Commercial Confidentiality Disclosure Agreements (CDA)

NJRO-FDCOM-SOP-001

Contents

1. Background/Introduction

A Confidentiality Disclosure Agreement (CDA); also referred to as non-disclosure agreement (NDA) or secrecy agreement is a legal agreement between a minimum of two parties which outlines information the parties wish to share with one another, but wish to restrict wider use. This is particularly used in commercial research enabling sponsors/CROs to release protocols without concern or wider dissemination.

2. Purpose

The purpose of this SOP is to describe the process for obtaining a Confidentiality Disclosure Agreement (CDA) at NuTH to deliver commercial research studies and allow sensitive information to be shared between organisations.

3. Scope of Document

This SOP is applicable to all personnel carrying out clinical research where a commercial company/CRO is sponsoring a research project with the Industry Team taking responsibility for review and completion.

4. Definitions

CDA	Confidentiality Disclosure Agreement
NDA	Non-Disclosure Agreement
CRO	Contract Research Organisation
PI	Principle Investigator
GDPR	General Data Protection Regulation
PE	Partially executed
FE	Fully executed

5. Roles & Responsibilities

It is the responsibility of all research staff to ensure all CDAs, from a commercial company, should be forwarded to the Industry Manager via nuth.Trustindustry@nhs.net

The Trust Industry Manager, along with the Head, NJRO and Regulatory Compliance Manager is authorised signatories as agreed by Board.

6. Procedures

6.1. Template and receipt

- The CDA/NDA template will be released to site by the commercial sponsor/CRO for review
- In the absence of a suitable template a NuTH standard is used following Trust Industry Team advice
- PIs and study staff to forward CDA to Industry inbox for review

6.2. Review

- Industry Manager review clauses and negotiate Trust standard text in conjunction with CDA working instructions
- A master agreement may be drawn up if requested by sponsor/CRO to prevent per study CDAs and will sit at an organisation level
- GDPR or privacy notices will be assessed

6.3. Completion

- Upon agreement by both parties the signature process will begin. Trust Industry Manager to sign, scan and return to sponsor providing a PE copy if sponsor/CRO not initiated
- PI and study team are copied in to the return so aware study information will be safely disseminated.

6.4. Logging and archiving

- Trust Industry team log and track CDAs through the signatory process and specific pre-study reference developed
- CDAs logged and saved to LPMS

- PDF FE version saved by Industry Team to local folder and wet copies are not required, unless specified by sponsor/CRO.

7. References

No references.

8. Appendices

CDA working instructions