The IRB has deemed that the research and procedures described in this protocol application are exempt from federal regulations under 45 CFR 46.101 category 2 due to the fact that this research will involve the use of interview procedures. Although information obtained is recorded in such a manner that human subjects can be identified, disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exempt protocols do not have an expiration date; however, if there are any changes made to this protocol that may cause it to be no longer exempt from CFR 46, the IRB requires another standard application from the investigator(s) which should provide the same information that is in this application with changes that may have changed the exempt status.

There are two aspects of your application that I must comment on. First, the UNO IRB recommends that your consent form be labeled as a consent form rather than as a release form. Typically, a release form permits use of audio/visual documentation to be shared directly with others (rather than remaining confidential). Second, the study dates on your consent form run from January 1 through October 31, 2013, yet you are not receiving IRB approval until July 25. IRB approval must be obtained before any data are collected.

If an adverse, unforeseen event occurs (e.g., physical, social, or emotional harm), you are required to inform the IRB as soon as possible after the event.

Best wishes on your project!

Sincerely,

Robert D. Laird, Chair
UNO Committee for the Protection of Human Subjects in Research