



## **Position Statement: Part 11 Compliant Regulatory System for Clinical Trials at the University of North Carolina at Chapel Hill**

### **Overview**

At the University of North Carolina at Chapel Hill (UNC-Chapel Hill), we are committed to upholding the highest standards of regulatory compliance and data integrity in all aspects of clinical trial conduct. As part of our rigorous approach to clinical trial management, we utilize Veeva SiteVault, a *21 CFR Part 11* compliant regulatory system, to ensure that our processes, documentation, and data management practices align with the requirements set forth by the U.S. Food and Drug Administration (FDA) for electronic records and electronic signatures.

### **Commitment to Compliance**

Our institution's clinical trial infrastructure is fully aligned with *21 CFR Part 11* to support the secure and compliant electronic capture, storage, and submission of clinical trial documents. This includes the implementation of systems that ensure:

- **Document Integrity:** All electronic records are maintained in a way that ensures authenticity, accuracy, and reliability, safeguarding the integrity of the documents throughout the trial lifecycle.
- **Electronic Signatures:** Our system supports the use of secure, FDA-compliant electronic signatures that are equivalent to handwritten signatures, ensuring accountability and traceability of actions taken throughout the trial process.
- **Audit Trails:** We maintain detailed, time-stamped audit trails that track all changes made to electronic records. These audit trails are fully accessible for review, providing full transparency and accountability for all users involved in the clinical trial.
- **Access Controls:** Robust access control mechanisms are in place to ensure that only authorized personnel can access or modify electronic records, safeguarding confidential information and ensuring compliance with privacy regulations.
- **System Validation:** All electronic systems and software used in the management of clinical trials undergo rigorous validation to ensure they meet Part 11 requirements, ensuring compliance with regulatory standards and the highest data security practices.

### **Why This Matters to Our Sponsors**

By using Veeva SiteVault, UNC-Chapel Hill assures sponsors that their clinical trial information will be captured, managed, and maintained in full compliance with FDA regulations. This reduces the risk of non-compliance and ensures that the clinical trial documents are admissible for regulatory submission and review.

Our adherence to *21 CFR Part 11* also streamlines the trial process, enabling more efficient and secure handling of electronic records and reducing the administrative burden of paper-based



documentation. This results in a smoother, more reliable trial process, benefiting our sponsors by ensuring that their studies are completed with both efficiency and regulatory integrity.

### **Conclusion**

At UNC-Chapel Hill, we prioritize the integrity, accuracy, and security of clinical trial data. Our Part 11 compliant regulatory system ensures full compliance with FDA requirements while promoting operational efficiency and transparency. This ultimately supports the successful execution of clinical trials and the advancement of medical research.

For additional information or to discuss specific compliance requirements, please contact Valorie Buchholz, Senior Director Clinical Research Compliance at [buchholz@unc.edu](mailto:buchholz@unc.edu).

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