## COE-102.00

## Attachment 2 – Employee Guidelines during the Audit Process

**Do:**

1. Become familiar with the process and purpose of the audit.
2. Ensure your training records are current and complete.
3. Make yourself, or a qualified designate, readily available upon the request of the auditor.
4. Remain available during the entire time of the visit in case additional questions or information is needed.
5. Be cooperative and polite; make precise, concise and honest statements. Be sure that you understand the question posed by the auditor prior to replying; ask for clarification if needed.
6. Be cooperative but do not volunteer information.
7. Discuss only those items or trials identified on the audit agenda.
8. Allow the auditor time to take notes during conversation.
9. Answer only the question asked and only questions relevant to your Job Description/study involvement. If you do not know the answer, say so and defer to another employee, if applicable, or provide an answer at a later time during the audit.
10. Be professional at all times (i.e. NO chewing gum, NO inappropriate conversation, NO interrupting or arguing with the inspector). Assure that appearance is clean and professional at all times.
11. Keep confidential information filed away and office areas neat.
12. Provide documentation as requested by the auditor to the audit lead or designate in a timely manner.
13. For Regulatory Agency audits, interview or meet with the auditor only if the audit lead or designate is present.
14. Answer all questions truthfully to the best of your ability.

**Do not:**

1. Do not keep the auditor waiting.
2. Do not provide confidential records (i.e. Personnel, salary records).
3. Do not interrupt the auditor when they are talking or asking a question.
4. Do not be defensive, do not withhold information, do not argue or complain about any involved party (e.g., Sponsor/IRB).
5. Do not use your personal cell phone during interactions with the auditor, they should be muted or placed on vibration mode.
6. Do not provide any gifts to the auditors; as such action may be interpreted as coercive. Do not offer refreshments or lunch.
7. Do not provide documentation directly to the auditor(s) without prior permission from the audit lead or designate.