York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
SOP
R&D/S93

Intellectual Property

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Signature:	
	Date:	23rd March 2022
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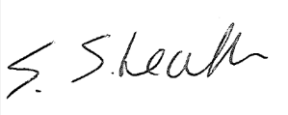
	Signature:	
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This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	12th October 2017	
2.0	20th April 2022	Change of link to R&D website. Change of Trust name. Updates and clarifications to all process. Inclusion of the new Commercial Research Manager post.

Contents

1 Introduction, Background and Purpose

Intellectual Property (IP) refers to the intangible creative property created by the generation of innovative and inventive ideas. IP can hold great practical and commercial value to its owner and as such it is very important that it is appropriately protected. The most fundamental and important protection of IP is confidentiality but additional legal protections such as copyrighting and patents may also be applied.

In the context of healthcare IP doesn't just apply to clinical intervention innovations such as new drugs or medical devices; other materials such as training aids, software, smartphone apps, clinical support documents and patient information guides may also contain potentially valuable IP that should also be protected.

In the environment of clinical research in which innovative ideas are frequently being generated and tested IP is a huge factor. As such when conducting clinical research within the Trust it is vital that all research staff are fully aware of and maintain the protections of IP whether they belong to the Trust or an external Sponsor.

Within clinical research IP is most commonly present in Phase I and II clinical trials of brand new, pre-marketed medicinal products and with brand new medical device studies, such studies can hold significant financial potential and as such rival organisations may attempt to attain and utilize IP for their own benefits where possible.

Failure to maintain strict IP protections can have significant consequences for the Trust such as a loss of potential income from the commercialisation of an innovation, legal consequences, damaging the Trust's reputation when conducting clinical research for external Sponsors, and the loss of recognition for an innovation to the Trust and its true inventor.

The purpose of this SOP is to provide guidance on the Trust's professional responsibilities in maintaining the protection of IP in the context of conducting clinical research

2 Who Should Use This SOP

Trust employed Chief Investigators, Principal Investigators, Research Teams, R&D Staff and any of members of the Trust who will be involved in conducting or supporting clinical research within the Trust.

3 When this SOP Should be Used

This SOP should be referred to in any situation in which IP needs protecting.

This includes any innovative research project ideas generated by Trust employees, the planning and proposal stages of Trust Sponsored clinical research studies and any Trust hosted externally Sponsored research studies in which IP is present.

4 Procedures for Protecting Intellectual Property in Clinical Research

The following sections refer to situations in which Intellectual Property is present and what procedures should be followed by research staff to ensure it is fully protected;

4.1 Intellectual Property generated within the Trust

1. **As soon as a Trust employee thinks of a research project that has the potential to be commercially viable they must immediately get in contact with the R&D Department before proceeding to discuss this idea with anyone else;** the R&D Department can be contacted by email at research.governance@york.nhs.uk or telephone 01904 72 6996

    a. If a member of a local directorate Research Team has been approached by a member of staff who they believe has such an idea it is their **responsibility** to immediately direct the researcher to contact the R&D Department immediately and advise the researcher not to discuss the project with anyone further until they have spoken to the department.

    b. Even if the researcher have doubts or are unsure over the commercial potential of an innovation it is recommended that they still approach the R&D Department as a precaution.

    Remember, IP doesn't just apply to inventions such as new drugs or devices; other materials such as training aids, software, smartphone apps, clinical support documents and patient information guides may also contain potential valuable IP.

    c. If the project has been thought up in conjunction with a member of another organisation such as another Trust or University then any IP generated will be jointly shared, however to protect the Trusts interests and professional relationship with such organisation the researcher must still treat their project with strict confidence.

2. The R&D Department has an assigned IP Reviewer and Commercial Manager who will review the proposal or protocol and determine if there is potential for any IP being generated from the project, where the IP presides, whether it is exploitable and how to protect it.

3. Until IP has been determined it is vitally important that the researcher does not discuss their project with **anyone** outside of the NHS Trust;

    a. This includes colleagues at other NHS Trusts, Universities, visiting Commercial companies, patients, friends and relatives. Even if discussed with the best of intentions.

    b. To limit the spread and accidental loss of potential IP it is also highly recommended that the researcher limits who he discusses the project with within Trust.

4. If the IP Reviewer/Commercial Manager determines that there is unlikely to be any IP gained from the project they will confirm this with the researcher.

5. If the IP Reviewer/Commercial Manager determines that there is potential IP attached to a project they will confirm this with the researcher and will begin to liaise with the Trust's supporting IP and Innovation experts Medipex (NHS Innovation Centre for the Yorkshire and Humber region).

    a. Medipex are a non-profit organisation that works solely with NHS organisations to develop innovations and inventions. They have no commercial interests beyond that of the NHS Trust they support and as such all IP discussed with them will be protected.

6. The IP Reviewer/ Commercial Manager will send the researcher an Invention Disclosure Form for completion. This form requires details of the invention, potential applications for the invention, where the idea has been generated from and the current status of the invention to be provided. Upon completion this will be forwarded to Medipex to begin their review.

7. On receipt of the form, Medipex determines if the invention has commercial potential and considers what, if any, form of protection is required. The appropriate form of protection will depend upon the type of IP to be protected.

8. Medipex will negotiate and manage IP on behalf of the Trust. IP ownership is retained by the Trust.

    a. Where it is identified that IP is jointly owned, e.g. with a University or company, Medipex will act on behalf of the Trust in negotiating the transfer of IP rights to/or from the Trust and the proportion of any income to be received.

9. Should the project develop into a clinical trial delivered by the Trust it is important that the Research Team continue to maintain IP protection throughout the project;

    a. The Research Team must maintain confidentiality about the project at all times, discussing the project only with those within the Trust associated with it.

    b. Should the Trust wish to extend the research project to include other NHS Trusts the R&D Department will arrange for a Confidentiality Disclosure Agreement to be signed prior to sharing information.

    c. Research projects should never be discussed with any patients or any documents shared until the project has received approval via the Confirmation of Capacity & Capability and, if applicable, via the Sponsors 'Green Light'.

    d. Sensitive drug, devise or product information should be kept out of sight and securely locked up when not in use.

    e. To minimise the loss, sensitive study information should not be discussed openly in public spaces or in environments outside of the Trust or Research Site.

10. Should the Trust become aware of a breach of IP protection at any point of the project the researcher must inform the R&D IP Reviewer immediately who will in turn alert Medipex and work with them to seek a potential resolution.

a. Some parties may be agreeable to sign a back-dated Confidentiality Disclosure Agreement and agree to not disclose or exploit the IP, but they are within their rights to refuse and the Trust would be powerless.

4.2 Externally Sponsored Research Projects

1. When a Research Team and/or R&D Staff are approached to potentially deliver a research project that has potential IP associated with it, it is usually expected that the Sponsor or delegated Clinical Research Organisation (CRO), whether commercial or non-commercial, provides the Trust with a Confidentiality Disclosure Agreement (CDA) or Non-Disclosure agreement (NDA) that must be completed before further information on the project is shared.

    a. The Care Group's assigned Research Delivery Facilitator (RDF), or where necessary Commercial Manager, will arrange for completion of these forms.

    b. A Confidentiality or Non-Disclosure Agreement is a legal document that states that the Trust will not disclosure any information about the project outside of the organisation.

    c. Breaching this agreement can significantly damage the reputation of the Trust and as such the Research Team and R&D staff should treat the protection of such IP of such projects as if it were their own.

2. If the Trust has worked previously with the external organisation the project may be covered by an existing CDA/NDA and may not require an additional one; this is at the Sponsors discretion.

3. The CDA/NDA will require an authorised signature on behalf of the Trust; this will be the Head of R&D or deputy. Once signed the agreement will cover all staff within the Trust

    a. The Sponsor may request an additional signature from the local Principal Investigator.

4. Once fully signed the Study Sponsor will then release the associated study documentation to the site. The assigned RDF will then disseminate this information to the appropriate parties and the Trust will begin it's feasibility review and study setup process as required.

5. The Research Team should ensure that this confidentiality is maintained throughout the project;

    a. Research projects should never be discussed with any patients or any documents shared until the study has received approval via the Confirmation of Capacity & Capability and, if applicable, via the Sponsors 'Green Light'.

    b. Sensitive drug, devise or product information should be kept out of sight and securely locked up when not in use.

c. To minimise the loss, sensitive study information should not be discussed openly in public spaces or in environments outside of the Trust or Research Site.

d. Before sharing sensitive study information to an unknown individual claiming association with the Sponsor/CRO, the Research Team or R&D staff member must confirm the identity of said individual with a known member of the Sponsor/CRO team first. Generally speaking a member of said teams would not need to request such info in the first place as they would already have it on their own records if genuine.

6. Should the Trust need to delegate certain activities of the project to an external organisation as part of a Service Level Agreement (SLA) or other third party involvement (e.g. to cover radiology scans or if activity is to take place at a non-Trust premises) the Research Delivery Facilitator will approach the Sponsor/CRO to request a CDA/NDA is arranged with the external organisation prior to sending any information about the project

5 Related SOPs, Links and Documents

York & Scarborough Teachings Hospital NHSFT Intellectual Property Policy

Medipex Information on Intellectual Property

Patents Act 1977

Copyright, Designs and Patents Act 1988