

Research NEWS

 Washington University in St. Louis

Subject: WUSM FDA Part 11 Certification for Research Subject to FDA Regulations

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Message :

WUSM FDA Part 11 Certification

Washington University School of Medicine has submitted our certification letter to the FDA indicating that the Washington University owned clinical applications are FDA Part 11 Compliant. A copy of the letter submitted is attached. **Please note that this certification does not cover any of the systems owned by BJC or its entities (for example, ClinDesk), which will need to be certified separately by BJC.**

We can now respond that Washington University owned clinical systems are FDA Part 11 Compliant. We have documentation of the review for **Allscripts, Cederon Connect, MARS, WUMED and the Pediatric database** specifically. Any other or new Washington University owned systems should be reviewed for FDA Part 11 compliance. Please do not make this assertion about any hospital owned applications such as ClinDesk.

If you have a question about a particular system and whether it meets FDA Part 11 requirements, please contact the medical school central IT services helpdesk at 314-362-7798. Thank you.

Attachments and other information related to this message can be found at:
<http://intramed.wustl.edu/r.nsf/0/958A6A9E3A6A3091862577EE0072C0E7>

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