

**SCHEDULE OF EVENTS MEMO & REVIEW**

IDENTIFICATION OF SERVICES PROVIDED TO CLINICAL TRIAL PARTICIPANTS

PI:

Sponsor:

Study Title:

**FOR ALL STUDIES:** The University of Arizona Health Sciences (UAHS) requires source documentation that shows the detail for all required study procedures and a determination of who is paying upfront and before the trial starts. Using the clinical trial protocol schedule of events please identify research-specific services/procedures by circling items and services provided solely to satisfy data collection and analysis needs and those services/procedures that would not otherwise be routinely performed for the direct clinical management of the patient at the discretion of the physician investigator.

Items and services left unmarked will represent routine care/costs, which (per [CMS guideline NCD 310.1](https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA)) can include:

* Items or services that are typically provided absent a clinical trial (e.g., for conventional care/medical necessity);
* Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent),
* Items or services for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications (e.g., safety labs, pre-meds/supportive medications)

Please indicate the type of study: [ ]  INTERVENTIONAL [ ]  RETROSPECTIVE [ ]  REGISTRY

[ ]  OBSERVATIONAL [ ]  OTHER (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  **AMENDMENT TO EXISTING STUDY**

**FOR AMENDMENTS ONLY:** This memo is intended to evaluate the service/procedure revisions from protocol version\_\_\_\_\_\_\_ to the most recent protocol version \_\_\_\_\_\_\_. Please briefly describe the protocol changes: \_\_\_\_\_\_\_\_\_\_\_\_
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**FOR ADMINISTRATIVE CHANGES ONLY:** No further action required. This memo will serve as documentation of notification and internal review. If further action is needed, we will reach out to you.

**REQUIRED INFORMATION:**

1. Lead Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Lead Coordinator Contact Info: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Where will this study take place? (select all that apply)

[ ]  INPATIENT [ ]  OUTPATIENT
[ ]  CATS [ ]  OTHER RESEARCH SPACE (please identify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Where will labs be processed: [ ]  Locally   [ ]  Sponsor’s central lab [ ]  N/A

**Your signature below will serve as your attestation that, following your review of the clinical trial protocol, all clinical services you expect to perform have been identified and labeled as either clinical trial/research-related or routine care.**

Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

For questions, contact crc@email.arizona.edu.