Example Human Subject Research Determination Worksheet

“Human subject” means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, OR the use of identifiable private information.

- Data which describe organizational dynamics, external trends, environmental factors or other non-human factors, even if collected from humans, does not itself constitute human subjects research, unless primarily opinion-based.
- “About who” = The information being elicited for the research is about the [living] individual (the whom). The focus on the investigation is the opinions, characteristics, or behavior of the individual(s).

Does the proposed activity involve human subjects?

1. Y □ N □ Did you collect data through intervention\(^a\) or interaction\(^b\) with and individual, including interviews, surveys, physical procedures, manipulations of the subject’s environment, and any other direct contact or communication with the subject (regardless of whether resulting data is identifiable or not)?
   a. Intervention: Includes both physical procedures by which data are gathered, and manipulations of the subject or subject’s environment performed for research purposes.
   b. Interaction: Communication or interpersonal contact between investigator and subject.

2. Y □ N □ Did you obtain, view or otherwise handle and private information\(^c\) which identifies individual subject(s) through the use of either direct identifiers\(^d\) (name, address, etc.), OR indirect identifiers in the form of a code that links back to the identity of subject through an existing key.
   a. Private information includes, but is not limited to:
      - Medical records and charts, specimens, data or tissue repositories.
      - Employment or educational records, and observations of behavior which the subject could reasonably expect no observations to be taking place.
      - Personal thoughts, feelings, opinions, attitudes, beliefs, etc.
   b. Direct identifiers include, but are not limited to: name, street address, audio/video recordings, telephone, fax, email, SSN, medical record number, etc.
      - If codes and key exist, check NO here (official correspondence from the holder of the key which states that the researcher will NOT be given access to the key under any circumstances would be required).

**If you answered YES to either question, you ARE conducting human subject research. Consult your IRB to determine next steps.**