

Key Elements for Monitoring Adherence

There 8 key elements to consider when monitoring your studies for quality assurance:

I. Study Enrollment Status

- Is there adequate tracking and reporting of research participant involvement in a research study?
- Has enrollment information and participant status been reported appropriately to HRPO?
- Has tracking of participant withdrawal or screen-fail been documented appropriately
- Are screening, enrollment, and master logs being maintained accurately and in line with your approved application & protocol?

II. Execution of Informed Consent/Assent

- Has informed consent/assent been obtained/documentated according to the process approved in the myIRB application?
- Did the informed consent/assent process contain errors, including but not limited to:
 - Use of an outdated or expired consent/assent document
 - Use of an invalid consent or assent document
 - Are any consent/assent documents missing
 - Within a consent/assent were answerable items left blank
 - Study procedures executed prior to or without consent
 - Lack of full execution of signature boxes
 - Signature date discrepancies
 - Consent not obtained by appropriate Legally Authorized Representative (LAR) or Legal Parent/Guardian
 - Consent obtained by non-HRPO-approved person
- Example of an invalid HRPO stamp:

```
FOR IRB USE ONLY
$STAMP_IRB_ID
$STAMP_APPRV_DT
$STAMP_REL_DT
$STAMP_EXP_DT
```

III. Maintaining Privacy/Confidentiality

- Has the participants' private information and study data been used, maintained, and/ or disclosed appropriately?
- Are study records being retained according to University Record Retention Policies (minimum of 7 years post study closure in myIRB)?
- Have there been any confidentiality/privacy/and/or HIPAA breaches?
- Is study data being maintained and/or shared according to protocol?

IV. Participant Eligibility

- Have there been any deficiencies identified with the tracking, documentation, and/or enrollment of research participants? This includes but is not limited to:
 - Lack or inconsistent documentation of inclusion/exclusion criteria,
 - Enrollment of ineligible participants
 - Lack of documentation of the source inclusion/exclusion were verified from (per the participant, per EMR on XX/XX/XXXX value X, per interview/survey, etc.)
 - Duplicate enrollment without HRPO Approval
 - Enrollment of a non-HRPO approved population

V. Documentation of Interventions/Observations & Study Procedures

- Have there been any deficiencies identified with how the investigational plan was implemented and/or documented in the research record? This includes, but is not limited to:
 - Deviations from the approved protocol/study plan
 - Errors in study documentation (incomplete CRFs, lack of good documentation practices, etc.)
 - Inconsistent or lack of documentation of study procedures
 - Lack of documentation of research team member/PI involvement and oversight

VI. Safety Monitoring/Adverse Events

- Have there been deficiencies identified with the monitoring, tracking, and reporting of participant safety? This includes, but is not limited to:
 - Safety monitoring not conducted or documented according to protocol
 - Errors in the monitoring and/or collection of adverse and serious adverse events
 - Lack of adherence to safety reporting requirements (DSMB, FDA reporting/annual reporting, sponsor reporting requirements, coordinating center reporting requirements etc.)
 - Lack of adherence to HRPO reporting requirements

VII. Regulatory Documentation/Multisite Study Management

- Have there been deficiencies identified with the maintenance of essential regulatory documentation at the local site or multisite level? This includes, but is not limited to:
 - Failure to maintain essential regulatory documentation
 - Discrepancies within essential regulatory documentation
 - Participant payment discrepancies

VIII. Required Research Education/HIPAA Training

- Have all research team members completed the required research education (CITI Human Subjects Training, Good Clinical Practice Training, and HIPAA 101) as applicable?