Worksheet #2

Criteria for Determination of **Routine Costs** of a Qualifying Clinical Trial
(not applicable to device trials)

1. Is Item or service generally available to Medicare beneficiaries? (i.e. has a Medicare benefit category, not statutorily excluded, does not fall under Medicare national non-coverage decision)?

   **Yes** - Continue to Step 2.
   **No** - Stop, Not covered as a routine cost.

2. Is the item or service in one of the following categories:

   a. The non-covered investigational item or service, itself; or

   b. Item or service used solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient (e.g. monthly CT scans for a condition requiring only one CT scan); or

   c. Item or service customarily provided by research sponsors free of charge for any enrollee in the trial.

   **Yes** - Stop, Not covered as routine cost
   **No** - Continue to Step 3

3. Is the item or service contained in one of the following categories:

   a. Item or service is typically provided absent a clinical trial (e.g. medically necessary conventional care).

   b. Item or service is required for the provision of the investigational item or service (e.g. administration of a non-covered chemo-therapeutic agent)

   c. Item or service required for the clinically appropriate monitoring of the effects of investigational item or service or the prevention of complications from item or service.

   d. Item or service is medically necessary for diagnosis or treatment of complications arising from provision of an investigational item or service

   **Yes** - Go to Step 4
   **No** - Stop, Not covered as routine cost
4. The item or service satisfies the requirements for routine costs in qualified clinical trials and a claim may be submitted.