

PI CERTIFICATION OF SEVEN DESIRABLE CHARACTERISTICS FOR RESEARCH STUDY

Study Title _____

IRB number _____

PI _____

A study must meet the seven desirable characteristics to qualify for Medicare coverage of routine costs; however, studies will be deemed to have these seven desirable characteristics and be a Qualifying Clinical Trial (QCT) if the study satisfies one of these four criteria: funded by NIH, CDC, AHRQ, CMS, DOD, or VA; or if supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD or VA; or if conducted under an investigational new drug application (IND) reviewed by the FDA; or if trial is IND exempt under 21 CFR § 312.2(b)(1).

If the study does not satisfy one of these four criteria, the Principal Investigator (PI) can certify that the trial has the seven desirable characteristics of a QCT under the Medicare Clinical Trial Policy.

The Office for Clinical Research (OCR) has determined that your study does not meet the four aforementioned criteria so requests the PI review the seven desirable characteristics below and certify if these characteristics are met with this study:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

I certify that the above mentioned study meets the seven desirable characteristics listed above for a QCT.

Signature

Date