I. Overview

One component of the definition of "human subject research" is that the study must involve the collection of information about one or more living individuals. That is, the study must be entirely or partly "about whom," as opposed to being solely "about what." If the study is wholly "about what," it is *not* human subject research, and it does *not* require IRB review.

II. "About Whom" as a Component of "Human Subject Research"

- 1. **Regulatory guidance:** Per 45 CFR §46.102 and 32 CFR 219.102(f), for your project to constitute research involving a human subject:
 - a. It must be research, which means it must be a systematic investigation designed to develop or contribute to generalizable knowledge; and
 - b. It must involve a humans subject, which means that you are either
 - *i.* Collecting information about a living individual through intervention or interaction with that individual; *or*
 - ii. Collecting information about a living individual that is (1) private and (2) personally identifiable.
- 2. **Any living individual can be a human subject:** Collecting information about subject matter experts (SMEs), public officials, and/or elites as defined by other criteria is human subject research. Note that consultation with SMEs—or for that matter, anyone—during the developmental stages (e.g., the development of a research question) of a project is not human subject research, because it is not a "systematic investigation," which means that research—and thus human subject research—is not being conducted.
- 3. **Asking someone their opinion is not necessarily soliciting "about whom" information:** Survey or interview questions that elicit opinions about topics other than individuals do not place a study within the category of human subject research.

III. Examples

The following examples are guidance and do not provide the necessary training or authority to make determinations as to whether an activity involves human subjects. Per SECNAVISNT 3900.39d only the NPS IRB Chair and Vice Chairs can determine if an activity involves human subject research.

1. <u>Not human subject research</u>: Asking a company commander to describe the different functions performed by positions at the platoon and company levels, and communication processes between the two levels *if no private, personally identifiable information is collected about individuals who have filled different positions*.

- 2. <u>Not human subject research</u>: Asking a squad leader to describe the training techniques that are used in a classroom or on a training range.
- 3. <u>Human subject research</u>: Asking a squad leader to describe his personal experiences using different training techniques. *Note: Such questions would place the study in the category of human subject research even if the overall purpose of the study were "about what," for instance, about training techniques.*
- 4. <u>Not human subject research:</u> Asking a squad leader to evaluate the effectiveness of training techniques based on a set rubric or on the performance of students *in the aggregate, without providing private, personally identifiable information about individual students*.
- 5. <u>Human subject research</u>: Asking a squad leader what the biggest threats are to national security. *Note: This opinion question is "about whom," as it seeks a general attitude from—that is, something about—the squad leader; and not a concrete assessment of something within the squad leader's realm of expertise.*
- 6. <u>Not human subject research:</u> The purpose of the research is to determine whether System A or B is better. The researchers ask 30 soldiers who have used both systems to evaluate the systems (e.g., with instructions to rate each system on a scale of 1 to 10). The researchers perform an analysis that determines statistically which system is better.
- 7. <u>Human subject research</u>: The purpose of the research is to determine within-rater reliability. The researchers ask soldiers who have used both systems to evaluate the systems (e.g., with instructions to rate each system on a scale of 1 to 10). The researchers perform an analysis that determines the soldiers have low within-rater reliability.