

CONFIDENTIALITY AGREEMENT FOR RESEARCH MONITORS/AUDITORS

Research Study Sponsor: _____

Study Title: _____ (the “Study”)

Duke University (“Duke”), a nonprofit research, educational and healthcare institution having its principal place of business in Durham, North Carolina, has legal and ethical responsibilities to safeguard the privacy of its employees, students, and patients and their families and to protect the confidentiality of protected health information and all other types of confidential information (collectively, “Confidential Information”). You are expected to uphold these legal and ethical responsibilities as a condition of being allowed access to Duke’s medical records. These obligations apply to information that is collected or maintained verbally, in paper, or electronic format during your monitoring/audit of this study.

You are being given access to Duke medical records and the highly confidential and sensitive information contained therein solely for the purpose of confirming the accuracy of data submitted to the Study sponsor and the proper conduct of the Study (the “Purpose”). As a condition of and in consideration of your being granted this access, you agree as follows:

1. You shall hold in strict confidence all Confidential Information, including but not limited to Protected Health Information (PHI) as defined in the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”).
2. You shall not make electronic or paper copies or remove any Confidential Information from Duke premises or Duke electronic systems.
3. You will access, use, and disclose Confidential Information only as authorized and needed to accomplish the Purpose.
4. You will take reasonable and appropriate measures to safeguard the privacy and security of any Confidential Information that you access, use, or disclose in the conduct of your visit.
5. You will immediately notify representatives of Duke if you have reason to believe that the privacy or security of any Confidential Information has been compromised.
6. If you are granted access to Duke electronic systems in order to access medical records:
 - a. You will safeguard and not disclose your individual user identification and/or password codes to anyone;
 - b. You accept responsibility for all activities undertaken using your passwords, access code and other authorizations;
 - c. It is your responsibility to log out of any system to which you have logged on. You will not under any circumstances leave unattended a computer to which you have logged on without first either locking it or logging off the workstation.
7. You understand that Duke has the right to conduct and maintain an audit trail of all accesses to its electronic systems, including its medical records, and that Duke may conduct a review to monitor appropriate use of system activity at any time and without notice.

IN WITNESS WHEREOF, I agree to the terms and conditions of this Agreement.

Signature of Monitor/Auditor: _____

Name of Monitor/Auditor: _____

Company: _____

Date: _____

Name of Duke Employee providing access: _____

Monitor identity confirmed? _____ (yes/no)