

Risk in Social and Behavioral Research with Active Duty Military

Socio-Behavioral Research Session
Human Subjects Protection: DOD Unique Issues
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How “risky” can social and behavioral research be and why are we even concerned about it?

- **Assumption:** Social and behavioral research does not pose a risk of physical harm, injury, or death; therefore it should be exempt from IRB review and oversight.
- **Fact:** Any information that can negatively impact the participant’s self worth, psychological wellbeing, social standing, economic wellbeing, legal rights or liability presents a risk of harm.

Objective

- Increase understanding of the complex roles and responsibilities of the subject, the investigator, and the IRB that affect the risk associated with social and/or behavioral research with an active duty military population.

Content

- Beyond surveys: What constitutes “social” and “behavioral” research?
- Case examples illustrating several concerns re: ethical principles and regulatory requirements
- Translating the case examples into a military situation: Military culture & concerns regarding the Uniform Code of Military Justice (UCMJ)

What constitutes “social” and “behavioral” research?

- Direct observations, self reports (1st or 3rd party), and/or examination of existing records about:
 - Social **interactions**
 - **Shared** values, expectations, beliefs, mores, norms, goals, actions (behaviors)
 - **Influences** on values, expectations, beliefs, mores, norms, goals, actions (behaviors)
 - Health and other **outcomes** of social interactions or individual behaviors

- Structured, semi-structured, or unstructured observations or interviews
- Investigator-developed or standardized tests
- Retrospective, cross-sectional, prospective, longitudinal designs
- Non-interventional (observational or descriptive)
- Interventional (non-therapeutic or therapeutic)
- May include biological, physiological, and/or health related data

How is social and behavioral research conducted?

- **By Social Scientists & Qualitative Researchers**
 - Direct or concealed observations with field notes
 - Face-to-face interviews
 - Focus groups
 - Diaries or journals
 - “Testing”
- **As most commonly seen in Department of Defense**
 - Pencil & paper questionnaires
 - Computer-based or Internet surveys
 - Mailed surveys
 - Telephone surveys

How are social and behavioral research data recorded?

- Field notes (unstructured >>structured)
- Interview guides (unstructured >>structured)
- Questionnaires (open-ended >> forced choice)
- Pre-coded questionnaires or answer sheets
- Direct entry into computerized data files
 - PDA's, Notebook Computers, physiological monitors, computers stationed at kiosks, homes, offices
- Audio- or video-recordings
- Transcriptions

Examples of Social/Behavioral Research that Presented Risk Issues:

- Identification of Potential Subjects
- Recruitment & “Conversions”
- Risks/Benefits
- Issues of Privacy and Confidentiality
- Follow-up
- Debriefing

Let's Consider:

- **WHAT** was the investigator thinking?
- **WHERE** was the IRB?



Participating in Social and Behavioral Research from the Military Perspective

■ **The military culture:**

- Duty first (Service above self)
- Responding to the call: Researcher's mandate is to support individual autonomy in a hierarchical, authoritarian culture.

■ **Who protects the service person**

- Risks of participating – not participating

■ **Who protects the scientist?**

- Military versus non-military Investigator

Uniform Code of Military Justice

■ Examples of Behaviors Addressed in the UCMJ

- Substance use/abuse
- Sexual conduct
- Violence

■ **Duty to Report** (as conditioned by UCMJ, federal & state laws & regulations)

- Military Investigator
- Non-military Investigator or CRO

Uniform Code of Military Justice, cont.

- **Consequences for Violations of UCMJ: Non-judicial punishment or Court Martial**
 - Monetary fines
 - Incarceration
 - Stuck in place (non-promotable – not an actual penalty but is a common and likely consequence of having been convicted)
 - Reduction in grade
 - Dishonorable discharge (only if convicted at court martial)

Research Issues with Active Duty Military Personnel

- **Identifying potential participants**
 - Accessing databases & databanks
 - Obtaining support from the Chain of Command
- **Individual recruitment**
 - Newspaper, flyers, posters, e-mail or web-based
 - Introduction & endorsement letters (Role of Commanding Officer)

■ **Group Recruitment**

- Setting
- Ombudsperson
- Ensuring autonomy

■ **Enticements (incentives)**

- Compensation
- Rewards or penalties

Consent Issues

■ Obtaining consent

- Who [Military vs. civilian]
- How [One-on-one or group setting]
- When [On-duty vs. off-duty]
- Where [On-base vs. off-base]
- Potential for coercion
- What & Why ...

- 32 CFR 219.117 (a): “...informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject’s legally authorized representative. A copy shall be given to the person signing the form.”

32 CFR 21.117 (b): “...the consent form may be either of the following:

(a) A written consent document that embodies the elements of informed consent required by Sec. 219.116...may be read to the subject...adequate opportunity to read it before it is signed.

(b) A short form stating the elements of informed consent...presented orally to the subject...witness to the oral presentation...IRB shall approve the written summary of what is to be said to the subject or representative...”

■ Waiving **Elements** of Consent

- Conditions [32 CFR 219.116, (d)(1-4)]
 - Research involved is minimal risk
 - Will not adversely affect rights & welfare
 - Could not be done PRACTICABLY without waiver/alteration
 - AND Subjects will be presented information after participation

■ **Waiving Requirement for Obtaining Signed Consent** [32CFR 219.117 (c) (1-2)]

- Only record linking Subject to research; risk = potential harm from breach of confidentiality; Subject **MUST** be given option of signing a written consent document
- Research minimal risk with **NO** procedures that require written consent outside context of research.

Deception vs. Incomplete Disclosure

- **Deception:** To deliberately lead astray
 - E.g., “...creation of plausible but inaccurate cover stories and procedures designed to misdirect the participant’s attention for the sake of examining spontaneous behavior.” (Slone & Hull, p.214 in Bankert & Amdur)
- **Incomplete Disclosure:** To withhold information that might bias or otherwise alter the participant’s responses

Privacy Issues

- **I'm a Department of Defense Investigator...**
 - **Are there limits on the data I can access?**
 - Research with prisoners of war is not permitted (DoD Directive 3216.2, Sec. 4.4.2)
 - **How do I handle questions re suicidal or homicidal ideation/intent and/or violations of UCMJ?**
 - Anonymous vs. identifiable data
 - Real-time vs. delayed analysis
 - In consent, disclose intent to report/not report
 - **What information needs to be included in the military subject's health or personnel records?**

Protecting Privacy and Confidentiality

- **Separate personal identifiers from data sets**
- Anonymized vs. de-identified vs. coded
- Demographic & Other Data: What is “nice” to know vs. what “needs” to be known
- Aggregate vs. Individual Data: When is the “cell” too small to protect identity?

Confidentiality Issues:

- **Basic e-security** [lap tops & hand-held devices]
- **Advanced e-security** & use of internet [firewalls, encryption, back up files]
- **Hard copy security**
- **Storage:** e-files & hard copy
- **Access** (Who, when, how, what)
- **Disposition** (When, how, by whom?)

Summary

- Military personnel are a population with special characteristics.
- Social & behavioral data can jeopardize the participant's military career and personal wellbeing.
- Under the UCMJ, Military investigators have special responsibilities.

- Essential elements for social and/or behavioral research with an active duty military population:

- **Knowledge:**

- Human subjects research protection regulations
- How military regulations extend or expand on the Common Rule
- Service branch, base, state/local policies re: reporting requirements

– **Skill:**

- Use of ethical principles in decision making when applying human subjects protection regulations to research with special populations.

Conclusion

- **Social and behavioral research with an active duty military population is important and is possible.**

Key References

- 32 CFR 219 Protection of Human Subjects, 1 July 1999
- AR 70-25, Use of Volunteers as Subjects of Research, 25 January 1990
- DoD Directive 3216.2, Section 4.4.2, 25 March 2002
- Bankert, EA & Amdur RJ. Institutional Review Board Management and Function (2nd Ed), Sudbury, MA: Jones and Bartlett Publishers
- Oakes, JM (Oct 2002) Risks and Wrongs in Social Science Research, Evaluation Review, 26 (5), 443-479.
- Resnik, DB & Sharp, RR (Jul-Aug 2006) Protecting Third Parties in Human Subjects Research, IRB Ethics & Human Research, 28(4), 1-7.

Disclaimer

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