



Policy:

FIN 003 - Intellectual Property Management Policy

| | |
|--------------------------------------|---|
| Executive or Associate Director lead | Executive Director of Finance |
| Policy author/ lead | Assistant Contracts Manager & Bid Advisor |
| Feedback on implementation to | Assistant Contracts Manager & Bid Advisor |

| | |
|-----------------------|---|
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| | |
|-------------------|--|
| Summary of Policy | The policy provides information and guidance on intellectual property management |
|-------------------|--|

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|-----------------|--|
| Target audience | All SHSC staff employed on a permanent, temporary or consultancy basis, and staff conducting research on behalf of the Trust |
|-----------------|--|

| | |
|----------|--|
| Keywords | IP, Intellectual Property, trademark, innovation, patent, copyright, licence |
|----------|--|

Storage
 This is version 3 of this policy. This replaces version 2, ratified in November 2017 and version 1, ratified in March 2014.

This policy will be available to all staff via the intranet and on the Trust's website. The previous version will be removed from the Intranet and Trust website and archived. Printed copies of the previous version (v1.0 and v2.0) should be destroyed and if a hard copy is required, it should be replaced with this version. Word and pdf copies of the current and the

previous version of this policy are available via the Director of Corporate Governance.

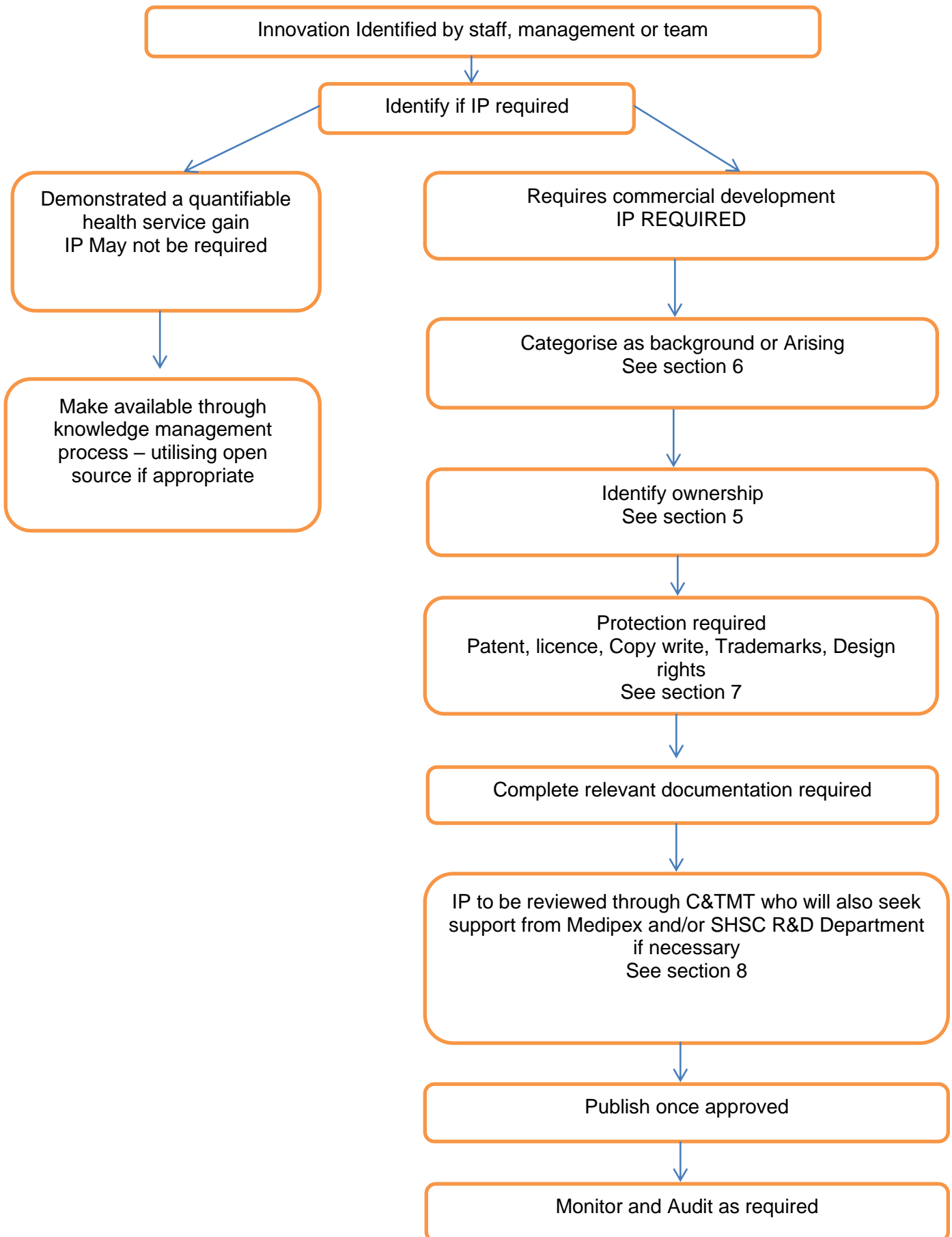
Version Control and Amendment Log

| Version No. | Type of Change | Date | Description of change(s) |
|--------------------|----------------------------|---------------|--|
| 0.1 | New draft policy created | March 2014 | New policy written in line with legislation. |
| 1.0 | Approval and Issue | March 2014 | Amendments made during consultation, prior to ratification |
| 2.0 | Review on expiry of policy | October 2017 | Review of policy and addition of flow chart. |
| 3.0 | Review of policy | December 2019 | Review completed as per schedule |

Contents

| Section | | Page |
|-------------------|---|------|
| | Flow chart | 1 |
| 1 | Introduction | 2 |
| 2 | Scope | 2 |
| 3 | Purpose | 2 |
| 4 | Definitions | 2 |
| 5 | Intellectual Property considerations and typical clauses used | 3 |
| | 5.1 Ownership of IP | 3 |
| | 5.2 Background IP | 4 |
| | 5.3 Arising IP | 5 |
| | 5.4 Protection of IP | 6 |
| | 5.5 Exploitation of IP | 6 |
| 6 | Duties | 7 |
| | 6.1 Managers | 7 |
| | 6.2 All Staff | 7 |
| 7 | Guidance to staff for protection of Intellectual Property | 7 |
| | 7.1 External Organisations | 7 |
| | 7.2 Confidentiality | 7 |
| | 7.3 Research Contracts | 8 |
| 8 | Development, consultation and approval | 9 |
| 9 | Audit, monitoring and review | 9 |
| 10 | Implementation Plan | 9 |
| 11 | Dissemination, storage and archiving (control) | 10 |
| 12 | Training and other resource implications | 10 |
| 13 | Links to other policies, standards, references, legislation and national guidance | 10 |
| 14 | Contact details | 10 |
| APPENDICES | | |
| | Appendix A - Version Control and Amendment Log | 11 |
| | Appendix B - Dissemination Record | 12 |
| | Appendix C - Equality Impact Assessment Form | 13 |
| | Appendix D - Human Rights Act Assessment Form and Flowchart | 15 |
| | Appendix E - Development, Consultation and Verification | 17 |

*Flow chart supported by further detail within policy sections



1. Introduction

NHS policy frameworks and guidelines supported by the Health and Social Care Act 2001 place a duty on the Trust to protect and exploit Intellectual Property (IP) generated by its employees during their normal duties for the benefit of patient care, staff and the wider health care community.

The Trust has a responsibility, via general obligations issued by the Department of Health and via our contracts with commissioners, to ensure that innovations, including novel treatments, devices, data, software, training materials or a new management system, are disseminated as widely as possible for the benefit of patients and the NHS in general.

Most innovations are best implemented by making them freely available through normal knowledge management processes once they have demonstrated a quantifiable health service gain, known as Open Source. Some innovations can however only be realised through their commercial development and for these innovations the professional management of IP is vital. The NHS recognises that the protection of IP improves rather than impedes the uptake of innovations with commercial potential.

The policy of our Trust is to encourage the generation of (IP) that has a potential value in both service and financial terms. This process may include publishing the IP in the public domain, or exploiting it through commercial channels in order to potentially acquire monetary gain.

2. Scope

This policy applies to all staff employed by the Trust on either a permanent, temporary or consultancy contract.

3. Purpose

To ensure the benefits of any innovations are maximised, this policy sets out the rules for the ownership, protection and exploitation of IP.

4. Definitions

Intellectual Property (IP)

Intellectual Property (IP) refers to knowledge, creative ideas, or expressions of human mind. IP includes, but is not limited to, inventions, designs, information, specifications, formulae, software, improvements, discoveries, know-how, data, processes, methods and techniques. IP when working in collaboration with others can be defined as either Background IP or Arising IP.

IP is owned and that ownership can be licenced or sold. The inventor or creator of the IP may or may not be its owner. Protecting IP allows the owner to control and be rewarded for the value of the IP.

Intellectual Property Rights (IPR) are rights which are protected by law that provide protection to the owner of the IP. IPR include patents, copyrights, database rights, design rights, trademarks, trade names and service marks, as well as applications for any of the above. Some forms of IPR must be registered, whilst others are conferred automatically.

IP can be protected by formal agreements, including confidentiality (or non-disclosure) agreements and collaboration agreements, which define the ownership of IP and limit its disclosure.

For this policy, IP will refer to any form of original creation as described above and in the associated IPR.

Confidentiality Agreement

An agreement made to protect confidential information if it has to be disclosed to another party. This is also known as a non-disclosure agreement (NDA) or confidential disclosure agreement (CDA).

NHS Innovation Hub

The innovation hubs offer support to NHS organisations to protect, manage and commercialise IP.

Patent

Applicable for inventions, new processes and equipment.

A patent confers a set of rights to a creator or assignee of an invention for a limited period of time, including the right to prevent others from making, using or selling that invention. Publication of any results before seeking patent protection could be fatal to the protection of the asset/invention. Patents are granted by a governing authority (see <https://www.gov.uk/apply-for-a-patent> for further information).

Licence

A legal agreement between two or more parties granting specific rights to the licensee, including the rights to use the licensor's IP, such as copyright, patents, trademarks and software.

Copyright

Applicable for written works, drawings, photographs, recordings, computer software, data collections, written or computer based protocols and forms.

Copyright arises automatically in most cases but it is desirable to ensure that documents or other works which may be covered by copyright contain an appropriate notice such as:

"© Sheffield Health & Social Care NHS FT All Rights Reserved. Not to be reproduced in whole or in part without the permission of the copyright owner."

Trade Names

E.g. the Trust's name and brands used by the Trust.

Open Source

Popular method of making innovation in digital form accessible free of charge to all.

5. Intellectual Property Policy

5.1 Ownership of IP

It is the Trust's intention to maintain a balance between wishing to benefit from potentially valuable IP and the provision of a creative working environment for employees in which they can be encouraged to innovate and to declare such innovation to the Trust.

In order to maintain this balance, and in line with the Department of Health (DH) guidance (reference document 1) for exploitation and commercialisation of IP, the Trust may, where appropriate, use the services of Medipex Ltd (the local NHS Innovation Hub) to support the exploitation of IP in conjunction with, and on behalf of, the Trust. The DH established these IP Hubs to advise Trusts on whether or not identified IP has any commercial potential and to support IP development and protection.

IP created by an individual in the course of his/her employment, or training arising out of his/her employment, belongs to their employer (the Trust) and any benefits accrued in the work will belong to the Trust. This includes copyright of research records, training or educational materials, clinical screening or assessment tools and other related material. However, the Trust may authorise an author to publish materials in academic or professional journals and will waive its rights to benefits arising from such publications. The Trust reserves the rights to reproduce and use such publications for its own non-commercial purposes.

If the Trust does decide to commercially exploit and protect IP rights then it may be appropriate for members of staff who created or developed the IP to have a share in the benefits for example through a royalty income or other recognition.

In certain circumstances the Trust may decide not to take up its rights and ownership may be assigned to the employee.

Where an employee has joint contracts with other organisations, where appropriate, a partnership agreement on IP will need to be developed. This will, wherever possible, be before the joint contractual period commences. In general, the organisation with the main contract will be responsible for protecting the IP rights and for any commercialisation. Agreement will need to be reached as to the way the costs and benefits will be split between the employing organisations and clarity as to whether IP will be classed as Background or Arising IP.

Partnership agreements will need to cover situations where NHS staff would be considered a secondary employer or where more than one member of staff is involved. In general, the organisation holding the main contract is responsible for protecting the IP rights and any commercialisation. Agreement will need to be reached re the apportionment of costs and benefits across the organisations. As the exploitation of IP incurs both costs and risks, it may not be appropriate or cost effective to protect and exploit all instances of IP.

Where the patenting or licencing of IP may be the most appropriate option, Medipex Ltd will undertake negotiations on behalf of the Trust and the inventor. In some cases, the IP may be a case of “best practice” which could be shared with other NHS organisations and the network of NHS IP hubs may be used to disseminate such innovations.

5.2 Background IP

Any Background IP that is pre-existing should be clearly described, either within the definition of Background IP or the definition can refer to a table in a contract schedule, depending on which is most appropriate. Once there is a clear baseline of

what constitutes the Trust's Background IP, it should be easier to identify any Arising IP that is created under the agreement.

Any improvements or modifications to any Background IP under a project which cannot be severed from the Background IP will become part of the Background IP. Therefore, if all IP created by a project cannot be severed from the Background IP then it would be owned by SHSC. It is possible that this provision would assist SHSC to retain ownership of rights created by a project but, ideally, the Trust would not want to have to rely on it to argue that it owns all rights in whatever is developed by a project.

It's also been suggested that a more extensive definition of IP is included as well as a definition of "Know-how" to cover any information relating to inventions, ideas, methods, etc. which may fall outside of the definition of IP.

5.3 Arising IP

Where a clause identifies that Party A creates Arising IP then Party A will own that Arising IP (unless it cannot be severed from the background as above). Party B may be granted an irrevocable free-of-charge licence to use the other's Arising IP for a defined reason (e.g. "academic and research purposes, including research involving projects funded by third parties"). So, if Party A creates the Arising IP then they would own it and Party B would only have a licence to use that Arising IP for the defined reason. However, if Party A is simply paying Party B to develop software, and the software is developed solely by Party B, then Party B will own the IPRs in that software.

Where IP is created or generated by both parties jointly and "it is impossible to segregate each Party's intellectual contribution to the creation of the Arising Intellectual Property" then the Arising IP will be jointly owned by the parties in equal shares.

Some clauses may specify that each joint owner can deal and exploit the jointly owned Arising IP as though it were a sole owner, with no limitation as to field or purpose of use, and without accounting to the other for a share in revenues. Similarly, a clause may specify that if Party A owns any Arising IP (either as sole owner or jointly), and it needs Party B's Background IP in order to do so, then Party B is required to grant a licence to Party A to use the Background IP to use and exploit the Arising IP. The reference to whether a party is "free to licence" would account for IP which is subject to restrictions

A Trust employee may have a part-time NHS contract and be self-employed part time (for example in private practice). If IP arises during the period of self-employment, it will be owned by the Trust if it is construed to relate to that employment. If there are circumstances which make it more likely for the IP to arise independently within the self-employment, the Trust may agree with the employee alternative terms for sharing benefit and will set these out in an agreement. In circumstances where IP may arise following partnerships then reference should be made to Background and Arising IP.

A Trust employee may have an honorary contract with another organisation. In the absence of any agreement to the contrary, IP generated by such an employee will be owned by the Trust.

IP generated by an employee outside the normal course of his/her NHS duties will be owned by the employee subject to the terms set out above. However, in determining ownership of IP in these circumstances, account will be taken of the extent to which the employee has used the Trust's resources (for example, equipment, expertise, facilities, information) to generate the IP.

In the case of visiting researchers, any honorary contract should make it clear that they are expected to be aware of the Trust policy and for IP rights to be agreed in advance. This includes agreement on the ownership of IP generated by the visiting researcher or to which he/she has contributed to during the period when they were engaged on Trust property or in Trust sponsored activity. Further advice is available from the Trust's Research & Development department.

Ownership of IP generated as a result of activity of organisations hosted by the Trust will be subject to agreements set out in the relevant host arrangement contracts and also relevant collaboration agreements with partner organisations. However, income from IP which is attributable to the Trust will be subject to the provisions of this policy.

5.4 Protection of IP

IP can be protected by legal rights such as patents, copyright, design rights and trademarks although acquiring such rights can be costly and time consuming.

Patents in particular can be costly to obtain, and unless there is likely to be a significant opportunity to obtain income from the use or sale of the product, there is generally little benefit in obtaining a patent. Further guidance should be obtained from the Contracts & Tender Management Team (C&TMT).

5.5 Exploitation of IP

Exploitation of IP involves both costs and risks. Consequently, it will by no means always be appropriate or cost effective to seek to protect and exploit potential IP. In many instances the product could be an example of "best practice" to be shared with other NHS bodies where copyright will suffice. Copyright is an automatically conferred right. In cases where patenting or licensing may be the most appropriate option, the C&TMT (with advice from Medipex Ltd and/or our Research Department where appropriate) will undertake negotiations on behalf of the inventor and the Trust.

All matters relevant to the development and management of IP will be channelled through the C&TMT who will have a lead responsibility for the management of the Trust IP rights. The C&TMT, (with advice from Medipex Ltd and/or our Research Department where appropriate), will assess the potential of identified IP and, in conjunction with the relevant Directorate and Corporate Functions, decide the benefits and overall value of protecting and exploiting individual products.

6. Duties

6.1 Managers

All Managers within the Trust are responsible for ensuring that all staff they manage can access copies of this policy.

Managers are also responsible where applicable for bringing this policy to attention of staff, and any contractors/suppliers they are working with and for ensuring that the C&TMT are contacted, if they, or a member of their team, develop an idea or concept which may have commercial potential. Contact should be made at the earliest opportunity and before disclosure of the idea to any party outside the Trust either orally or in writing.

6.2 All Staff

If an employee develops an idea or concept, which may have commercial potential, they must report this to their Director or Senior Manager, who should contact the C&TMT at the earliest opportunity and, in any event, before the disclosure of the idea to any party outside the Trust either orally or in writing.

Employees are also reminded of the importance of keeping accurate, dated and detailed records, including development notebooks so that in the event of similar IP being generated elsewhere, the creation and ownership of an invention can be legally attributed in accordance with this policy.

Employees must not, under any circumstances, disclose before protection, sell, assign, licence, give or otherwise trade in IP without the Trust's written agreement.

7. Guidance to staff for protection of Intellectual Property

7.1 External Organisations

Do not involve external organisations or companies in testing or prototyping, or send any written material containing novel IP to external organisations, without a written agreement together with a confidentiality agreement being in place and have such agreements checked with the C&TMT before commencement.

Do not sign any contract or agreements or begin any related activities, including giving or selling samples, until they have been reviewed by the C&TMT. This would include any provider or buyer contracts, Alliance contracts, Collaboration or Partnership Agreements or Grant or Research applications.

7.2 Confidentiality

It can be difficult to protect IP and advice is needed at the earliest stages. The following guidelines should be followed:

- Keep potential IP as secret as possible and resist pressure to announce or publish details until the matter has been discussed with the CTMT.
- Staff should avoid giving away or selling samples.

- External organisations or companies should not be involved in testing or prototyping without a written agreement together with a confidentiality agreement.
- Public disclosure (other than under a Confidentiality Agreement) is likely to invalidate any subsequent patent application and severely diminish both potential commercial value and benefits accruing to the Trust and the originator. Disclosure without entering into a Confidentiality Agreement may prejudice future negotiations of commercial arrangements.
- Confidentiality Agreements must be used when discussing IP with external parties and can be obtained from the C&TMT.

All staff, but particularly those who are involved in any clinical trials or studies, should also be reminded that the form the study or trial takes, its effects or results, are generally subject to IP terms and conditions relating to the trial. Sharing of this information for purposes other than those directly associated with the study or trial can dilute or remove the value of the associated IP. As such this would normally be a breach of contract or confidentiality agreement and may leave SHSC at risk of legal action.

7.3 Research Contracts

Employees will sometimes be engaged in contracts for Research and Development (R&D) that may be funded wholly, or in part, by external bodies. These contracts will ensure that provision is made for the ownership and exploitation of IP and for the Trust to acquire or retain IP ownership when appropriate. Employees should ensure that they understand their legal position and their obligations relative to IP within these contracts.

The Trust should benefit from an appropriate share of the profits from any commercial exploitation of IP derived from R&D that it has funded, or which it has been funded externally, even when the arising IP is to be owned by people or organisations outside the NHS. The size of such share will be subject to negotiation by the Trust prior to entering into the R&D contract and will vary from case to case.

Employees engaged in R&D will on occasions be involved in discussions related to research funding with external bodies and internal funding. Employees are reminded that it is the responsibility of the Trust to agree a price for conducting the work and in so doing give due regard to the value of any IP. Employees should contact the R&D department to discuss this at the earliest opportunity.

At the research application stage, the C&TMT should be consulted regarding any IP obligations that a subsequent form of contract not previously known and understood would demand of the Trust were the application to be successful.

Employees are reminded that all R&D contracts, whether commercially funded or funded through research grant programmes should be approved by the Director or Deputy Director of R&D before being submitted and any contract related activity commences.

8. Development, consultation and approval

This policy has been developed by the C&TMT in conjunction with relevant guidance from the NHS Innovation Hubs and the Intellectual Property Office (the official UK government body responsible for intellectual property (IP) rights including patents, designs, trademarks and copyright).

9. Audit, monitoring and review

The C&TMT, with the assistance of Medipex Ltd may, from time to time, arrange for an audit of Trust activity to identify IP of potential commercial value. All members of staff are required to co-operate fully with any such audit.

A Register of IP will be maintained centrally by the C&TMT and this will be made available to auditors if required. All staff are reminded of the need to comply with the NHS Standards of Business Conduct and Trust policies related to Declaration of Interest.

The policy will be reviewed every two years or sooner if any major changes to legislation occur.

| Monitoring Compliance Template | | | | | | |
|---------------------------------------|------------------------|--|-------------------------|---|--|--|
| Minimum Requirement | Process for Monitoring | Responsible Individual/group/committee | Frequency of Monitoring | Review of Results process (e.g. who does this?) | Responsible Individual/group/committee for action plan development | Responsible Individual/group/committee for action plan monitoring and implementation |
| Application of policy | Review and Audit | Finance | Annual | Assistant Contracts Manager and Bid Advisor | Head of Contracts and Tender Management | Finance Senior Management Team |

10. Implementation Plan

| Implementation plan Action / Task | Responsible Person | Deadline | Progress update |
|--|------------------------|--|-----------------|
| Upload new policy onto intranet and Trust website and remove old version | Head of Communications | Within 5 working days of ratification. | |
| Publicise policy to staff via the Communications Digest immediately following publication. | Head of Communications | Within 5 working days of issue. | |
| IMST to implement this policy re any future development and/or contractor work SHSC engage in. | Director of IMST | Immediately upon ratification. | |

11. Dissemination, storage and archiving (Control)

This policy will be available to all staff via the SHSC intranet.

12. Training and other resource implications

There are no specific training needs in relation to this policy but staff do need to be aware of its contents.

13. Links to other policies, standards and legislation (associated documents)

<https://www.gov.uk/intellectual-property-an-overview>

<https://www.gov.uk/government/organisations/intellectual-property-office>

<http://knowledge.nic.nhs.uk/Documents.aspx>

14. Contact details

| <i>Title</i> | <i>Name</i> | <i>Phone</i> | <i>Email</i> |
|---|--------------------|---------------------|-------------------------|
| Head of Contracts & Tender Management | Emma Smith | 0114 2716723 | emma.smith@shsc.nhs.uk |
| Assistant Contracts Manager & Bid Advisor | Liz Caterer | 0114 2264095 | liz.caterer@shsc.nhs.uk |

Appendix A – Version Control and Amendment Log

(Use Arial bold point 14 for titles)

| Version No. | Type of Change | Date | Description of change(s) |
|--------------------|-------------------------------|----------------|---|
| 0.1 | New draft policy created | September 2014 | New policy written in line with legislation. |
| 0.2 | 2 nd draft policy | November 2014 | Sent out for consultation, amendments made prior to ratification. |
| 1.0 | Review / ratification / issue | March 2014 | |
| 1.1 | Review on expiry of policy | | Consultation with Medipex. Responsible SHSC team name updated. Reviewed by Procurement and IMST leads |
| 2 | Review / ratification / issue | November 2017 | Review of policy and addition of flow chart. |
| 3 | Review / ratification / issue | December 2019 | Review of policy to include small amendments to wording in the policy for ease of application and readability |

Appendix B – Dissemination Record

| Version | Date on website (intranet and internet) | Date of “all SHSC staff” email | Any other promotion/ dissemination (include dates) |
|----------------|--|---------------------------------------|---|
| 1.0 | | | |
| 2.0 | November 2017 | November 2017 | |
| 3.0 | February 2020 | February 2020 | |

Appendix C – Equality Impact Assessment Form

Equality Impact Assessment Process for Policies Developed Under the Policy on Policies

Stage 1 – Complete draft policy

Stage 2 – Relevance - Is the policy potentially relevant to equality i.e. will this policy potentially impact on staff, patients or the public? If **NO** – No further action required – please sign and date the following statement. If **YES** – proceed to stage 3

See below

This policy does not impact on staff, patients or the public (insert name and date)

Stage 3 – Policy Screening - Public authorities are legally required to have ‘due regard’ to eliminating discrimination , advancing equal opportunity and fostering good relations , in relation to people who share certain ‘protected characteristics’ and those that do not. The following table should be used to consider this and inform changes to the policy (indicate yes/no/ don’t know and note reasons). Please see the SHSC Guidance on equality impact assessment for examples and detailed advice. This is available by logging-on to the Intranet first and then following this link https://nww.xct.nhs.uk/widget.php?wdg=wdg_general_info&page=464

| | Does any aspect of this policy actually or potentially discriminate against this group? | Can equality of opportunity for this group be improved through this policy or changes to this policy? | Can this policy be amended so that it works to enhance relations between people in this group and people not in this group? |
|--------------------------------|--|--|--|
| AGE | N/A | N/A | N/A |
| DISABILITY | N/A | N/A | N/A |
| GENDER REASSIGNMENT | N/A | N/A | N/A |
| PREGNANCY AND MATERNITY | N/A | N/A | N/A |
| RACE | N/A | N/A | N/A |
| RELIGION OR BELIEF | N/A | N/A | N/A |
| SEX | N/A | N/A | N/A |

| | | | |
|---------------------------|------------|------------|------------|
| SEXUAL ORIENTATION | N/A | N/A | N/A |
|---------------------------|------------|------------|------------|

Stage 4 – Policy Revision - Make amendments to the policy or identify any remedial action required (action should be noted in the policy implementation plan section)

Please delete as appropriate: Policy Amended / Action Identified / no changes made.

Impact Assessment Completed by

Liz Caterer, Assistant Contracts Manager and Bid Advisor, December 2020

Appendix D - Human Rights Act Assessment Form and Flowchart

You need to be confident that no aspect of this policy breaches a person's Human Rights. You can assume that if a policy is directly based on a law or national policy it will not therefore breach Human Rights.

If the policy or any procedures in the policy, are based on a local decision which impact on individuals, then you will need to make sure their human rights are not breached. To do this, you will need to refer to the more detailed guidance that is available on the SHSC web site

<http://www.justice.gov.uk/downloads/human-rights/act-studyguide.pdf>

(relevant sections numbers are referenced in grey boxes on diagram) and work through the flow chart on the next page.

1. Is your policy based on and in line with the current law (including case law) or policy?

Yes. No further action needed.

No. Work through the flow diagram over the page and then answer questions 2 and 3 below.

2. On completion of flow diagram – is further action needed?

No, no further action needed.

Yes, go to question 3

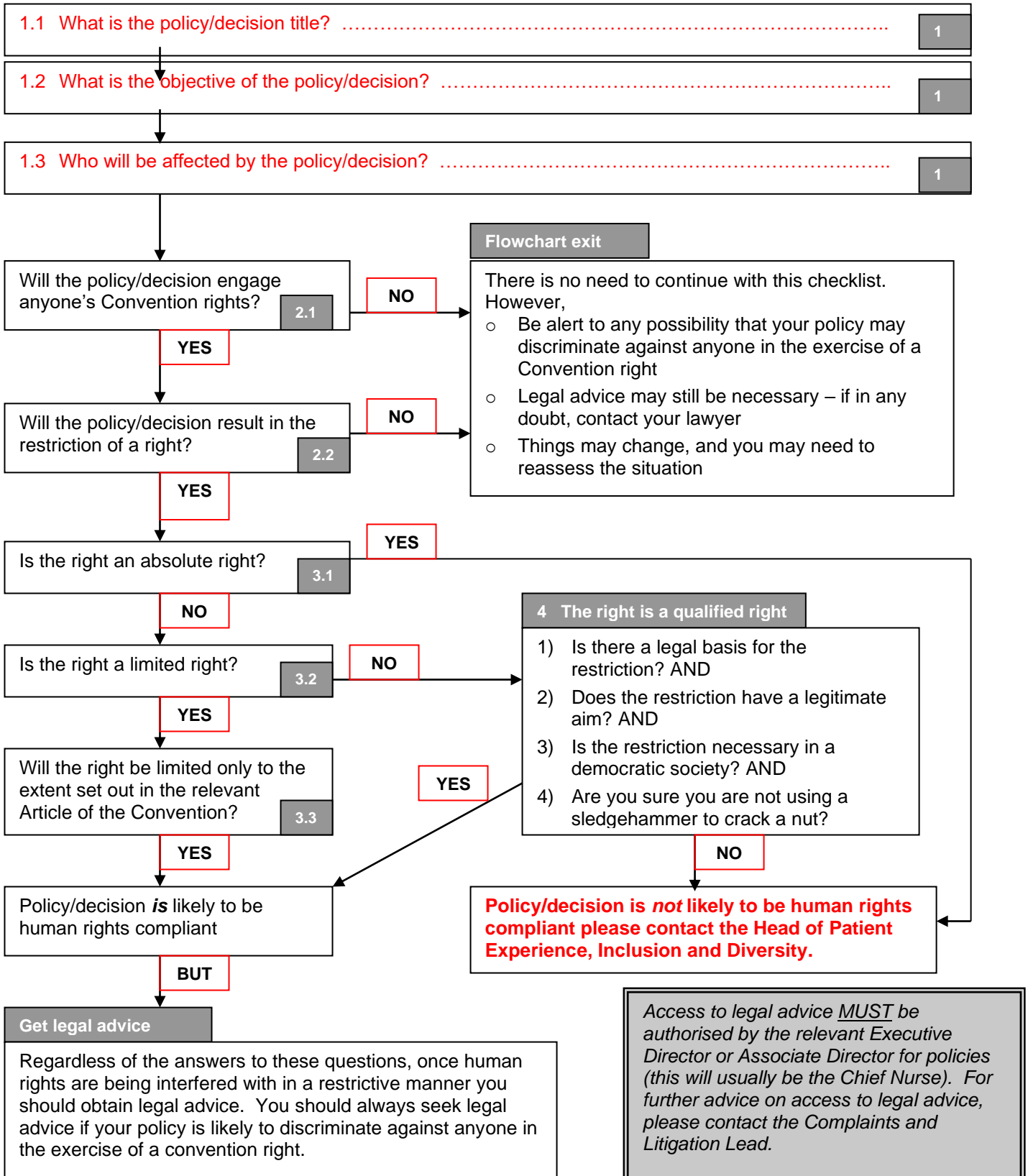
3. Complete the table below to provide details of the actions required

| Action required | By what date | Responsible Person |
|-----------------|--------------|--------------------|
| | | |
| | | |
| | | |
| | | |

Human Rights Assessment Flow Chart

Complete text answers in boxes 1.1 – 1.3 and highlight your path through the flowchart by filling the YES/NO boxes red (do this by clicking on the YES/NO text boxes and then from the Format menu on the toolbar, choose 'Format Text Box' and choose red from the Fill colour option).

Once the flowchart is completed, return to the previous page to complete the Human Rights Act Assessment Form.



Appendix E – Development, Consultation and Verification

1. First Draft produced September 2013
2. Second draft produced after consultation with Director of Commercial Relations Nov 2013.
3. Second draft sent out for consultation 15th November 13
4. Final draft submitted to BPG March 2014.
5. Consultation with Head of Procurement and Chief Information Officer updated October 17
6. Consultation with Director of Information Management, Systems and Technology updated October 2017
7. Updated v2 submitted to Policy Governance Group meeting 6 December 2017
8. Consultation with Principal Accountant and Deputy Director of Research December 2019