Policy for Aperio CS2 Digital Slide Scanning and Access of the eSlide Manager

PRINCIPLE

Digital Pathology is an image-based information environment which is enabled by computer technology that allows for the management of information generated from a digital slide. Digital pathology is enabled in part by virtual microscopy, which is the practice of converting glass slides into digital slides that can be viewed, managed, and analyzed on a computer monitor.

The Aperio Digital Imaging System consists of:

- Aperio CS2 Scanner: Automated whole-slide image scanner and controller computer, able to create high-quality digital slides.
- eSlide Manager Server and Software: Digital pathology information management system that stores high-resolution digital slides, which can be viewed, managed, and analyzed, as an integrated element in pathology workflow. eSlide Manager displays information in context, high quality microscopic digital images and other associated documents. The software facilitates instant archival and intelligent retrieval of histological-pathological data in a searchable, context-sensitive manner. Configurations for clinical, research and educational use are available.

USER ROLES DEFINATION AND PERMISSIONS

1. **Operator:** This role defines users performing work based on scientific research. Users defined in this manner should not have access to view protected health information.

   Operator Permissions:

   - Add, delete, assign, export and clone cases
   - Generate, view and sign case reports
   - Share cases on eSlideShare
   - Add, delete, assign, export and clone projects
   - Add, generate, delete, view, sign, assign, export and clone project reports
   - Share project reports on eSlideShare
   - Add, delete, assign, export and clone lessons
   - Add, assign, export, clone and delete specimens

- Add, assign, export, clone and delete eSlides
- Add, delete, assign, export, clone, analyze, move and copy image
- Import and delete image annotations
- View images label and macro images
- Add, delete, assign, export and clone attachments
- Add, edit and delete stains
- Add, edit and delete body sites

2. **System Administrator:** This role is responsible for the various administrative functions of the eslide Manager digital pathology information management system.

System Administrator Permissions:

Besides the operator permissions, system administrator has the following administrative permissions:

- Add, edit system settings
- Cancel analysis jobs
- Add, edit data tables
- Add, edit and delete data groups
- Add, edit and delete roles
- Add, edit and deactivate users
- Add, edit and delete user groups
- Add, edit and delete stains
- Add, edit and delete body sites
- Add, edit and delete analysis macros
- Add, edit and delete slide specific processing
- Add, edit and delete reports
- Add, edit and delete comments
- View calibration results
- Add, edit license administration
- Log in ScanScope
- Add, edit search settings

In addition, system administrators are responsible for ensuring that security measures are in place.

PHYSICAL SECURITY:

Hardware access: Only authorized individuals have physical access to the Aperio digital imaging system and server at any time.

SOFTWARE SECURITY:

User password creation:

- User passwords require more than 8 characters.
- Special non-alphanumeric character !, @, #, $, %, ^, &, *, (,), _, + must be included in the password(at least one).
- User Account will be locked out after 5 times attempts.
- Previous 3 passwords can't be used when change user password.

USERS ACCOUNT REMOVAL/DEACTIVATION

Users account will be removed/deactivated under the following circumstances**:**

- Users no longer employed or associated with the institution will be removed from the system.
- As required by principle investigator listed in the **"**Aperio User Account Request Form". Refer to the Appendix Form-1.
- Other situations as discussed and determined by Translational Research/Pathology Shared Resource Core Facility.
- Both PI and the user will be informed of the users account removal/deactivation.

INITIALIZATION

New users who request for access to the eSlide Manager application must

- Complete the "Aperio User Account Request Form" with PI's approval signature
- Forms are to be submitted to Translational Research/Pathology Shared Resource Core Facility for approval.

TRAINING:

New users must first receive formal training and be signed-off before access can be granted.

ACCESS:

- Once the training is completed, user's account will be created in the system by a system administrator and a generic password will be generated and provided to the user, which must be changed the first time the user logs in to the application.

- Users should not share their login information with others.

SLIDE SCANNING

Slide scanning is to be performed by trained and authorized personnel of the core facility only.

- Requestor must complete and submit "Aperio CS2 Digital Image Scanning Sample Information Collection Form" in electronic format to Translational Research/ Pathology Shared Resource Core Facility. Refer to Appendix Form-2.
- Requestor also need submit a "Histology/Immunohistochemistry Request" through "Shared Resource Reservation/On-Line Ordering Systems"
- Requestor must deliver slides that will be scanned together with forms mentioned above to Translational Research/ Pathology Shared Resource Core Facility.

DATA RETENTION

- Digital slides scanned into eSlide Manager will be hosted on the server for a period not exceeding 180 days (6 months) unless formally approved by the Translational Research/ Pathology Shared Resource Core Facility.
- Slides remaining on the server past the aforementioned threshold will be permanently deleted from the system.
- If users wish to keep their digital slides, a request can be submitted to the system administrator for transferring them to a peripheral storage device (i.e., USB stick, external hard disk drive) or alternate location (if applicable). Users are responsible for providing an appropriate storage device at cost to the requestor.

CHANGE CONTROL

Any changes to the system(s) by a system administrator should be adequately documented to ensure adequate change control and auditability. Changes must be approved by the Translational Research/ Pathology Shared Resource Core Facility director.

SYSTEM DOWNTIME

In the event that either the Aperio digital imaging system or eSlide manager is down and non-operational, a system administrator will contact Aperio Technical Support:

Technical Support:

Tel: (866) 478-3999

Email: support@aperio.com

Remote Desktop Support: https://aperio.webex.com/

Direct Contacts:

1. Jesse Currier

    Technical Support Engineer, Pathology Imaging, Leica Biosystems

    1360 Park Center Drive, Vista, CA 92081

    Tel: (760) 304-

    Email: Jesse.Currier@Leica-Biosystems.com

2. Michael Reagin

    Senior Application Specialist, Pathology Imaging, Leica Biosystems

    1360 Park Center Drive, Vista, CA 92069, USA

    Tel: 760.207.

    Email: michael.reagin@Leica-Biosystems.com