University of Rochester Medical Center
Department of Pediatrics
Golisano Children's Hospital at Strong Health Strong Health
Pediatric Clinical Research Office

PEDIATRIC CLINICAL RESEARCH OFFICE
RESEARCH QUALITY ASSURANCE and RESEARCH CLINICAL BILLING REVIEW

PRE-AUDIT INFORMATION FORM

Study Title:

Principal Investigator:

RSRB/WIRB Number:

Sponsor (if any): _____

Procedures/Services Covered/Billed Under Study/Grant: _____
_____

- Please provide a copy of your **APPROVED Study Budget**.
- What is PI estimated percent time & effort for this study: _____%
- What is the account number (e.g., ledger-3, ledger-5) from which the costs (sources of funds) for the study are supported? _____ .

- Current list of **enrolled Subjects** (Please attach)

- Are you planning of registering your study with ClinicalTrials.gov? YES ___ NO ___

- Status of Study: (*Please check(√)*) :

Active: [ ] **Accrual/Recruitment Continues** [ ] **Open to Accrual, but no Enrollment**
[ ] **Accrual Complete** [ ] **Follow-Up Data Collection Only**
[ ] **Data Analysis Only**

Closed: [ ] **Closed, Completed per Protocol** [ ] **Closed Before Completion,**
Why? [ ] **No Benefit** [ ] **Safety Issue**
[ ] **Sponsor Decision**
[ ] **PI Decision**
[ ] **Other:** _____

- Where are Subjects seen for study related visits: _____
_____

- Where are study files stored (location)? _____

- Initial RSRB/WIRB Approval date: _____

- Most Recent RSRB/WIRB Approval Date: _____

- Clinical Research Intervention: (Please check (√))

  Drug [ ] **Device** [ ] **Behavioral** [ ] **Other** [ ] _____

- Phase of Trial (√ if applicable):

  Phase I [ ] **Phase II** [ ] **Phase III** [ ] **Phase IV** [ ]
  Other [ ] (specify): _____ .

- HIPAA Regulations:

  1. Do you have a process for tracking disclosures (when required)? YES ___ NO ___

     If NO (disclosures not tracked), explain: _____
     _____

  2. Do you have (maintain) documented approved waiver of authorizations on file?
     YES ____ NO ____ If NO, Explain: _____
     _____

- Study Staff and Staff approved to Consent: (List all study staff directly responsible for conducting Study and Staff/persons approved to Consent)

  _____ _____
  _____ _____
  _____ _____
  _____ _____

- Study Staff **HSPP/EPRP** Numbers: (Provide number and renewal date):

  _____ _____
  _____ _____
  _____ _____
  _____ _____

- Number of Study Suspensions (if any): _____
- Number of Amendments made to Study (if any): _____

- Number of Adverse Events (if any): _____
- Number of SAE's (if any): _____

- Please check (√ if applicable):
  [ ] Our division has an established system of regular study analysis/audit.
  [ ] This study undergoes regular, external monitoring visits.

(Please use additional space on reverse of this page, if necessary)

Return to: Cassandra Horihan, Rm: 4-5227, Ext. 5-7746, Box 777 ***1-2 weeks prior to date of audit***.

Clinical Research Quality Assurance Review Process

- Memo sent to principal investigator via email indicating tentative date and time that a study under their auspices is scheduled for review. If original date/time is not convenient, an alternate, mutually agreed upon date/time will be arranged.

- Accompanying the notification of review memo is a Pre-Audit Information Worksheet that the Principal Investigator/Study Coordinator is requested to complete and forward to the PCRO QA Coordinator prior to the date and time of the review.

- Once notification is received by the Principal Investigator, a pre-review meeting can be established at the Investigator's request to discuss the plan and purpose of the review as well as answer any questions. At any time during the review, the Principal Investigator can request to meet with the PCRO QA Coordinator to discuss the status of the review.

- The review is conducted over a sufficient period of time necessary to conduct a through and comprehensive review. This could be from one day to a week, depending on the amount/volume of records to be reviewed. The PCRO QA Coordinator will make every effort to minimize Principal Investigator/Study Staff time.

- Records can be reviewed on-site at a location where the records are stored, at a location requested by the Principal Investigator, or reviewed in the PCRO QA Coordinator office in 4-5227.

- If a deficiency(s) are noted during time period of the review, the PCRO QA Coordinator will endeavor to substantiate whether or not the deficiency(s) exist with the Principal Investigator/Study Staff. If the Principal Investigator can substantiate that a deficiency(s) does not exist, the deficiency(s) will be removed from the review findings.

- Upon completion of the review a Draft Review Summary will be completed and reviewed by the Director, Operations, PCRO and the Director, PCRO.

- Upon internal PCRO review of the Draft Review Summary, it will be forwarded to the Principal Investigator for review, comments, additions, clarifications, etc. If no revisions are noted, a Final Review Summary will be submitted to the Principal Investigator.

- If the Principal Investigator requests incorporation of a revision(s) to the Draft Review Summary for the purpose of clarification, as a response to a deficiency(s) noted, to respond to steps taken to correct a deficiency(s), etc., the revision(s) will be incorporated into the Final Review Summary and submitted to the Principal Investigator.