Coverage Analysis Qualifying Clinical Trials (QCT) Form

Phase

Sponsor:

Study Title:

Study Coordinator:

Principal Investigator Name:

Department:

Prepared By:

Date Prepared:

Instructions: Use this QCT Form to determine when a trial is considered qualified to bill Medicare (even if the patients you may enroll don’t use/have Medicare).

* Stop at the end of each step to determine if you need to proceed to the next section.

**Coverage Analysis = QCT Form (Part 1) + Billing Matrix (Part 2)**

Step 1. Preliminary Analysis

1. Does your **NEW or Modified** study include patient care services billed within UT Health RGV or any health system? (i.e., patient procedures at a health facility, scheduled in an EMR)

 Yes [ ]  No [ ]

1. If submitting modifications to the IRB, does your modification include changes to patient care services?

 Yes [ ]  No [ ]

1. Does the study sponsor pay for ALL services? (All services = nothing is billed to the participant or their insurance)

 Yes [ ]  No [ ]

Step 2. Does this trial qualify to bill patient care services under Medicare rules?

1. Is the trial’s aim or purpose to evaluate an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage? (i.e., eye exams, cosmetic surgery, massage therapy, etc.)

 Yes [ ]  No [ ]

1. Does the trial have therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology?

 Yes [ ]  No [ ]

Quote the objective that supports this: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Does the trial enroll patients with a diagnosed disease/condition rather than only healthy volunteers?

 Yes [ ]  No [ ]

(If you checked “No” to any question listed in Step 2, STOP! Your trial does not qualify for Medicare coverage. The Billing Matrix is not required.)

Step 3. Automatically Qualifying “Deemed” Trials (check all that apply)

1. Funded by NIH, CDC, AHRQ, CMS, DOD, and/or VA?

 Yes [ ]  No [ ]

1. Funded by centers or cooperative groups supported by the above agencies?

 Yes [ ]  No [ ]

1. Conducted under an Investigational New Drug (IND) Application reviewed by the FDA?

 Yes [ ]  No [ ]

1. Exempt from having an IND under 21 CFR 312.2(b) (1)?

 Yes [ ]  No [ ]

(If you checked “Yes” to any of the questions in this section, STOP! Your trial meets requirements for coverage under Medicare Rules. The Billing Matrix is required. If you checked “No” to all the questions in this section, proceed to next section.)

Step 4. “Desirable” Characteristics (check all that apply)

1. Is the principal purpose of the trial to test whether the intervention potentially improves the participants’ health outcome?

 Yes [ ]  No [ ]

1. Is the trial well supported by available scientific and medical information or intended to clarify or establish health outcomes of interventions already in common clinical use?

 Yes [ ]  No [ ]

1. Do you agree that the trial does not unjustifiably duplicate existing studies?

 Yes [ ]  No [ ]

1. Is the trial’s design appropriate to answer the research question(s) being asked?

 Yes [ ]  No [ ]

1. Is the trial sponsored by a credible organization?

 Yes [ ]  No [ ]

1. Is the trial in compliance with the Federal regulations relating to the protection of human subjects?

 Yes [ ]  No [ ]

1. Are all aspects of the trial conducted according to the appropriate standards of scientific integrity?

 Yes [ ]  No [ ]

(If you checked “No” to any questions in this section, STOP! Your trial is determined not to qualify for coverage under Medicare rules. The Billing Matrix is not required. If you checked “Yes” to all seven (7) questions, your trial meets requirements for Medicare coverage. The Billing Matrix is required.)

Conclusion: Does this trial qualify for Medicare coverage?

Yes [ ]  - Proceed to part 2 of Coverage Analysis – the Billing Matrix

No [ ]  - Billing Matrix is not required

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date (DD/MMM/YY):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_