

MRC INTELLECTUAL PROPERTY AND COMMERCIALISATION POLICY

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MRC Intellectual Property and Commercialisation Policy

Version 4.0

Document Control Summary

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Policy statement

It is the MRC's policy and ultimate goal to promote the successful translation of its intellectual property for the benefit of human health care and the national economy. The MRC has a number of policies and procedures which underpin how translational work is supported, how activities are assessed through the reviews, and how decisions are taken to further develop IP beyond the initial invention. The purpose of this 'Intellectual Property and Commercialisation Policy' is to outline the contractual position in relation to intellectual property generation within MRC establishments i.e. MRC Units and Institutes.

Subject to case-by-case contractual arrangements to the contrary, this Policy applies to all individuals working within MRC establishments including: those employed by the MRC; visiting workers; students; and also intellectual property generated in MRC establishments by workers provided by a third party agency. Where managers have any doubt as to whether this Policy should apply, advice must be sought from local technology transfer staff or MRC Technology.

The Policy is also designed to inform MRC employees who wish to engage in personal/private consultancy work. The Policy is referred to in the MRC employee's Main Statement of Terms and Conditions of Employment and has been agreed with the National Trade Union Side and complies with statutory legislation as well as ACAS best practice. In addition, MRC's policies are assessed for language accessibility and equality impact. The MRC's operational activities are regularly reviewed with key stakeholders and Trade Unions, which in turn contribute to the further development of the MRC's policies.

1 Policy

- 1.1 One of the MRC's ultimate goals is the translation and exploitation of its Intellectual Property ("IP") for the benefit of human health care and the national economy. To this end, all MRC employees have a responsibility to be alert to the possible commercial application of their work and the work of those whom they supervise. It is for this reason that the provisions of this Intellectual Property and Commercialisation Policy ("Policy") must be applied.
- 1.2 The MRC works together with its technology transfer partner, MRC Technology ("MRCT"), to identify, protect and exploit a range of IP such as inventions, discoveries, and technological developments resulting from the MRC's research activities, and facilitate the translation of that IP into products and the clinic. Where possible, the exploitation of IP results in an income generation for the public purse.
- 1.3 Subject to case-by-case contractual arrangements to the contrary, this Policy applies to all individuals carrying out research and/or related activities on behalf of the MRC within MRC establishments i.e. MRC Units and Institutes ("Establishments" (note this does not include University Units or MRC Centres)) including:
 - a) Any MRC employee ("Employee");
 - b) Visiting Workers (defined below);
 - c) MRC-funded Students ("MRC Students").

- 1.4 Definitions: This Policy contains terms and phrases that have certain specified meanings. The following is a list of terms and phrases used in this Policy that are not defined elsewhere in the text. They should be read as having the specific meaning set out below when used in this Policy.

"Catalogue Reagents" are research tools such as antibodies and hybridomas which can be licensed to a company for them to sell.

"Intellectual Property" or **"IP"** means methodology, innovations, formulae, ideas, know-how, technologies, developments, improvements, technical and scientific information and data, prototypes, processes, circuitry, computer programs, databases, designs, drawings, plans, performance data, manufacturing techniques, materials, compounds, processes, research results and other tangible/intangible research properties, including software and other copyrighted works.

"MRCT Business Manager" means an MRCT staff member who manages IP matters on behalf of specific MRC Establishments or individuals.

"Visiting Worker" means any individual working within an MRC Establishment who is not an Employee or MRC Student, such as seconded workers, fellows and scientists and externally funded students. For further clarification see the Non-MRC Employee Policy.

2 How the MRC exploits and commercialises Intellectual Property

2.1 The MRC approach

2.1.1 MRCT acts as the MRC's exclusive agent for protection, exploitation and commercialisation of MRC IP, working to facilitate the translation of cutting edge scientific discovery and research into health and therapeutic products.

2.1.2 All individuals involved in MRC research are likely to create many different forms of IP in the course of their activities. They are numerous and diverse in nature, but by way of illustration, might include:

- a) Inventions or processes that can be patented and licensed to companies (including start-up companies) to develop and exploit, with the MRC benefiting from royalty or licence payments, or equity shares;
- b) Copyright works such as computer programmes which can be licensed or sold to third parties;
- c) Designs for new technology or devices that can be developed and produced commercially by third parties and sold to end users;
- d) Databases of information that can be sold or licensed to third parties;
- e) Materials including libraries of materials.

2.1.3 Protecting IP should not impede research endeavour and/or publication of research results but due consideration is needed to ensure that IP protection and exploitation is not jeopardised (see section 4 of this Policy).

2.2 Who benefits?

- 2.2.1 The creation of IP and its exploitation can have many benefits for the population, the scientific community, the MRC and the individual researcher(s) who created it.
- 2.2.2 To encourage innovation and discovery, the MRC operates an 'Awards to Inventor' ("ATI") scheme recognising that individuals may be entitled to some monetary reward for their contribution to any IP that is subsequently exploited. Further details of the ATI scheme are provided in section 5 of this Policy. The ATI scheme is not necessarily limited to those named as inventors on patents and may also recognise significant contributors.

2.3 Who decides what should be protected?

- 2.3.1 MRC has a Service Level Agreement ("SLA") with MRCT in respect of IP management services, [REDACTED].
[REDACTED]. MRCT is responsible for evaluating all research carried out by individual researchers including by looking at draft manuscripts and other research results pre-publication, and deciding whether the IP therein has commercial value and, therefore, whether it should be protected before disclosure (by e.g. patent application) or if it could be exploited "as is".
- 2.3.2 [REDACTED] the decision on what protection is necessary for IP developed within an MRC Establishment in consultation with the researcher who generated it. This will include any decisions as to whether to apply for patents, whether information relating to research and discoveries can be published, and whether such IP can be shared with third parties.

3 The Legal Position

3.1 General

The ownership of IP created within MRC Establishments is dependent upon on the status of the individual(s) creating it. For MRCT to be able to most efficiently and most effectively exploit MRC IP:

- a) The MRC must own IP created from research carried out within MRC Establishments, and
- b) Details of this MRC-owned IP must be kept confidential and not disclosed to any third party without adequate consideration being given to its potential commercial value. Individuals working in MRC Establishments may seek the advice of MRCT or local technology transfer staff before considering any type of IP disclosure so that, if necessary for example, a confidential disclosure agreement may be put in place or a patent application filed. See section 4.1.2 of this Policy for why this is important.

3.2 Studentships

- 3.2.1 Legally, all IP created by any person on a studentship belongs to the student unless their terms of funding state otherwise.
- 3.2.2 Subject to individual funding terms and conditions to the contrary, the MRC requires that students complete formal assignments of the IP they create during the course of their studentship to the MRC. The MRC can then seek to exploit the IP created by a student and the student may benefit from that exploitation in the same way as Employees or Visiting Workers (see section 5 of this Policy for how students might benefit from the exploitation of their research).

3.3 Visiting Workers

- 3.3.1 Generally, IP created by Visiting Workers will belong to them or to their employer.
- 3.3.2 Where a Visiting Worker's employer or other institution owns the IP that the Visiting Worker creates, the MRC requires the relevant organisation to assign its ownership to the MRC. Such assignment would normally be through an assignment and revenue share agreement negotiated by MRCT once IP is generated (see section 4.4 of this Policy). NB: Subject always to a Visiting Worker's employing organisation's internal policies and procedures, this assignment agreement may include arrangements for the employing organisation to reward such individuals.
- 3.3.3 Where 3.3.2 does not apply, in consideration of the use of, and access to, its facilities and scientists, the MRC requires Visiting Workers to assign ownership of all IP created during their time at the MRC to the MRC. Where the IP is so assigned, the Visiting Worker is eligible for benefits under the ATI scheme (see section 5 of this Policy).
- 3.3.4 All Visiting Workers are required to sign HR Form 1.25 'Visiting Worker General Conditions' available on KnowledgeBase.

3.4 Employees

- 3.4.1 The MRC owns all IP created by Employees during the course of their employment.

4. Obligations

4.1 Confidentiality

- 4.1.1 It is vital to the protection and exploitation of IP created by individuals involved in MRC research that all details of their research and the IP they develop are not disclosed without prior consideration being given to e.g. patent protection and exploitation.
- 4.1.2 Any disclosure of IP, such as publication of research results, may severely prejudice the MRC's ability to exploit it, or for third parties to use it in the development of novel treatments, devices, etc. In particular:
 - a) inventions or processes that are patentable might lose this route of protection if there is any evidence that they have been made available (in

whole or in part) to the public prior to patent applications being filed – as any disclosure would form part of the "prior art" which would prevent an application for a patent succeeding on grounds of novelty;

- b) any designs suitable for registration e.g. for new machinery, apparatus, devices or other equipment, might lose this route of protection if they have been made available to the public prior to registered protection being sought – as they would no longer be considered "new" or "novel".

4.1.3 Establishment Directors should be aware that it is good practice to remind staff that before any presentations are given a statement concerning the confidentiality of the research to be presented must be made. Without this statement future opportunities could be jeopardised.

4.1.4 While MRC expects data and other research resources to be shared, all those working in an Establishment owe a duty of confidentiality to the MRC and must keep all details of research and activities confidential until brought into the public domain through appropriate publication and/or other means. This duty of confidentiality includes not prematurely disclosing details of any research to others who are not involved in the research. For collaborative projects, collaboration agreements should be put in place to record the obligations of confidentiality on third parties. The MRC reserves the right to require individuals to enter into additional confidentiality and non-disclosure agreements as necessary.

4.1.5 In some circumstances, third parties may wish to obtain research materials developed by the MRC. To protect the MRC's interests, such materials should not be provided without a suitable material transfer agreement ("MTA") being in place. Local technology transfer and/or Establishment administration staff should be able to advise, but if no local expertise is available, MRCT must be contacted. If the party requesting MRC materials is a commercial company, MRCT must be contacted. The requirement for sharing materials with academic organisations being subject to conclusion of appropriate MTAs is not incompatible with the expectations of e.g. scientific journals (in which the materials have been published) and the recipient academic institutions.

4.2 [REDACTED]

4.2.1 All inventors or creators of potentially exploitable IP are required to [REDACTED]. Employees have a designated MRCT Business Manager listed on MRCT's website who can be contacted for any IP matters [REDACTED].

4.2.2 [REDACTED]

a) [REDACTED]

b) [REDACTED]

c) [REDACTED]

4.2.3 It is not always easy to determine when [REDACTED], but as a general guide, the invention, process, design or other development should be more than just an idea – there should be some tangible result of the work carried out. For example, researchers should have:

- a) Taken steps to produce prototypes of inventions or designs for new equipment;
- b) Carried out experiments to test out a new process or concept and obtained initial test results;
- c) Obtained *in vitro* test results to support a hypothesis.

4.2.4 It is important that MRCT are engaged as early as possible. If in doubt, researchers should contact MRCT [REDACTED] early in their research.

4.3 Assignment of Intellectual Property

4.3.1 Employees

4.3.1.1 In the event of registerable IP applications being filed e.g. patent applications, Employees will be required to complete a formal assignment of the relevant IP to the MRC. This is a formality required for the patent prosecution process in certain countries, including the US and Canada, though many other (non-EU) countries also require such a formality.

4.3.2 Studentships and Visiting Workers

4.3.2.1 When a student or Visiting Worker creates exploitable IP, they must complete a TDF in accordance with section 4.3 of this Policy. IP created by Visiting Workers and students will be assigned to MRC in accordance with Section 3 of this Policy. In the event of a patent being filed, students and Visiting Workers will be required to complete a formal assignment of the invention to the MRC (subject to the terms of their employment or studentship).

4.3.2.2 In view of the fact that negotiation of such assignments with a Visiting Worker's employer or student's funder may take time, it is important that MRCT is advised and involved as early as possible in order to put the necessary documentation in place at the appropriate time.

4.3.2.3 Assignment in these cases may be rather more complex than that required for Employees and will depend upon specific circumstances. For example, if a Visiting Worker is employed by a third party they may be required, under the applicable patent laws, to assign their IP to their employer. Where the Visiting Worker has no employer, as is the case for students, then an assignment agreement should be put in place (obtainable from MRCT or local technology transfer staff). For various legal reasons, the assignment documents must be completed when the IP has actually been created (an assignment cannot be made before IP has been created but an intent to assign in the event of creation can be agreed in advance). For this reason, Visiting Workers and students are required to acknowledge their intention and obligation to assign IP to the MRC when they commence research at an Establishment (see section 3.3 of this Policy).

5 The Awards to Inventors ("ATI") Scheme

5.1 When individuals have created IP that the MRC is able to exploit for commercial benefit, those individuals might be entitled to a share of the income that the exploitation of that IP generates for the MRC. 'Inventors' as used in this section 5 means collectively the *inventors* of patented IP and the *creators* of non-patented IP.

5.2 All income received under the ATI scheme is subject to income tax.

5.3 Income received by the MRC is first used to meet any obligations to third parties, for example, other funding bodies pursuant to a revenue sharing agreement. Remaining income ("MRC Income") is then shared between inventors and the MRC without deduction of costs (e.g. patent fees).

5.4 The ATI Scheme operates as follows:

5.4.1 For patented IP and non-patented IP (excluding Catalogue Reagents)

- a) Inventors responsible for the generation of patented IP and non-patented IP (excluding Catalogue Reagents) will generally be entitled to a share of any MRC Income (set out in the table below). If more than one inventor is responsible, this income will be split between them, subject to point b below.
- b) The Director of the Establishment in which the inventors work will be responsible for deciding how the share of MRC Income is split between eligible individuals. This split is reviewed on an annual basis by the Establishment Director [REDACTED]. The Director may also decide that some of the MRC Income share be paid to others who significantly contributed to the development of the IP.
- c) The ATI scheme for income from non-patented IP, excluding Catalogue Reagents, applies only where the non-patented IP was generated on or after 01 April 2012. This change in policy in respect of payments to inventors for non-patented IP will not supersede any existing agreements.

For patented IP and non patented IP (excluding Catalogue Reagents):

Cumulative MRC Income from exploitation	Allocation of income to contributing individuals
[REDACTED]	

Note: Table correct for 2013-2014 income. The income ranges are indexed annually for inflation to the nearest £100 and latest figures can be obtained from MRCT.

5.4.2 For Catalogue Reagents

- a) MRC Income arising from the commercialisation of Catalogue Reagents is allocated to inventors in accordance with the table below and is treated on a year by year basis (not cumulative). If more than one inventor is responsible, the income will be split between them, subject to point b below.
- b) The Director of the Establishment in which the inventors work will be responsible for deciding how the share of MRC Income is split between eligible individuals. This split is reviewed on an annual basis by the Establishment Director [REDACTED]. The Director may also decide that some of the MRC Income share be paid to others who significantly contributed to the development of the IP.
- c) The ATI scheme for income from Catalogue Reagents, applies only where the Catalogue Reagent was first generated on or after 01 April 2012. This change in policy in respect of payments to inventors for Catalogue Reagents will not supersede any existing agreements.
- d) Where an Establishment incurs significant operating costs in producing Catalogue Reagents, such costs will be met separately by the MRC.

For Catalogue Reagents:

Annual MRC Income from exploitation	Allocation of income to contributing individuals
[REDACTED]	

5.5 General Principles

- 5.5.1 An individual allocated a share of MRC Income will remain eligible for a share of that income if that individual leaves the MRC, and this share would also be paid to the estate of any individual who passes away.
- 5.5.2 Individuals who wish to waive their entitlement to any share of royalties may do so.
- 5.5.3 The ATI scheme will apply to income arising from patented IP where there is an MRC inventor(s) as outlined in a legally valid patent filing (in any territory) which is pending (at the point of revenue received) or granted. Where a patent is subsequently revoked, terminated, expired or is allowed to lapse, ATI obligations will cease on the first day after that event.

- 5.5.4 The ATI scheme will apply to non-patented IP and Catalogue Reagents for as long as MRC Income is generated under any type of licence agreement. Distribution of MRC Income from non-patented IP and Catalogue Reagents will end when such income ceases to be generated.
- 5.5.5 MRC Income generated by external scientific staff (ESS) will be treated in exactly the same way as for Employees, unless an agreement already exists which covers income distribution or where such an agreement may be merited.
- 5.5.6 Individuals should be aware that the MRC ATI scheme is more generous than patent legislation provides for.

5.6 Grievances

- 5.6.1 Individuals who are not satisfied with any decision made by an Establishment Director may process their claim through the MRC's normal grievance procedures. Refer to the MRC's Grievance Policy on Knowledgebase for further information.

5.7 Conflicts of interest

- 5.7.1 Where there is a conflict of interest resulting from an Establishment Director also being an inventor, MRCT will advise the MRC Chief Operating Officer ("COO") (or appropriate nominee) of the most appropriate course of action with the final decision resting with the MRC COO (or appropriate nominee).

5.8 University Units (UUs)

- 5.8.1 Where an Establishment is transferred to a University any relevant IP commercialisation income generated after the date of transfer, will be dealt with as part of the Strategic Alliance Agreement. For further information on the transfer of University Units refer to the MRC Unit to University Consultation Policy available on KnowledgeBase.

6 Consultancies

6.1 General approach

- 6.1.1 The MRC recognises that other organisations and companies may seek to draw on the expertise and knowledge of Employees. The MRC will therefore allow an Employee to act as a consultant to a commercial firm or company ("Company") where such a consultancy may be expected to provide benefits to the national economy, the MRC's scientific work or human health. The consent of the Employee's Establishment Director is required before any consultancy agreement can be entered into with a third party in line with the MRC Code of Conduct. The Employee can retain the full amount of any agreed consultancy fee, but the Employee is responsible for declaring this income to the HRMC via a self-assessment.
- 6.1.2 In general, an Employee will be able to act as a consultant where the consultancy role involves:
 - a) the provision of general oral or written advice that does not require the use of MRC resources for testing, preparation etc., other than a minimum amount of administrative work;

- b) attending meetings or discussions at the premises of the Company engaging the Employee as a consultant, provided this does not materially interfere with the individual's commitments to the MRC; or
- c) Commenting on articles, reviews, proposals, lectures, and other literature or writing sent to the consultant by the Company engaging the consultant for the purposes of internal review by that Company.

Any consultancy agreement entered into by an Employee must never commit the MRC (or its staff, including the consultant) to undertake any research work.

6.1.3 A research collaboration agreement or licence agreement will generally be more appropriate in circumstances where:

- a) the use of MRC research facilities or consumables, such as carrying out experimental work or testing, is necessary before the individual acting as consultant is able to formulate any advice;
- b) The assistance of other individuals in the Establishment is required; or
- c) The Company seeks access to any intellectual or other property of the MRC, such as inventions or confidential information e.g. unpublished data.

6.2 Approval

6.2.1 If an Employee wishes to undertake a consultancy, there must be a formal written consultancy agreement between the Employee and the Company. Full details of the proposed consultancy (including copies of any proposed agreement) must be disclosed to the relevant Establishment Director before any agreements are concluded or work is undertaken. If an Establishment Director decides that the scope of the proposed consultancy might impact on the MRC's activities or require more than incidental use of the MRC's facilities, the Director can withhold consent to the consultancy agreement. If the Director's consent is not given, the Employee must not undertake the consultancy. However, any Employee who does not agree with the Director's decision may appeal through the MRC's normal grievance procedures. As consultancy agreements are generally with a commercial company

[REDACTED]

Amendments may be required to protect the interests of the MRC and separate agreements could be required where the scope of the proposed consultancy is beyond that acceptable to the MRC.

[REDACTED]

6.2.2 [REDACTED]

6.2.3 To protect the MRC's investment in each Employee, any consultancy agreement must limit the duration of the consultancy and limit the amount of time a consultant is required to commit to the Company. This is to ensure that

Employees are able to devote a sufficient amount of their time to MRC related research.

- 6.2.4 To ensure that the MRC is able to fully exploit all research and IP, consultancy agreements must not attempt to transfer any IP that belongs to the MRC to the consultant or to the Company.

6.3 Confidentiality

- 6.3.1 As a result of working at the MRC, individuals will have access to confidential information relating to the MRC's research including unpublished data and results. Individuals acting as consultants must not disclose any confidential information relating to the MRC's research to the Company or any other third party and must always abide by their confidentiality obligations in this Policy and the terms of any confidentiality agreement they have signed with the MRC. If confidential information does need to be disclosed, the MRC will enter into a separate agreement between the MRC and the Company governing disclosure of the confidential information.

- 6.3.2 As the MRC may be required to provide certain information in relation to its activities to third parties, the MRC reserves the right to disclose the existence of consultancies held by Employees. The MRC will not however, disclose the terms of any individual consultancy agreements. Employees also have a responsibility to declare the consultancy on the Establishment's Conflict of Interest register.

6.4 Liability

- 6.4.1 Employees are acting in their personal capacity as consultants and as such engaged on their own business and are not acting in the course of their employment with the MRC. For this reason, the MRC will not be liable or responsible for any act or omission arising out of a consultancy agreement.
- 6.4.2 As the MRC is not liable for any Employee when acting as consultant, an individual who wishes to be a consultant is advised to consider obtaining professional indemnity insurance and seek appropriate advice.
- 6.4.3 A consultant acts in a personal capacity and so must avoid making any statement that could lead the Company to believe they are acting in their capacity as an employee of the MRC or otherwise on behalf of the MRC when providing the consultancy services or when negotiating the terms of the consultancy agreement. Failure to comply with this Policy may lead to disciplinary proceedings.

7 Links to other related documents and information

- 7.1 Visiting Workers General Conditions – HR Form 1.25 available on KnowledgeBase: MRC > HR > Starting work > Guidance > MRC Visiting Worker General Conditions.
- 7.2 MRC Studentships are governed by RCUK Terms and Conditions (<http://www.rcuk.ac.uk/funding/grantstcs/>)

7.3 Information about MRC's policies and support for translational research can be found on the MRC website. For guidance on the assessment of translational activities and exploitation during Unit and Institute quinquennial reviews, please consult the MRC Reviews Team (qq@headoffice.mrc.ac.uk)

7.4 Information about MRCT can be found at <http://www.mrcttechnology.org/>

8 Effective date

8.1 This Policy is effective from 1 July 2015.

9 Review date

9.1 This Policy will be regularly reviewed to incorporate any legislation changes and will be formally reviewed in June 2017.

10 Amendment history

Version	Date	Comments/Changes
0.3	February 2009	Amended by Corporate HR as part of project review of HR policies.
1.0	1 st March 2009	Release of revised policy.
1.1	6 th December 2010	Update MRCT web-link at 5.1
2.0	June 2013	Updated to reflect changes to Awards to Inventors (ATI).
3.0	July 2015	Policy review and refresh to reflect operational changes
4.0	March 2018	Reviewed and agreed no amends required