



# INTUITIONAL REVIEW BOARD

## CONCEALMENT VS. DECEPTION

### Principle

The primary consideration in assessing the use of concealment/incomplete disclosure requires a determination of whether concealment meets the criteria of deception. In such a case, it would be fundamentally wrong to use concealment *if* it violated the principle of respect for persons/autonomy (note: one can be deceived without a violation to his/her autonomy). This type of violation of principle also includes circumstances in which subjects are wronged without being harmed (in a literal sense).

### Consequence

The second issue requires a determination as to whether there are considerable risks and/or harms which stem from the use of concealment.

### Elements to Consider when Assessing Concealment (Incomplete Disclosure)

1. Incomplete disclosure versus deception
2. Appropriate use of incomplete disclosure
3. Comparison of incomplete disclosure to placebos in biomedical research

#### INCOMPLETE DISCLOSURE VS. DECEPTION

- Deception, involves lying, misleading, manipulation and misrepresentation.
- Violation of one's autonomy presumes that there is/will be a negative impact on things such as: self-esteem, moral values, privacy, trust in authority, trust in research (and its reputation)
- While deception may involve concealment, it does not follow that all concealment is deception. Concealment only becomes deception when it involves misinformation or misrepresentation.
- Withholding information is only inconsistent with autonomous choice when the subject is led to believe what is false.<sup>1</sup>
- "From the fact that actions are never *fully* informed, voluntary, or autonomous, it does not follow that they are never *adequately* informed, voluntary, or autonomous."<sup>1</sup>

- “APA distinguishes research in which the participants are uninformed (concealment) from research in which they are misinformed (deception); the former is seen as ethically less problematic.”<sup>2</sup>
- Subjects can consent to remain ‘uninformed’ for the sake of the scientific integrity of the study. There are valid categories for concealment in informed consent in order to achieve valid research objectives:
  - a) Informed consent to participate in one of various conditions
  - b) Consent to deception (In cases of deception, subjects are still generally willingly participate in research if they are brief afterwards.)
  - c) Consent to waive the right to be informed.<sup>3</sup>

### APPROPRIATE USE OF INCOMPLETE DISCLOSURE

- Even *if* it were the case that concealment was categorically equivalent to deception, federal regulations and ethical guidelines allow justified use of deception and/or concealment in order to control for independent confounding variables. And,
  - “That regulations allow for deception in research that presents no greater than minimal risk.”<sup>3</sup> (45 CFR 46.116.c/.d)
  - “In cases where the study can only be conducted with subjects who are less than fully informed, the missing information should not increase the risks of the study.”<sup>3</sup>
- “Relatively risk-free research that requires deception or incomplete disclosure is often warranted in fields such as behavioral and physiological psychology. But deception should only be permitted in research only if:
  - a) It is essential to obtain vital information
  - b) No substantial risk is involved
  - c) Subjects are informed that deception or incomplete disclosure is part of the study
  - d) Subjects consent to participate under these conditions.”

Likewise, “Under disclosure and non disclosure are also usually less difficult to justify [than deception].”<sup>1</sup>

### COMPARISON OF INCOMPLETE DISCLOSURE & USE OF PLACEBO

- The use of placebos “invites [subjects] to agree to remain ignorant.” Subjects are informed that information is intentionally being withheld.<sup>2</sup>
- Analogously, concealment also requires a necessary level of ignorance to achieve scientific objectivity.

- While research must be ethical to be ‘valid’ it must also be scientifically valid to be ethical. “Scientific validity constitutes a fundamental ethical protection. Scientifically invalid research cannot be ethical no matter how favorable the risk-benefit ratio for study participants.”<sup>5</sup>
- The use of concealment as a scientific control is a sound scientific methodology as well as an ethically acceptable research tool. Independent behavioral variables must be controlled for in order to obtain uncompromised data. Concealment—if low-risk—is a scientifically and ethically valid technique which adequately isolates independent factors of interest in subjects’ behavior. As a result, the causal effects of the dependent variable(s) can be reliably determined.

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1. Beauchamp, T. and Childress, J. Principles of Biomedical Ethics (fifth edition). New York: Oxford University Press, 2001.
2. Sieber, Joan. Planning Ethically Responsible Research. Applied Social Research Methods (Volume 31). California: Sage Publications, 1992.
3. Levine, Robert. Ethics and Regulation of Clinical Research (second edition). Connecticut: Yale University Press, 1986.
4. McGuire Dunn, C. and Chadwick, G. Protecting Study Volunteers in Research. Massachusetts: CenterWatch Publications, 2002.
5. Emanuel, E. and Miller, F. “The Ethics of Placebo-Controlled Trials—A Middle Ground.” *New England Journal of Medicine*, Volume 345, Number 12; September 20, 2001: 915-918.