Information about electronic Records Management System

Version I – Date: 2022,08,25

Region Nordjylland

System Name:	Version Number: Release Date:		
Questions	**Yes**	**No**	Detailed clarification: **If yes**, please specify *how* the question is fulfilled **If no**, please specify reason for this / alternatives
A. Computerised System			
1. Are there some data transferred from one electronic system to another electronic system?	X		
2. Did the site test the software before it was applied to manage patient data?	X		
3. Were the test results documented?	X		
4. Does the site have written policy on: a. System validation b. Problems management (i.e. system failure...) c. System use	X		
5. Does the system have a virus scanning program?	X		Servers and PC's have virus scanning programs
6. If the network is connected to the internet, is there any firewall?	X		

B. Access			
1. Do the users receive training for operations they have to do in the system?	x		
2. Are there any ID and passwords for users to access the system?	x		
3. Is each user provided with his/her own password (not shared password)?	x		
4. Are the users required to change the password periodically?	x		
5. Is there an automatic log-off after a period of inactivity?	x		
6. Is the name of the person who recorded clinical observations displayed?	x		
7. Is it possible to edit the list of users who were authorized to make data changes during the study?		x	Full traceability available
8. Are monitors, auditors, inspectors provided with read-only access, limited to specific patients participating in a specific ongoing clinical trial? a. If so, how does the individual gain access? b. how is limited access tracked?	X		

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C. Audit trails			
1. Can the system capture and display all time sequenced data such as:			
a. All changes?	X		
b. All deletions?	X		
c. Who changed?	X		
d. When changed (time and date)?	X		
e. Why changed?		X	
2. Does the system have function of clock protection?	X		
3. Is the audit trail protected from modifications and from being inactivated?	X		
4. Do monitors, auditors, inspectors have access to audit trail?	X		On request as printout or pdf.

D. System maintenance			
1. Is there routine data backup?	X		
2. Has the back-up process been tested and verified by vendor or site so the integrity of the back-up can be assured?	X		
3. Are backup stored in a secured location (e.g. different from source data location...)?	X		
4. Does the site have written policy for restoring data from damaged files?	X		

E. Archiving			
1. Does the site ensure that reasonable and useful access to electronic records (including audit trail) is possible during 15 years after end of trial? (After implementation of Clinical Trials Regulation, EU No 536/2014, 25 years will apply)		X	The Region has never deleted electronic records and have no such plans. In the case of changing HER system, all data will be stored if not migrated into the new system. How to access non-migrated data is not yet defined
2. Does the system allow generating electronic copies of electronic records?	X		It is possible to print the record as pdf
3. Does the system allow generating paper copies of electronic records?	X		It is possible to print the record as pdf
4. In case of update or change of system, does the site ensure that all electronic data will be maintained in new system?		X	Access to old data will be maintained

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Electronic Records Management Systems in the Danish public healthcare sector are regulated by Danish law e.g. "Lov om krav til sikkerhed for net- og informationssystemer inden for sundhedssektoren", Law No. 440, May 8 2018.

The electronic Records Management System described in this document is in accordance with The General Data Protection Regulation (GDPR) (EU) 2016/679.

Update of this his document is required if the electronic Records Management System described in this document is changed. Verification of answers in this document is required every second year.

Name and title: LARS LILHOLT, VICEKONTORCHE

Signature: _____

Date: 25/8-22