron Emission Tomography (PET),

} Functional Magnetic Resonance Imaging (fMRI),

- } Functional Near-Infrared-Spectroscopy (fNIRS),
- } Transcranial Magnetic Stimulation (TMS)



Challenges:

- } Ethical Challenges during the Conduct of Research
- } Ethical Challenges when used on Public



Responsible Conduct of Research in Psychophysiology and Neuroscience -Based Technology

- } The NRC (2003, p. 9) report states that:
- } *"The research program [in this case the detection of deception] should follow **accepted standards** for scientific research, use rules and procedures designed to **eliminate biases** that might influence the findings, and operate under normal rules of scientific freedom and openness to the extent possible while protecting national security."*



Why the Concern?

} **Nuremberg Code, 1947**

} **Helsinki Declaration**

(1964, World Medical Association)

} **Tuskegee Syphilis Study**

**“You, the scientists of the world,
must remember that the research
is done for the sake of mankind,
and not for the sake of science.”**

Eva Mozes Kor, a survivor of Nazi experiments conducted on twins by Dr. Josef Mengele during World War II speaking at the ACRP 2009 Global Conference & Exhibition about her childhood experiences as an unwilling subject of Nazi genetic experiments.

<http://newsmanager.commpartners.com/acrpwire/issues/2009-04-30/index.html>

Accessed on April 30, 2009



RCR Elements:

- } Honesty.
- } Objectivity.
- } Respect for research subjects.
 - Scientific validity
 - Social value
 - Informed consent
 - Beneficence
 - Equitable subject selection
 - Protection for vulnerable subjects
 - Independent review. [Example - the use of Institutional Review Boards (IRBs)].



Sources of Research Funding

- } Federally supported (NIH, DOD, DOE,...etc)
 - "Common Rule" (45 CFR 46)(Regulates Research only)
 - Oversight Agency: OHRP

- } Private Industry but FDA-Bound
 - FDA bound (*FDA Regulations*) (Regulates Research and marketing)
 - Oversight Agency: FDA

 - Private Sources (*No regulations*)

Drug Development

- } The FDA follows (i.e. 20 CFR 50, 56, and others) which closely resembles the 45 CFR 46.
 - IND (Research)
 - Phase I, II, III, IV(post-marketing)
 - NDA (Marketing the drug)



FDA-Regulated

- } Phase I
- } Phase II
- } Phase III
- } Phase IV (*Post-Marketing*)

Device Development

- } Prior to 1976:
 - } **Class I Devices** (low risk), e.g. crutches and tongue depressors.
 - } **Class II Devices** (Medium risk), e.g. oxygen masks, tampons and cardiac monitors.
 - } **Class III Devices** (High risk), (used to support or sustain life (e. g. stents and heart valves)
- } Post 1976,
 - } the sponsor apply 510(k) to FDA to determine equivalency to pre-1976 devices.
 - } If the device is not equivalent, the device most likely will be classified as **Class III** device.



Current Status

} Federally Supported:

- Research in cognitive, social, behavioral science and technology must follow 45 CFR 46.
- All research proposals using human subjects, regardless of the risks, must be submitted for an IRBs' approval prior to commencing the study.
- Compliance Issues??

} Privately funded – no regulation????



These new devices:

- } 1. Are there privacy concerns?
- } 2. Are the benefits to the individual outweighing risks? And
- } 3. Does the benefit to society outweigh the risks to the individual?



} Ethical and Cultural Challenges in Psychophysiology and Neuroscience-Based Technology



- } . Retired General and former Chairman of the Joint Chiefs of Staff Richard Myers expressed
- } strong sentiment, during his tenure, in his support of the moral high ground as well as in following the Geneva Convention

(Eyes on the Horizon, Myers, 2009).



The New Neuroscience Research and Devices:

} *"perhaps the most threatening
to our liberty."*

(Annas, 2007,)



Markus and Kitayama (1991)

- } raised serious questions to the old assumptions of:
- } *"what have been thought to be culture-free aspects of cognition, emotion, and motivation."*



(Moll et al, 2005),

} *"moral cognition depends strongly on situational and cultural context."*

The final sentence in their report states:

"The implications of this new knowledge for how societies conduct business, regulate social behavior and plan for their future remain to be seen."



Issue of informed consent on human subjects

- } Sufficient information as to the risks of technology to the subject (Fenton et al, 2009).
- } Privacy and confidentiality of the information obtained from subjects during the conduct of research.
- } **Vulnerable e.g. (PTSD) such as among the occupying/invited force or the citizens of the occupied/visited nation.**
- } One of the novel issues associated with research in this area is the accidental discovery of pathology and how to handle.



Ethical Challenges during the Use of Technology on the Public:

} Rights.

do no harm, privacy, confidentiality, profiling, cognitive freedom,

} Balancing risks/benefits.

potential risks, blowback, PTSD

} Justice.

- Social justice, cultural context, Muslims



The Counterinsurgency field manual (Petraeus, and Amos, 2006), states:

- } *“No person in the custody or under the control of DOD, regardless of nationality or physical location, shall be subject to torture or cruel, inhuman, or degrading treatment or punishment, in accordance with, and as defined in, U.S. law.” (P. 7-7).*

- } Furthermore, the manual states:

- } *“Abuse of detained persons is immoral, illegal, and unprofessional. Torture and cruel, inhuman, and degrading treatment is never a morally permissible option, even if lives depend on gaining information. No exceptional circumstances permit the use of torture and other cruel, inhuman, or degrading treatment.” (P. 7-8).
(Emphasis added).*



} Solution: Adherence to regulation of research with human subjects:

Problem: The use of these devices on American public or abroad????

} New Regulation:

} Class I: would be the least potentially risky to human beings.

} **Class III: the most risky to well being of the individual.**

} Class II: would have moderate risks.

} Require that all of the technology should have an equivalent to an IND application. **Implications?**



Conclusions



Thank You

Your Questions?

