IRB Review of Non-exempt Human Subjects Research Involving Deception

Abstract and definitions: In some cases, deception is believed to be methodologically necessary and ethically justifiable in order to answer meaningful scientific questions. It is more commonly used in social, psychological, and behavioral research and rarely in clinical trials. However, such research raises significant ethical tension particularly since denying potential participants full information appears to violate the principle of respect for persons which "demands that subjects enter into the research voluntarily and with adequate information" (Belmont Report). For this reason, non-exempt research involving deception often requires a waiver or alteration of consent. IRB members must understand the potential ethical concerns and conditions under which such research may be approved and ensure that 1) criteria for IRB approval of the research are met and 2) if applicable, the criteria for waiver or alteration of consent are met.

Deception is the act of causing someone to accept as true or valid what is false or invalid.[1]
Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests[2]

Categories of deception used in research

- **Outright deception**: Subjects know they are participating in research but are not informed of use of deception.
- **Covert deception**: Subjects are unaware they are in a study, but their environment is manipulated such that the subject has a false understanding of what is occurring.
- **Incomplete disclosure**: Information such as the real purpose of study or the nature of procedures is withheld.
- **Authorized deception**: Subjects are told that they will be misled regarding some aspect of the study.

Relevant regulations: The Common Rule does not discuss research involving deception, but the Belmont Report notes: "In all cases of research involving incomplete disclosure, such research is justified only if it is clear that

1. incomplete disclosure is truly necessary to accomplish the goals of the research,
2. there are no undisclosed risks to subjects that are more than minimal, and
3. there is an adequate plan for debriefing subjects, when appropriate . . ."

Waiver or alteration of consent

- If waiver or alteration of consent is being requested, the IRB must determine that the required criteria are met.[3]
- If the IRB approves waiver of consent, it can still require that specific information be provided to potential subjects (e.g., what procedures will occur, statement that they can withdraw at any time during the study)
- Considerations related to approvability of **alteration of consent** under the 2018 Common Rule:
  - The consent may omit or alter the basic elements of informed consent (§ 46.116(b)) and the additional elements of informed consent (§ 46.116(c))
  - However, general requirements for informed consent apply, one of which states that the prospective subject "must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate" (§46.116(a)(4)). This means the basic and additional elements of consent cannot be removed in the altered consent unless all general requirements are still met.

Additional IRB considerations (that should also be addressed in the protocol):

- Is deception justified given the potential value of the study vs. risk to participants?
- Are there any other effective ways to collect the necessary data that do not include deception?
- Is the study minimal risk and without risk of significant harm?
- If appropriate, can language regarding authorized deception be included in the consent form?
- Are participants being deceived about factors that would affect their willingness to participate? (not acceptable)
- Will participants be debriefed after the research? If not, is there justification? What methods will be used to debrief? Has a script of the debriefing been reviewed by IRB? Will subjects be permitted to withdraw their data?

[1] Merriam-Webster: https://www.merriam-webster.com/dictionary/deception downloaded 9/14/2023.
[2] 45 CFR 46.102(j) (2018 Common Rule)
[3] 45 CFR 46(f)(3) (2018 Common Rule)