| **12 Quality Assurance and Research Compliance:**<br>12.1 Quality Assurance Audits - Random | Effective Date: **6/12/2009**<br>Revised: **5/6/2011** |
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NDSU is responsible for ensuring compliance with relevant ethical principles, federal and state law and institutional policies for the protection of research participants. In addition, federal regulations provide the IRB with authority to verify that no material changes have occurred in approved projects without IRB approval. To accomplish this objective, periodic routine audits are performed to verify that research was reviewed and conducted in compliance with federal regulations, NDSU policy, and the IRB approved protocol.

Collective results of the random audits and feedback from investigators are used to improve the quality, efficiency and effectiveness of NDSU's human research protection program by identifying gaps in training, policy, procedures, or oversight mechanisms.

1.0 Selection of protocols:

HRPP staff, IRB chair, or qualified designee perform routine audits, at a frequency consistent with the number of currently active protocols (approximately 2-5% per year). Protocols are selected from any 3 categories of review (exempt, expedited, or full review) on a random basis; selection does not imply any suspected noncompliance. On a monthly basis, 2 or 3 random numbers are generated (using programs such as random.org) between 1 and the total # of currently approved protocols recorded in the electronic database record. The protocol corresponding to the *nth* record in the database report is selected. Every effort will be made to involve multiple departments/units, as well as investigators in the selection process. For example, if an investigator has recently been involved in a protocol audit resulting in no compliance concerns, another protocol will be randomly selected. A risk-based selection process may also be utilized, randomly selecting from those studies reviewed by either expedited or full board procedures.

Investigators are contacted in advance to arrange a convenient time for the evaluation, informed of the process, and the type of records to provide for review. The department Chair/Head or unit supervisor will also be notified of the selection. With the cooperation of the principal investigator, it is expected that the audit visit can be scheduled in a timely manner. It may include evaluation of any or all of the following:

- review of the IRB protocol file
- review of investigator's research records
- meetings with investigator, and/or other research team member(s)

2.0 Evaluation of IRB records:

IRB records are evaluated by a non-conflicted HRPP staff, IRB chair, or qualified designee to verify that applicable ethical issues were addressed, the appropriate category of review was utilized, and the relevant determinations required for approval were documented in the initial, as well as ongoing review(s). Using the *QA Audit Checklist*, any of the following may be evaluated:

- protocol submission materials and timeline of approval process
- documentation of reviews and correspondence with investigator

- relevant approved meeting minutes
- grant proposal, cooperative agreements
- electronic database records and training records

3.0 Evaluation of research documentation:
Using the *QA Audit Checklist*, the research records are evaluated to verify compliance with federal regulations, NDSU policy and adherence to the protocol approved by the IRB. The principal investigator is responsible for making all relevant records available for an evaluation:

- records of IRB approvals
- informed consent documentation and recruitment materials
- data records (hard-copy and electronic records)
- records of complaints, problems, or unanticipated events involving risk to participants or others

Investigators are encouraged to perform a self-assessment at any time, utilizing the *QA Audit Checklist*.

4.0 Investigator(s) or research team visit:
The audit visit may include a meeting with the principal investigator, and/or or members of the research team to discuss the research, preliminary evaluation results, or their use of any best practice methods that could be shared with the research community. In addition, feedback will be sought regarding the IRB review process, education/training program, as well as other aspects of the human research protection program at NDSU.

5.0 Summary and report:
The auditor completes the *QA Audit Checklist*; possible outcomes may include:

- conducted in compliance with federal regulations, IRB policies and approved protocol
- potential issue of minor noncompliance
- potential issue of serious or continuing noncompliance

The research records section of the QA Audit Checklist is distributed to the investigator, IRB chair and staff, and the relevant department Chair/Head or unit supervisor. The entire QA Audit Checklist is retained with the protocol file.

Periodic summaries of audit reports are presented at convened meetings of the IRB, and results utilized to improve the quality, efficiency and effectiveness of the human research protection program.

In the event a potential issue of minor or serious noncompliance or subject safety is identified, procedures as described in SOP *12.3 Complaints or Allegations of Noncompliance* will be followed.

**DEFINITIONS:**

Noncompliance: the failure of a person or an organization to act in accordance with the requirements of a law, regulation, policy, or the requirements and/or determinations of the IRB. Noncompliance may be intentional or unintentional, and may range from minor to serious or continuing.

Serious noncompliance: an act or omission that negatively impacts the rights or welfare of compromises the integrity or validity of the research or the human research protection program. Examples of serious noncompliance may include, but are not limited to: initiating or conducting nonexempt human subjects research without IRB approval; inappropriate use of the exempt or expedited review categories; failure to obtain legally effective informed consent from participants; failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or inappropriate oversight of the research to insure the safety of human subjects and the integrity of the research/data.

Continuing noncompliance: any noncompliance that occurs repeatedly after appropriate remedial education or corrective action. Examples of continuing noncompliance may include, but are not limited to: repeated failures to provide or review progress reports resulting in lapses of IRB approval, repeated failure to obtain prospective exempt determinations, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

Minor noncompliance: any noncompliance that is not serious or continuing. Examples of minor noncompliance may include, but are not limited to: lapses in continuing IRB approval, failure to obtain a prospective exempt determination from the IRB, minor changes in or deviations from an approved protocol, or administrative errors.

**REFERENCES:**
45CFR46.109(e) IRB Review of Research
21CFR56.109(f) IRB Review of Research
45CFR46.103(b)(4) Assuring compliance with this policy
21CFR56.108(a) IRB Functions and Operations
OHRP Guidance on Written Procedures, January 2007
OHRP FWA Assurance Training
Terms of the FederalWide Assurance #4, Written Procedures

**RELATED FORMS:**
Quality Assurance Audit checklist

**RELATED HRPP SECTIONS:**
12.2 Directed Audits of Research
12.3 Complaints or Allegations of Noncompliance
12.4 Reporting Noncompliance, Suspensions, Terminations, and Unanticipated Problems