ALBERTA CLINICAL RESEARCH CONSORTIUM
Managed by Alberta Innovates

**Tool Time**

# Validation of Computerized Systems – Guidance Document

***Clinical Research Stage:***

*Concept*

***Development***

*Feasibility*

*Project In Setup*

*Active Study*

*Close-out*

***ACRC Partner Organizations***

*Alberta Health Services*

*Alberta Innovates*

*Alberta SPOR Support Unit*

*College of Physicians & Surgeons*

*Covenant Health*

*University of Alberta*

*University of Calgary*

The ACRC is committed to quality and continuous enhancement. We welcome your input! Forward comments, suggestions and any feedback from Health Canada inspections to: acrc@albertainnovates.ca

Any electronic system used to capture, process, manage and/or archive clinical health research information should be adequately validated, and evidence of validation should be readily available to Health Canada`s Inspectors. (Health Canada – Annex 11)

Computer system validation and related components is based on compliance requirements referenced in Health Canada Tri-Agency Statement of Principles on Digital Data Management and the US Code of Federal Regulations 21CFR11. Any organization that has customers in the European Union (EU), operates in the EU, or collects, uses or discloses personal information of EU data subjects should also ensure the system meets General Data Protection Regulation (GDPR) requirements.

Computer System Validation (CSV) is a process of establishing and documenting that the specified requirements of a computerized system can be consistently fulfilled from design until decommissioning of the system, or transition to a new system. The approach to validation should be based on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human subject protection and reliability of trial results. (ICH GCP R2 1.65)

The Alberta Clinical Research Consortium (ACRC) has developed a ***sample* System Validation Package** that was specifically developed for the EDGE research management system. This can be used as a guide for groups looking at validating a system that contains clinical data. The level of risk should be determined for the specific system, and validation be performed with the rigor appropriate to the type of data contained and in compliance with the regulations. System validation is not required for systems that are *only* collecting administrative data (CRF Part 11).

Sponsors are ultimately responsible for all aspects of the clinical trials they initiate in Canada, including any electronic systems used to manage patient information for those trials. A CSV must be done if required by the sponsor. Sponsors may have their own system and documentation for this process, however, if they do not and you are required to do a CSV, you may use this package to work through the process.

Any use of an electronic system such as a database or electronic regulatory binder must be fully validated and supported by documented procedures and appropriate training for staff. If there is revision/customization of the computer system at the site level, then the site additionally is to perform a CSV. Specifically, sites are responsible for understanding the regulations that apply to their study have basic computer security SOPs and develop a risk-based validation master plan (VMP).

The proper controls should be in place to assure that only the appropriate person is using the system, that data is secure, and that patient confidentiality is protected. Limited access and/or passwords should be used appropriately. Logins and passwords

**Relevant Regulations**

Health Canada - Annex 11
International Council on Harmonisation - GCP R2
FDA 21 eCFR Part 11
General Data Protection Regulation (GDPR)

ICH GMP Q7



should never be saved for automatic login, and each time leaving the program users should logout of the system rather than simply close the program. Furthermore, the data should be backed-up at regular intervals. The back-up data should be stored as long as necessary in a separate and secure location. (ICH GCP E6 5.5.3) Any interface with other systems or devices must also be validated and a determination made that the interface is operating as expected in normal conditions as well as anticipated abnormal conditions.

There are three steps involved in the system validation process. 1. Administering a risk assessment; 2. Working through the steps of a validation worksheet; and, 3. Developing a VMP.

The ACRC has developed a package (documents listed below) that helps navigate the process of validating your computerized system:

**Sample Risk Assessment Worksheet**

The CSV utilizes the GAMP 5 (Good Automated Manufacturing Practice) standard for validation of automated systems. GAMP has become the acknowledged expert body for addressing issues of computer validation (as developed in partnership with the International Society for Pharmaceutical Engineering (ISPE). GAMP provides a documented assurance that a system is appropriate for the intended use before it goes "live." The validation worksheet, through a systematic series of questions, will help determine level of risk. Once level of risk is determined, either a full or reduced validation may be required.

**Sample Validation Worksheet**

The Validation Worksheet will help you walk through the process of writing and executing your validation plan. The worksheet provides requirements, specifications and sample test cases to give you the necessary steps on how to perform a system validation for your site. Note: The level of validation required will be determined by the Risk Assessment Worksheet. If a full validation is required a VMP should be developed.

**Sample Validation Master Plan**

System validation may be site specific and a VMP should be developed to the level of the risk determined by the risk assessment. The VMP should include objectives and scope, nature of and time at which validation activities should be performed, personnel delegated for the conduct of the validation, security measures, and main features of the system. If a reduced validation is required, an integrated document may be developed rather than developing a VMP with several supporting documents. We have provided a sample VMP to help you develop one for a system used at your site.

**Integrated Validation Document (Reduced Validation)**

When you perform the risk assessment and it is indicated that you may do a reduced validation, you can develop an *Integrated Validation Document*. We have not developed one for the purpose of EDGE. An integrated validation or reduced validation will combine the main features expected in a computer system validation.