

NeuroNEXT Network

Standard Operating Procedure (SOP) System Setup/Installation Version 4.0 SOP NN CS 701

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: <i>Christopher S. Coffey</i> <small>Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Feb 23, 2024 13:31 CST</small>	23-Feb-2024
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)	
Signature and Date: <i>Merit Cudkowicz</i> <small>Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 17:14 CST</small>	22-Feb-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)	
Signature and Date: <i>Marianne Chase</i> <small>Electronically signed by: Marianne Chase Reason: I approve this document Date: Feb 22, 2024 14:41 EST</small>	22-Feb-2024
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)	


NN CS 701

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
SYSTEM SETUP/INSTALLATION

SOP: CS 701 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SYSTEM SETUP/INSTALLATION	Supersedes Document Version : 3.0 Effective Date : 08Apr2023
---	------------------------------	---

Signature and Date:
Dixie Ecklund Electronically signed by: Dixie Ecklund
Reason: I approve this document
Date: Feb 29, 2024 16:07 CST
29-Feb-2024

Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)

Signature and Date:
 Electronically signed by: Stacey Grabert
Reason: I approve this document
Date: Feb 22, 2024 15:16 EST
22-Feb-2024

Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)

Signature and Date:
Joan Ohayon Electronically signed by: Joan Ohayon
Reason: I approve this document
Date: Mar 4, 2024 13:17 EST
04-Mar-2024

Name and Title: Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)

NN CS 701

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SYSTEM SETUP/INSTALLATION

SOP: CS 701 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SYSTEM SETUP/INSTALLATION	Supersedes Document Version : 3.0 Effective Date : 08Apr2023
---	--------------------------------------	---

1. POLICY

The purpose of this SOP is to provide guidelines to the NeuroNEXT Data Coordinating Center (DCC) Information Technology (IT) Team and The University of Iowa College of Public Health Office of Information Technology (UI CPH IT) regarding procedures and security measures related to the setup and installation of new computer systems (e.g., servers, workstations, laptops) for the NeuroNEXT Network.

The DCC and/or UI CPH IT only purchase computer systems from vendors approved by The University of Iowa purchasing department. Computerized systems must have a minimum of a three-year on-site maintenance agreement that covers hardware and online downloads, and includes driver support.

Initial setup procedures (e.g. installing firewalls and anti-virus software, managing system services) are performed offline in order to decrease the exposure of new systems to malicious attacks.

Software is installed based on system projected usage and user needs. All software must be approved and installed by UI CPH IT and/or DCC IT to ensure that licensing requirements are met and to decrease the exposure of systems to outside malicious attacks. Software is updated with the latest service packs and patches as they become available.

2. SCOPE

This SOP has been developed to be in alignment with federal regulations and Good Clinical Practices (GCP) as set forth in the 2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). The policies and procedures described in this SOP apply to the NeuroNEXT Clinical Coordinating Center (CCC) and DCC within the context of their oversight and advisory roles for the NeuroNEXT Network, and to all NeuroNEXT investigators, staff, subcontractors, or other entities associated with the NeuroNEXT Network who manage, oversee, and conduct research regulated by FDA and/or applicable review committees. This SOP is also in alignment with Information Technology policies set forth by Information Technology Services at The University of Iowa and UI CPH IT.

3. ROLES AND RESPONSIBILITIES

The University of Iowa DCC IT Team and UI CPH IT are responsible for adhering to the procedures outlined in this SOP, and for ensuring that any DCC or UI CPH IT personnel who perform system setup or installation of DCC computerized systems or servers for NeuroNEXT studies are in compliance with this SOP.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR Part 11	Electronic Records; Electronic Signatures
FDA	Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application (August 2003)
FDA	Guidance for Industry: General Principles of Software Validation; Final Guidance for Industry and FDA Staff (January 2002)
NIH	HIPAA Privacy Rule: Information for Researchers
University of Iowa	IT Security Best Practices, Information Security and Policy Office

NN CS 701

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SYSTEM SETUP/INSTALLATION

SOP: CS 701 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SYSTEM SETUP/INSTALLATION	Supersedes Document Version : 3.0 Effective Date : 08Apr2023
---	--------------------------------------	---

5. REFERENCES TO OTHER APPLICABLE SOPS

NN CS 704 System Security Measures and Website
Access NN CS 705 Data Backup, Recovery, and
Contingency Plans

6. ATTACHMENTS AND REFERENCES

NN CS 701 – A Document History

National Institute of Standards and Technology (NIST) Guides:

NIST Guide to Secure Web Services, Special Publication 800-95

(August 2007) NIST Guide to SSL VPNs, Special Publication 800-
113 (July 2008)

NIST Guidelines on Securing Public Web Servers, Special Publication 800-44
(Version 2) (September 2007)

NIST Technical Guide to Information Security Testing and Assessment, Special Publication 800-115
(September 2008)

NIST Information Security Handbook: A Guide for Managers, Special Publication
800-100 (October 2006)

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC Clinical Coordinating Center at Massachusetts General Hospital

CPH IT Information Technology at the University of Iowa College of

Public Health DCC Data Coordinating Center at The University of Iowa

DCC IT Information Technology Team at

the DCC GCP Good Clinical Practice

8. SPECIFIC PROCEDURES

A. University Licensing Agreement

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC IT	Comply with all software licensing agreements.		

NN CS 701

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SYSTEM SETUP/INSTALLATION

SOP: CS 701 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SYSTEM SETUP/INSTALLATION	Supersedes Document Version : 3.0 Effective Date : 08Apr2023
---	--------------------------------------	---

B. Initial Set-Up

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC IT or UI CPH IT	Repartition, format, and install new Microsoft operating system software obtained from the University of Iowa Information Technology Services or UI CPH IT Services on all computer systems (e.g., servers, workstations, laptops).		
2.	DCC IT or UI CPH IT	Assign a strong administrative password to each new computer system.		NN CS 704
3.	DCC IT or UI CPH IT	Name and register the computer system with the IT Security Office, according to UI CPH IT and DCC standards.		
4.	DCC IT or UI CPH IT	If needed, obtain a unique IP number for each computer system from The University of Iowa Information Technology Services.		
5.	DCC IT or UI CPH IT	If applicable, remove or disable all unnecessary services from computer systems.		

C. Security/Anti-Virus Software

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC IT or UI CPH IT	Install anti-virus software onto applicable computer systems.		NN CS 704
2.	DCC IT or UI CPH IT	If applicable, and prior to connecting to the Internet, set Firewall by setting local security policy (IP Sec), and restricting IP and port access.		
3.	DCC IT or UI CPH IT	Prior to connecting to the Internet, review system services and enable or disable services required for restricted operation.		
4.	DCC IT or UI CPH IT	Establish connection to the Internet, and update anti-virus software to latest definitions.		
5.	DCC IT or UI CPH IT	Update Windows operating system to install the latest security patches.		
6.	DCC IT or UI CPH IT	After any updates to servers, update server log in server binder.		

NN CS 701

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SYSTEM SETUP/INSTALLATION

SOP: CS 701 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SYSTEM SETUP/INSTALLATION	Supersedes Document Version : 3.0 Effective Date : 08Apr2023
---	--------------------------------------	---

D. Sever Software Installation

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC IT or UI CPH IT	Install anti-virus software onto applicable computer systems.		NN CS 704
2.	DCC IT or UI CPH IT	If applicable, and prior to connecting to the Internet, set Firewall by setting local security policy (IP Sec), and restricting IP and port access.		
3.	DCC IT or UI CPH IT	Prior to connecting to the Internet, review system services and enable or disable services required for restricted operation.		
4.	DCC IT or UI CPH IT	Establish connection to the Internet, and update anti-virus software to latest definitions.		
5.	DCC IT or UI CPH IT	Update Windows operating system to install the latest security patches.		
6.	DCC IT or UI CPH IT	After any updates to servers, update server log in server binder.		

E. Server Access Restrictions

#	Who	Task	Attachment/ Reference	Related SOP
1.	UI CPH IT	Limit physical access to servers to authorized staff.		NN CS 704
2.	DCC IT and/or UI CPH IT	Establish server user accounts and roles for usage rights.		
3.	DCC IT and/or UI CPH IT	Limit server drive access rights to appropriate users.		

NN CS 701

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SYSTEM SETUP/INSTALLATION

SOP: CS 701 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SYSTEM SETUP/INSTALLATION	Supersedes Document Version : 3.0 Effective Date : 08Apr2023
---	--------------------------------------	---

F. Workstation Software Installation

#	Who	Task	Attachment	Related SOP
1.	DCC IT or UI CPH IT	Install software based on user needs.		NN CS 704
2.	DCC IT or UI CPH IT	Install software that has been approved by UI CPH IT or DCC IT to ensure that licensing requirements are met and to decrease the exposure of systems to outside malicious attacks.		
3.	DCC IT or UI CPH IT	Run a program to confirm that new installations of, or updates to, SAS® software have been performed correctly, and document the results.		
4.	UI CPH IT	Per UI CPH IT guidelines, track the programs that are installed on computer workstations.		
5.	DCC IT or UI CPH IT	Enable Remote Desktop Connection permissions only for DCC users and/or system administrators.		NN CS 704

NN CS 701

**NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
SYSTEM SETUP/INSTALLATION**

SOP: CS 701 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SYSTEM SETUP/INSTALLATION	Supersedes Document Version : 3.0 Effective Date : 08Apr2023
---	--------------------------------------	---

Attachment NN CS 701 – A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Regulatory Authority Submission and FDA Contact SOP NN CS 701					
Version	Description of Modification	Reason or Justification for Modification	Issue Date	Effective Date	Reviewer(s)
1.0	New	N/A	30Mar2012	29Apr2012	N/A
2.0	Modified to reflect the increased involvement of The University of Iowa College of Public Health Office of Information Technology (UI CPH IT) in the installation and setup of computerized systems at the DCC. Added a provision for a quarterly confirmation that software programs and updates have been properly installed. Added a new section for workstation software installation. Additional minor updates throughout.	Transition of certain responsibilities to UI CPH IT, and updates for version 2.0.	21Sep2016	21Oct2016	N/A
3.0	Updated "1996 ICH E6 Consolidated Guidance" to "2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)". Updated signature block to accommodate for electronic signatures. Additional minor updates throughout.	Updates for version 3.0	22Feb2023	08Apr2023	N/A
4.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	N/A









NN CS 701 System Setup-Installation v4.0 clean


Final Audit Report

2024-03-04

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAATs74sZDm8E3Ct5V5LIUNisOJim8zWOKx
Number of Documents:	1
Document page count:	8
Number of supporting files:	0
Supporting files page count:	0

"NN CS 701 System Setup-Installation v4.0 clean" History

-  Document created by Tania Leeder (tleeder@mgb.org)
2024-02-22 - 7:16:51 PM GMT
-  Document emailed to christopher-coffey@uiowa.edu for signature
2024-02-22 - 7:19:19 PM GMT
-  Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
2024-02-22 - 7:19:19 PM GMT
-  Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature
2024-02-22 - 7:19:19 PM GMT
-  Document emailed to dixie-ecklund@uiowa.edu for signature
2024-02-22 - 7:19:19 PM GMT
-  Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
2024-02-22 - 7:19:19 PM GMT
-  Document emailed to ohayonj@ninds.nih.gov for signature
2024-02-22 - 7:19:19 PM GMT
-  Marianne Chase (mchase@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-02-22 - 7:41:05 PM GMT

 Document e-signed by Marianne Chase (mchase@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 7:41:21 PM GMT - Time Source: server

 Email viewed by christopher-coffey@uiowa.edu

2024-02-22 - 7:55:47 PM GMT

 Stacey Grabert (SGrabert@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.


Challenge: The user opened the agreement.

2024-02-22 - 8:16:29 PM GMT


 Document e-signed by Stacey Grabert (SGrabert@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 8:16:40 PM GMT - Time Source: server


 Email viewed by cudkowicz.merit@mgh.harvard.edu

2024-02-22 - 11:13:45 PM GMT

 cudkowicz.merit@mgh.harvard.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 11:14:00 PM GMT


 Signer cudkowicz.merit@mgh.harvard.edu entered name at signing as Merit Cudkowicz

2024-02-22 - 11:14:12 PM GMT

 Document e-signed by Merit Cudkowicz (cudkowicz.merit@mgh.harvard.edu)

Signing reason: I approve this document


Signature Date: 2024-02-22 - 11:14:14 PM GMT - Time Source: server

 Tania Leeder (tleeder@mgb.org) added alternate signer ecklundd@uiowa.edu. The original signer dixie-ecklund@uiowa.edu can still sign.

2024-02-23 - 7:14:15 PM GMT

 Document emailed to ecklundd@uiowa.edu for signature

2024-02-23 - 7:14:15 PM GMT

 Tania Leeder (tleeder@mgb.org) added alternate signer cscoffey@iowa.uiowa.edu. The original signer christopher-coffey@uiowa.edu can still sign.

2024-02-23 - 7:14:24 PM GMT

 Document emailed to cscoffey@iowa.uiowa.edu for signature

2024-02-23 - 7:14:24 PM GMT

 Email viewed by cscoffey@iowa.uiowa.edu

2024-02-23 - 7:30:53 PM GMT

✔ cscoffey@iowa.uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-23 - 7:31:07 PM GMT

👤 Signer cscoffey@iowa.uiowa.edu entered name at signing as Christopher S. Coffey

2024-02-23 - 7:31:27 PM GMT

👤 Document e-signed by Christopher S. Coffey (cscoffey@iowa.uiowa.edu)

Signing reason: I approve this document

Signature Date: 2024-02-23 - 7:31:30 PM GMT - Time Source: server

📧 Email viewed by ecklundd@uiowa.edu

2024-02-29 - 10:07:04 PM GMT

✔ ecklundd@uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-29 - 10:07:27 PM GMT

👤 Signer ecklundd@uiowa.edu entered name at signing as Dixie Ecklund

2024-02-29 - 10:07:57 PM GMT

👤 Document e-signed by Dixie Ecklund (ecklundd@uiowa.edu)

Signing reason: I approve this document

Signature Date: 2024-02-29 - 10:08:00 PM GMT - Time Source: server

📧 Email viewed by ohayonj@ninds.nih.gov

2024-03-04 - 6:16:32 PM GMT

✔ ohayonj@ninds.nih.gov authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-03-04 - 6:16:42 PM GMT

👤 Signer ohayonj@ninds.nih.gov entered name at signing as Joan Ohayon

2024-03-04 - 6:16:58 PM GMT

👤 Document e-signed by Joan Ohayon (ohayonj@ninds.nih.gov)

Signing reason: I approve this document

Signature Date: 2024-03-04 - 6:17:00 PM GMT - Time Source: server

✔ Agreement completed.

2024-03-04 - 6:17:00 PM GMT