NRG ONCOLOGY SITE VISIT AUDIT PROGRAM

Philadelphia, PA
July 14, 2017

Purpose

- Verify Reported Data and Protocol Compliance
- Ensure Adherence to Federal Regulations
- Educate

Requested Facilities

- **Wi-Fi access is needed for auditors to audit directly in Medidata RAVE.**
- **Access to a phone**
- **Adequate workspace – usually at least 2 auditors, more if high accrual.**

Electronic Records

- Please notify NRG in advance.
- Need 1 computer per auditor (site supplied) and an adequate work area.
- NRG prefers that all auditors be in one room if possible.
- Test run to make sure that all computers work and that auditors are able to access all needed systems and records.

Electronic Records cont.

- Have tech staff available to troubleshoot.
- Any records not available will need to be submitted to Lead Audit Office within 1 week.
- Allow extra time for orientating auditors to systems (a flow diagram of where to find records is helpful).
- Auditors may need more frequent assistance from staff until familiar with programs.

Time Frame

- Audit schedules are made 4 – 6 months in advance. The NCI is notified of planned audits at this time.
- Sites notified by emailed letter 2 - 4 months in advance.
- Announced cases emailed to site approximately 4 weeks prior to audit.
- At that time, specific IRB documents, consent form templates, and pharmacy materials will be requested for off-site NRG review prior to the audit.

Time Frame cont.

- Additional unannounced case(s) presented by auditors on the day of the audit. The full chart(s) will be reviewed.
- Preliminary findings are uploaded to the NCI within 1 working day.
- While it is expected that the research charts be complete, in the event of missing information, sites will be given 1 week to forward missing documentation to the Lead Audit Office.
- Final reports are prepared at NRG and sent to the NCI and the Contact Principal Investigator/Lead Research Associate within 10 weeks of audit.

Time Frame cont.

- CAPA due to NRG within 14 calendar days of report release. Specific due date will be listed in audit report.
- Specific CAPA format is listed in report – do not deviate.
- CAPA reviewed by NRG and then forwarded to the NCI.
- Letter accepting CAPA will be emailed to the site by NRG.
- Delinquent CAPA submission to NCI will result in suspension of accrual privileges.

Areas Reviewed By Auditors

IRB and Informed Consent Content

(reviewed prior to the audit at NRG HQ)

- **Annual Approvals – to cover current audit period and the last approval prior to this audit period**
- **Amendments/Revisions/Updates due for approval during current audit period**
- **Safety Updates required to be submitted to the IRB per local policy during audit period**
- **Current consent form templates**

Areas Reviewed by Auditors

Drug Accountability

(Paper review will be done off-site at NRG HQ)

Records will be reviewed for all investigational agents used on NRG or Legacy NRG protocols within the audit period as well as those used for other group protocol cases credited to NRG (additional materials may be requested to meet CTMB requirements).

- **Logs (Control and Satellite)**
- **Shipping Receipts**
- **Return forms**
- **Transfer forms**

Areas Reviewed by Auditors

Drug Accountability cont.

- Temperature monitoring
- Procedures to ensure current CTEP registration for prescribing PMB supplied agent
- Storage – On-site review at main facility
- Security – On-site review at main facility
- Cross-check of audited cases against the logs

Areas Reviewed By Auditors

Chart Review

- **Informed Consent – proper execution, patients re-consented for protocol amendments**
- **Eligibility – all criteria met and documented**
- **Treatment – chemo administration records, initiation/compliance with oral medications, required labs/tests reviewed prior to therapy, supportive therapy, dose modifications**

Areas Reviewed By Auditors

Chart Review cont.

- **Disease Outcome/Follow-up – protocol followed and data properly reported**
- **Toxicity – assessment and reporting per protocol**
- **General Data Quality - timely data/sample submission, minimal errors**

Case Selection is Based on Accrual

10% of the following (rounded up) for each CTEP ID*

- **NRG and legacy NSABP, RTOG, and GOG cases – treatment**
  (GY004 and GY005 audited 100%)
- **NRG and legacy NSABP, RTOG, and GOG cases - DCP**
- **Other group protocol cases credited to NRG - treatment**
- **Other group protocol cases credited to NRG – DCP**

***S1400, S1404, S1418, and B-55 are scheduled as separate audits and not included in the 10%. B-55 is audited 100%**

Examples of Major Deficiencies

IRB / Informed Consent Content

- Renewal delayed > 30 days for an open study or while patients remain on protocol therapy
- Amendment/Revision/Update approval > 90 days from site notification
- Safety updates submitted > 90 days from notification
- Expedited review when full board required
- Lack of IRB notification of local SAE (per policy)
- Major element missing from informed consent
- Consent questions altered, additional questions added, or not questions not answered

Examples of Non-Compliance

Drug Accountability

- **Incorrect type of logs (NCI Oral DARF required for oral agents, NCI log required for all other PMB supplied agents.)**
- **Incorrect or incomplete entries**
- **Errors not properly corrected**
- **Logs not kept in a timely manner**
- **Transfer of agent to another protocol without prior PMB approval**
- **Satellite and control logs not in agreement**

Examples of Non-Compliance

Drug Accountability cont.

- Satellite to satellite transfer
- Untimely returns/destruction (90 days)
- Use of commercial agent when drugs study supplied
- Patient specific logs not kept for double-blind studies
- Logs not Investigator specific
- Destruction of medication that is to be returned
- Errors noted during cross-check

Examples of Major Deficiencies

Chart Review

- Consent not properly executed (signatures, translation, short form, specimen/contact questions, re-consent)
- HIPAA authorization not obtained prior to entry (US patients only)
- Inclusion/exclusion criteria not met
- Pre-therapy evaluations not done or not reviewed prior to therapy
- Supportive therapy not given per protocol
- Dose modifications not made per protocol

Examples of Major Deficiencies

Chart Review cont.

- Incorrect dose calculation (GOG carbo calculator where required)
- Poor documentation of oral agents
- Endpoints not assessed, not reported, or not reported correctly
- Unreported non-protocol therapy
- Unreported grade 3 or 4 adverse events
- General lack of documentation

Overall Assessment
(Each category will be rated)

- Acceptable
- Acceptable, Needs Follow-Up*
- Unacceptable**

* May Require Re-Audit

** Will require Re-Audit

Best Advice for Successful Audit

- Be prepared
- Be organized
- Be available to the auditors
- Know the protocols
- Conduct self-audits
- Make sure everything reported is documented
- Make sure you have reported everything you should on the proper forms and in a timely manner
- Ask for help if you aren’t sure of requirements

Relax!