Information about electronic Records Management System

Version I – Date: 20,04,27

Region Sjælland

System Name: Sundhedsplatformen	Version Number: Epic aug2019 Release Date: 2019.12.10		
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		Integration between several systems.
2. Did the site test the software before it was applied to manage patient data?	X		ITIL change management processes.
3. Were the test results documented?	X		In the test system.
4. Does the site have written policy on: a. System validation b. Problems management (i.e. system failure...) c. System use	X		ITIL processes.
5. Does the system have a virus scanning program?	X		
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		All users are certified.
2. Are there any ID and passwords for users to access the system?	X		All users have unique ID and password.
3. Is each user provided with his/her own password (not shared password)?	X		All users have unique ID and passwords.
4. Are the users required to change the password periodically?	X		Policy based and controlled.
5. Is there an automatic log-off after a period of inactivity?	X		Policy based and controlled.
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		
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		Read only access is gained on request and only to the specified clinical trial via user management.

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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		Policy based and controlled.
4. Do monitors, auditors, inspectors have access to audit trail?		X	Printout can be provided on request.

D. System maintenance			
1. Is there routine data backup?	X		Standard operating procedure.
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		Standard operating procedure.
3. Are backup stored in a secured location (e.g. different from source data location...)?	X		Logical and physical separation.
4. Does the site have written policy for restoring data from damaged files?	X		Standard operating procedure.

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		Follows Clinical Trials Regulation, EU no 536/2014.
2. Does the system allow generating electronic copies of electronic records?	X		
3. Does the system allow generating paper copies of electronic records?	X		
4. In case of update or change of system, does the site ensure that all electronic data will be maintained in new system?	X		

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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.

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Signature: _____

Date: 29/10. 2020