

# STANDARD OPERATING PROCEDURE

## Confidentiality for Commercially Sponsored Clinical Research

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<i>Approved by</i>	<i>Research Manager</i>

## Standard Operating Procedure: STH Research Department

### Confidentiality

This SOP has been produced in accordance with Research Governance Framework. This SOP will outline the procedures in place for maintaining confidentiality of commercially sponsored clinical research studies undertaken at Sheffield Teaching Hospitals NHS Foundation Trust (STH).

#### Background

A clinical trial protocol and associated documentation developed by a commercial company remains the property of the commercial company. Before or when a commercial company provides a protocol for the Principal Investigator (PI) to review, the Sponsor often requests the Principal Investigator to sign a Confidentiality Agreement (CA). A CA signed on behalf of the Trust prevents disclosure to other than authorised individuals, of a commercial company's proprietary information. It is the commercial company's decision whether they require signature of a CA before releasing study information. The Director of Research will sign the CA on behalf of STH. STH does not permit individual researchers to sign a CA.

#### Definition

A Confidentiality Agreement (also known as Confidential Disclosure Agreement or Non-Disclosure Agreement) is a legally binding document which defines the scope of use and ownership of information shared between and developed by the parties. By signing a CA the Investigator (including their staff and their employing institution) agrees not to release any information (hard copy, verbal, soft copy) regarding the study to anyone without the written permission of the commercial company sponsor.

#### Procedure

##### Confidentiality Agreements

1. The commercial company sends the Principal Investigator (PI), or the R&D Coordinator based in the Research Department, an agreement regarding confidentiality. If required or applicable the STH template (Appendix 2) can be used.
2. The PI sends the R&D Coordinator in the Research Department a copy of the CA to review.
3. The R&D Coordinator arranges for the CA to be signed by the authorised STH signatory. Usually the Director of Research will sign the CA on behalf of STH. STH does not permit individual researchers to sign a CA otherwise they would incur sole responsibility for ensuring maintenance of confidentiality.
4. The R&D Coordinator retains a copy of the fully executed CA and sends a copy to the commercial company and the PI.
5. If the study goes no further, the PI files the CA appropriately in his/her personal files and the R&D Coordinator files the CA in the Research Department central files.
6. If the study proceeds to registration with the Research Department, the PI files the CA in the Investigator Site File and the R&D Coordinator files the CA in the R&D Master file.
7. For registered projects, on receipt of a protocol, the R&D Coordinator files the study protocol in the R&D Project Master file, which is accessible only by members of the Research Department staff.
8. The PI is responsible for securely storing their copies of the protocol and associated study documentation.

**Appendix 1**  
**STH Related Documents**

	<b>Document</b>	<b>Research Department Network Location</b>	<b>Website</b>	<b>Database</b>	<b>Created by</b>
1	STH Confidentiality Agreement	<a href="#">..\\..\\..\\Research Governance\\Project Authorisation\\Templates\\contract templates\\Confdisc_2 way_STH.DOC</a>	Yes	No	PC

**Appendix 2**  
**Confidentiality Agreement Template**

**CONFIDENTIALITY AGREEMENT**

**WHEREAS:**

**Sheffield Teaching Hospitals NHS Foundation Trust of Beech Hill Road, Sheffield S10 2SB**, and ..... ("the company") desire to enter into discussions, evaluations and reviews to explore subjects of mutual interest relating to ..... (hereinafter called the "Field")

and **WHEREAS:** The parties each possess valuable information, technical knowledge, know-how, experience, data and business background of a secret and confidential nature relating to the Field, ("Information") all of which are regarded by them as commercial assets of considerable value

and **WHEREAS:** Each party desires to protect its respective Information from unauthorised use or disclosure

**NOW**, in consideration of such disclosure to each other, **IT IS AGREED** by and between the parties hereto as follows:

1. The receiving party undertakes to treat as strictly confidential and not to divulge to any other party, in whole or in part, any of the Information disclosed under this agreement and not to make use of any such Information without the disclosing party's prior written consent. The receiving party also agrees not to reverse engineer or otherwise analyse any of the materials provided under this agreement. The receiving party further agrees not to reproduce any Information disclosed to it by the other party except for the Purposes set forth in the premises above and shall limit disclosure of Information to those persons employed or otherwise under contract with the receiving party who have a legitimate need to know such Information for the purpose set forth herein.
2. The above undertaking shall apply for a period of ten (10) years but shall not apply to:
  - a) Information, which at the time of disclosure is published or otherwise generally available to the public.
  - b) Information which after disclosure by the disclosing party is published or becomes generally available to the public, otherwise than through any act or omission on the part of the receiving party.
  - c) Information, which the receiving party can show, within 28 days, was in its possession at the time of disclosure and which was not acquired directly from the disclosing party.
  - d) Information rightfully acquired from others who did not obtain it under the pledge of secrecy to the disclosing party.
  - e) Information which was subsequently and independently developed by such of the receiving party's employees, or employees of any of its affiliates, who had no knowledge of the Information disclosed.

3. No party makes any representation or warranty as to the accuracy or completeness of the Information disclosed or as to any sample, material, item etc embodying the Information.
4. Nothing in this Agreement shall be understood as granting, expressly or by implication, any rights under any patents, technical or other information or know-how of the disclosing party except to the extent expressly set forth herein, nor as giving rise to any obligation on the part of any party, hereto to supply or purchase any materials, compositions or products.
5. The terms of this Agreement shall be deemed to apply also to the servants or agents of the receiving party. The receiving party shall take all reasonable steps to ensure that their said servants or agents observe the foregoing obligations.
6. This Agreement shall be deemed to be an agreement made in England and subject to English law.

If you agree to the above, would you please so indicate by signing and dating both copies of this Agreement and returning one copy to the Trust.

**Sheffield Teaching Hospitals NHS Foundation Trust**

**Acknowledged by (Principal Investigator)**

Signature .....

Name .....

Title .....

Date .....

Signature .....

Name .....

Title .....

Date .....

**ACCEPTED AND AGREED TO:**

Signature .....

Name (printed) .....

Title .....

Date .....