UNIVERSITY OF ALBERTA

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RE: Alberta Research Information SErvices (ARISE) Digital Signature Security and Validation

To Whom It May Concern:

The University of Alberta maintains an online ethics process management system with the Alberta Research Information Services (ARISE). The ARISE system, provides a module for online ethics application, review, approval and post-approval activiites. Similar systems are in place in a large number of university and health institutions in the United States, as well as in Canada at the University of British Columbia, the University of Calgary and the Ontario Institute for Cancer Research.

ARISE is compliant with US FDA 21 CFR Part 11 – Electronic Records. User entered usernames and passwords are sent to a campus-wide LDAP server for authentication over https. When user roles are assigned with ARISE, each role is evaluated based on the user's valid relationships with the University which are provided by an Identity-Management System. ARISE uses a digital signature which means that the name of the signer is the name of the person who exectuted a particular action in ARISE. This is always printed in the History Log and, in the case of correspondence, in the letters themselves. The date and time when the signature was executed equals the data and time when the corresponding activity was executed, and the date and time are always indicated in the History Log. Finally, the ARISE system uses Secured Sockets Layer for communication over network with appropriate SOPs for controlling physical access to the servers.

The system's signature security has been validated by the University of Alberta. Validation documentation is available upon request.

If you have any questions or require evidence of validation, please contact the Research Ethics Office at 780.492.0459 or by email at reoffice@ualberta.ca.

Sincerely,

Susan Babcock, MBA
Director
Research Ethics Office