Worksheet #1:

Determination of Qualifying Clinical Trials for Medicare Reimbursement of
Routine Care for Diagnostic Intervention and Drug Trials (For device trials
see ycci.yale.edu/comply/devices/index.aspx)

HIC #: ____________________________________________________________

PI name: ___________________________________________________________

1. Is the purpose or subject of the trial to evaluate an item or service that falls in Medicare
   benefit category (e.g. physician services, durable medical equipment, diagnostic test)?
   
   If Yes - Continue     If No - Stop, trial doesn't qualify

2. Has the item or service been statutorily excluded (e.g. cosmetic surgery, hearing aids)?
   
   Yes - Stop, trial doesn't qualify     No - Continue

3. Is the trial designed exclusively to test toxicity or disease pathophysiology? It must have
   therapeutic intent. (e.g. benefit for the participants)
   
   Yes - Stop, trial doesn't qualify     No - Continue

4. If the trial involves therapeutic intervention, do all participants have diagnosed disease (i.e.
   no participants are normal volunteers)?
   
   Yes – Continue to question 6       No – Go to question 5

5. If the trial involves diagnostic intervention, do all participants have diagnosed disease or, if
   healthy participants included, are they only assigned to proper control groups?
   
   Yes – Continue     No - Stop, trial doesn't qualify

6. Answer the following to find out if the trial falls in one of the following categories indicating it is
   deemed to be automatically qualified for Medicare coverage:
   
   a. Is the trial funded by NIH, CDC, AHRQ, CMS, DOD, or VA?

   Yes - Go to Step 8       No - Go to b.

   b. Is the trial supported by centers or cooperative groups that are funded by the NIH, CDC,
      AHRQ, CMS, DOD, and VA?

   Yes - Go to Step 8       No - Go to c.

   c. Is the trial conducted under an investigational new drug application (IND) application
      reviewed by the FDA?

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Yes - Go to Step 8  No - Go to d.

d. Is the trial a drug trial exempt from IND application under 21 CFR 312.2(b)(1)?
   Yes - Go to Step 8  No - Go to Step 7

7. If the answer to steps 6a, 6b, 6c, and 6d were NO, then trial doesn't qualify at this time.

8. If the answer to Step 6a, 6b, 6c, or 6d is YES, then the trial is deemed qualified for Medicare coverage. Please use Routine Cost Worksheet for routine costs in clinical trials to determine what clinical costs are covered.

Signature of Person completing form:_____________________________________

Date: ____________________________