

6.9. IPRs with respect to Indigenous Knowledge raise a number of complex issues, and are the subject of a national policy currently under development. Benefit sharing with communities is likely to involve a National Trust model. Until clarity on these issues is reached at a national level, IPRs with respect to Indigenous Knowledge must be dealt with within the framework of this policy and subject to any existing agreements or contracts that may be in place, as well as any future, new or revised agreements.

7. DISCLOSURES

7.1. Responsibilities of IP Creator(s)

Members of the MRC are obligated to disclose all newly created or discovered IP to the IC, and to cooperate with the IC in all matters, including technical, marketing, patenting and licensing.

The form for reporting IP is entitled “MRC IC Invention Disclosure Form” and may be obtained from the MRC website. In addition IP Creators are required to inform the project supervisor, department head or unit director of such disclosure. In cases where IP is generated at external MRC Research Units located within Universities, members must submit an Invention Disclosure Form to the IC as well as the technology transfer office or equivalent designated authority at the University. The mechanism for progressing the IP will be determined by the Collaborative Research Agreement entered into between the University and the MRC.

It is the responsibility of members of the MRC to keep thorough records of experimental work and know-how produced as part of good research practice as well as for IP purposes. Laboratory notebooks are essential for proving the date of invention and reduction to practice in cases of opposition to patents and in litigation. As these events can take place many years after the invention was filed, notebooks and other records associated with an invention patented by the MRC must be submitted for safekeeping to the IC on ceasing to be a member of the MRC.

7.2. Responsibilities of the MRC

This Policy is administered by the IC. Only those delegated with authority may execute this policy in the name of the MRC, including actions that bind the MRC in any IP agreement. Upon disclosure of a discovery, in cooperation with the IP Creator(s), the IC will determine the industrial relevance and commercial potential of the discovery. The IC will endeavour to make a preliminary decision on the processing of the disclosure within three months of invention disclosure.

The following practical considerations relate to Intellectual Property disclosures:

- The IC requires disclosure of newly created or discovered Intellectual Property whether or not it is considered patentable. Early disclosure of potential IP is encouraged to ensure that IP can be protected and fast-tracked where appropriate.
- Upon receipt of a written disclosure, the IC will contact the IP Creator(s) to discuss the matters in the written disclosure. All invention disclosures and discussions on inventions with members will be subject to full confidentiality.

- A decision will then be made as to whether the technology has commercial potential and whether technology transfer will be accomplished most effectively by applying for patent or other legal protection. The IP Committee (refer to section 12), on the recommendation of the IC, will determine whether the MRC desires to commit funding to obtain protection for the Intellectual Property discovered or created. The IP Creator(s) will be notified of the decision.
- The MRC may apply for a patent in respect of any IP, and shall be regarded as the assignee of the discoverer or inventor in question.
- The IC may make suitable arrangements consistent with the provisions of this IP Policy with IP Management agencies or organisations for the purpose of obtaining services and advice with respect to the patentability of new discoveries or creations, the obtaining of patents thereon and the management and licensing of such patents.
- Sponsors of research may be granted rights to elect a royalty bearing exclusive or non-exclusive license to technology for which legal protection is sought; the specific terms will be negotiated with the IC.
- In cases where the IP Committee decides to proceed with technology transfer, the IC will *inter alia* pursue the licensing of the Intellectual Property, researching the market for the technology, entering into discussions with potential licensees, developing a business plan, negotiating appropriate licenses or other agreements, monitoring progress and distributing royalties to the IP Creator(s)/Enabler(s) in accordance with the MRC Award for Inventors Scheme.
- In some cases, third parties may wish to disclose to members of the MRC information on the creation or discovery of Intellectual Property of those third parties. If confidentiality is required, then the members are required to inform the IC who will then, with the member, decide the appropriate course of action. Caution should be taken in such instances as it is rarely required to have full disclosure when discussing research with third parties and this should always be the preferred option.
- In some cases, an IP Creator may wish to disclose limited information on the creation or discovery of new Intellectual Property to third parties. In this case too it is rarely required to have full disclosure and this should always be the preferred option. However, if full disclosure is required, the IP Creator(s) has to inform third parties of the confidential nature of such disclosure and arrange for the third parties receiving such information to sign a non-disclosure agreement in form and substance acceptable to the IC before such disclosure. In accordance with clause 7.1, the IC should be consulted before any disclosure of intellectual property is made to third parties.
- In consultation with the IC and the IP Creator(s), the IP Committee may decide to place Intellectual Property in the public domain, subject to such conditions and the payment of such fees or royalties as the MRC may determine, if that would be in the best interest of technology transfer and if doing so is not in violation of the terms of any agreements that supported or governed the work.
- The MRC may decide to maintain ownership of IP but to provide access to the IP through a no-cost licence if that would be in the best interest of technology or knowledge transfer and if doing so is not in violation of the terms of any agreements that supported or governed the work.
- IP Creators may, at their own discretion, place in the public domain software, web pages and datasets that were created with the intention of providing open source licenses.
- The IP Committee may opt to use a technology transfer agency of its choosing or an agency recommended by the IP Creator(s). When utilising the services of such

agencies it is standard practice that the IP is assigned to the agency and the assignor is thereafter eligible for no more than 50% of the net royalties from income derived from the successful licensing of the IP by the agency to a third party. Net royalties are those obtained after all agency costs have been recovered. In using any such agency, the IP Committee may enter into any commercially-reasonable arrangement for the sharing of royalties with such agencies. In the division of royalties with the IP Creator(s)/Enabler(s), any royalties paid to such agencies shall be deducted prior to the calculation of any entitlement to the IP Creator(s)/Enabler(s).

8. PATENTING STRATEGY

The IC uses an internationally-accepted patenting strategy that involves balancing the investment in protecting Intellectual Property with the potential market for the product. This requires careful consideration of the commercial potential of IP before investing in patenting costs and ensures that the MRC does not end up with a large portfolio of patents without potential licensees. The IC strategy is therefore to file inexpensive provisional patents and, wherever possible, to desist from expensive filings except where a potential licensee has expressed interest in securing a license.

9. AGREEMENTS

9.1. Consortium, Collaboration and Research

It is the responsibility of members of the MRC to be aware of IP clauses of research, collaboration and consortium contracts, and to ensure that the terms of such agreements with third parties do not conflict with the terms in this Policy. Any questions regarding the MRC's policies may be directed to the IC.

9.2. Confidentiality Agreements (Non-Disclosure Agreements - NDAs)

It is the responsibility of members of the MRC to ensure that a signed NDA is in place should it be necessary to discuss proprietary creations or discoveries with third parties. In general, it is rarely required to have full disclosure when discussing research with third parties and this should always be the preferred option. The IC will advise on what may be disclosed without requiring a NDA. Should disclosure be necessary, then Unit Directors or the equivalent have the authority to sign NDAs, following signed approval by a duly authorised representative of the MRC. Such agreements must be in form and substance acceptable to the IC. The agreement should be signed in triplicate: one copy to be retained by the research unit or department, one to be retained by the recipient, and the third must be forwarded to the IC.

9.3. Material Transfer Agreements

Material transfer agreements cover the use of tangible materials such as monoclonal antibodies, genes, nucleic acid probes and promoters, clones, cell lines, plasmids, viruses, seeds, whole animals, etc. It is the responsibility of IP Creators to inform the Unit Director or equivalent, of any proposed transfer of MRC's material to either commercial or non-commercial concerns. The IC will assist in compiling the MTA if required. Unit directors or the equivalent shall inform the IC of any such agreement, which must be in form and substance acceptable to the IC. Unit directors or the equivalent have the authority to sign

MTAs following signed approval by a duly authorised representative of the MRC. The agreement should be signed in triplicate: one copy to be retained by the research unit or department, one to be retained by the recipient, and the third must be forwarded to the IC.

9.4. Consulting Agreements

Employees of the MRC should not enter into agreements related to outside employment, such as consulting agreements, without affirmative notice to the prospective employer that the Intellectual Property Rights of the MRC cannot be subordinated to a third party consulting or employment agreement.

9.5. Contracts involving Traditional Knowledge and Indigenous Knowledge Systems

All contracts relating to the research, use and application of traditional knowledge and traditional technologies must be reviewed and approved by the IP Committee, in consultation with the MRC Ethics Committee, where required, in order to ensure compliance with the Biodiversity Act. The IC will negotiate such agreements, which will be signed by the IC Director after approval from the IP Committee.

10. RIGHT TO PUBLISH

Members of the MRC are normally expected to publish and present the results of their work in pursuit of research excellence. The MRC does not wish to restrict this freedom. However, in cases involving research material with commercial potential, appropriate action should be taken to evaluate and protect the information before publication. It should be borne in mind that some research contracts may restrict open communication. Advice should be sought through the IC to avoid premature disclosure which will prevent any patent protection being sought.

11. MORAL RIGHTS

The MRC aims to respect and protect the moral rights of IP Creators, namely:

- the right of attribution of authorship
- the right not to have authorship falsely attributed
- the right of integrity of authorship of a work and not to have the work subjected to derogatory treatment.

In addition the MRC recognises the right of IP Creators to participate in decisions regarding the commercialisation and use of IP generated by them. IP Creators are entitled to full disclosure of the status of the IP and would normally be advised of the MRC entering into any contracts for the commercialisation, use or sale of that IP.

12. THE INTELLECTUAL PROPERTY COMMITTEE

The IP Committee is required to take decisions on IP issues which have substantial long term financial commitments for the MRC such as national phase patent filings, PCT applications, licensing and formation of spin-out companies. It is not required for decisions relating to short term, relatively low-cost commitments such as provisional patent applications. In the later cases decisions are made by the IC, which is responsible

for the implementation and administration of the policy and decisions made by the IP Committee.

The Intellectual Property Committee comprises:

1. The Executive Director of the Technology and Innovation Directorate
2. The Executive Director of Finance or their nominee from the Finance Directorate
3. A member of the IC, nominally the person who is in charge of the invention under discussion.

A person deemed to be an expert in the relevant technology or market under evaluation, if specifically nominated by the inventors in collaboration with the IC, can be co-opted onto the committee as required, and need not necessarily be an MRC member. This person will not have voting rights.

The Executive Director of the Technology and Innovation Directorate shall be the Chairperson of the IP Committee. As important decisions are often required at short notice the IC will distribute a technology brief with IC recommendations to all members. Decisions by members must be emailed to the IC for implementation. A minimum of 2 members of the IP Committee, one of which must be the Chairperson, must approve decisions. If there is a split vote then the full committee will be convened in person.

The functions of the Committee are:

- a. To take strategic decisions regarding the management and exploitation of MRC IP, based on recommendations from the IC.
- b. To settle any disputes that might arise in the application of this policy, and other IP-related decisions.
- c. To endorse recommended changes to the MRC IP policy for ratification by the President of the MRC.

13. COMMERCIALISATION

When commercialising technology that is related to MRC research, a number of policy issues must be considered. There is the strong potential for the public to view this entrepreneurial activity as creating conflicts of interest both for the IP Creator(s)/Enabler(s) and for the MRC. The IP Creator(s)/Enabler(s) and the MRC should benefit financially from commercialisation activities based on MRC IP, and thus the behaviour of both can be suspect in the eyes of the public. The MRC and the IP Creator(s)/Enabler(s) together have to manage the resulting perceived and potential conflicts of interest and commitment. The MRC is in the process of further developing its conflict of interest policy.

There are a number of means used for commercialising IP. For the MRC these mainly include:

- Licensing
- Spin-out companies and subsidiary companies of the MRC
- New ventures
- Management buy-outs
- Technology transfer agencies
- Direct sale of products and services
- Combinations of the above

The actual means to be used will be the decision of the IP Committee on the recommendation of the IC and will be determined on a case-by-case basis.

Related to these means is an “Awards for Inventors” scheme that determines the distribution of income received from MRC IP.

13.1. Licensing

Licence agreements will be negotiated with external parties to ensure commercialisation and the receipt of commercially reasonable royalties. All license agreements will include performance clauses and milestones. All direct costs will first be deducted from the licence fee. Direct costs include patenting, legal, promotion, negotiation, administrative and other costs directly associated with the commercialisation process but exclude costs associated with prior research and development. Any surplus will be divided and awarded to the beneficiaries according to the Awards for Inventors scheme.

13.2. Spin-out companies and subsidiary companies of the MRC

The MRC supports the formation of companies that can develop MRC IP into useful products and move them into the market. These may be independent companies or subsidiary companies of the MRC.

13.2.1. Equity Holdings

The MRC may take an equity stake in any spin-out company in exchange for granting an exclusive license with or without the right to sub-license. No member of staff in a position to influence the relationship between the MRC and a spin-out company, may own shares in a spin-out company, or act as a director of a spin-out company, except as the MRC's nominee. This clause does not apply in cases where such staff members are deemed to be IP Creators/Enablers.

IP Creators responsible for the technology used in forming the spin-out company and who remain as members of the MRC, may own shares in the company.

Shares owned by parties are subject to dilution in the event of investment by third parties e.g. Venture Capital Investment.

13.2.2. Directorship and Board Position

IP Creators who remain as members of the MRC may act as non-executive directors and sit on the Board of Directors or the Scientific Advisory Board of the Spin-out Company, within the framework of the MRC's employment policy (refer to 13.3 and 13.4). In doing so they will not serve as representatives of the MRC.

The MRC retains the right to appoint a non-executive director or observer at board meetings.

13.3. Conflict of Commitment

Members are expected to satisfy all the requirements of their employment, and should not permit outside activities to interfere with the performance of their MRC obligations. This form of conflict is easily defined and recognized since it involves a perceptible reduction of the individual's time and energy devoted to MRC activities. Time allocated to external activities should be defined in the annual performance management systems.

13.4 Conflict of Interest

A conflict of interest will exist when a member, member's direct family or associated legal entity (such as companies owned by members or their direct family) has an external economic interest that affects or provides an incentive to affect the individual's conduct and responsibilities at the MRC. Conflicts of interest can arise naturally from an individual's engagement with the world outside and the mere existence of a conflict of interest does not necessarily imply wrongdoing on anyone's part. When conflicts of interest do arise, however, they must be recognized, disclosed and either eliminated or properly managed.

The following principles are among those that underlie the current MRC policy on conflicts of interest:

13.4.1. Members should not seek to influence the MRC's technology transfer decisions in ways that could lead to personal gain.

13.4.2. Members should not participate directly in the negotiation of research agreements, license agreements or other arrangements between the MRC and external organisations in which the Member has a significant economic interest.

13.4.3. Professional effort may be directed to outside work resulting from IP generated at the MRC. This may be pursued in accordance with MRC conditions of service and in consultation with line management. If additional time is required of the Member to engage in outside work, then:

13.4.3.1. the member will require approval from the line manager who should make such a decision in consultation with the IP Committee;

13.4.3.2. the Company for which the member is providing outside work will be required to pay the MRC for this time at market related rates.

13.4.3.3. If the above time allocations are insufficient then the member may request a secondment from the EMC provided that all MRC duties and responsibilities of the member are accounted for during this period of absence. The member will be required to maintain existing benefits such as medical aid, pension and Group insurance.

The MRC is in the process of further developing its conflict of interest policy.

13.5. Disclosure of Commercial Involvement

Members who hold shares in commercial enterprises through, or receive royalties or consulting fees from, their involvement in external activities have an obligation to disclose such financial interests, in terms of the MRC's Conditions of Service.

14. BENEFIT SHARING

The MRC wishes to share with IP Creator(s)/Enabler(s) whatever material benefits that may arise from the beneficiation of this IP policy. This Policy sets out the way in which the MRC will achieve this goal.

14.1. Beneficiaries from the Exploitation of Intellectual Property

There are four possible beneficiaries from the exploitation of MRC funded research leading to intellectual property.

- the IP Creator(s)/Enabler(s)
- the Unit/programme/Centre/Group (the Entities) or Institution of which the IP Creator(s)/Enabler(s) are members - These Entities are funded by the MRC often in partnership with another PRO (e.g. University)
- the MRC IC
- the MRC – corporate contributions

14.1.1. Identification of Beneficiaries

All IP Inventors(s)/Enabler(s) and Units/Groups/Centres involved in the process of development and beneficiation of the IP must be clearly identified once a decision has been made by the IP Committee to proceed with the invention. An "MRC IC Intellectual Property Contributors Form", stating the relative contributions of the parties, must then be signed by the parties involved and submitted to the IC. This declaration will determine the sharing of the IP Creator(s)/Enabler(s)'s and Unit's portions of Awards. Any changes to these contributions and additional parties must be subject to a new agreement. If more than one individual is involved in IP creation and/or beneficiation, the extent of the contribution of each individual to the invention must be quantified to enable equitable sharing of the IP Creator(s)/Enabler(s)'s portion of Awards. The same applies where more than one Unit/Centre/Group is involved.

Should any dispute on any of the above-mentioned matters arise, the Director of the Entity within which the dispute arose must make a decision on the matter. If the Director is one of the inventors involved in the dispute, or if the Director is unable to resolve the dispute, the responsible MRC Executive Director and the Dean of Faculty (where applicable) will decide on the matter(s). If the dispute is still unresolved, the IP Committee will make a final decision on the matter(s).

14.2. Income derived from the Exploitation of Intellectual Property

A number of types of income may be derived during the process of commercialising IP owned by the MRC:

- (i) Licence fees
- (ii) Evaluation fees
- (iii) Milestone payments
- (iv) Royalty income
- (v) Outright sale of IP
- (vi) Sale of commercial ventures built around MRC IP
- (vii) Sale of shares in such commercial ventures
- (viii) Dividends derived from such commercial ventures
- (ix) Commissions

Income derived through the sale of products and services usually does not apply to this awards scheme.

14.3. Model for the Awards for IP Beneficiaries

Income	IP Creator(s)/Enabler(s) %	Unit/Group/Centre %	MRC %	IP Fund %
Income after deduction of all direct costs relating to the protection and exploitation of the IP	30	30	30	10

It is the responsibility of the IC to provide proof of direct costs incurred in the protection and exploitation of the IP through proper accounting procedures.

The MRC reserves the right to modify this model in accordance with international best practice in the best interest of firstly, the IP Creator(s)/Enabler(s) and thereafter the other beneficiaries. In cases where IP is shared with Universities through prior research agreements, only the MRC’s share of income resulting from the IP shall be divided in accordance with this model. This model will apply for all IP that produces a licence, royalty income or outright sale. An IP Creator/Enabler may therefore be able to benefit from more than one invention.

14.3.1. Continuation of Award for IP Beneficiaries in the event of the death of the IP Creator(s)/Enabler(s)

After death, awards will continue to be paid to the estates of the IP Creator(s)/Enabler(s). It is the responsibility of the beneficiary(s) of these estates to notify the MRC of any changes in contact details after death of the IP Creator(s)/Enabler(s).

14.3.2. Continuation of Award for IP Beneficiaries in the Case of Termination of Employment

Upon agreement from the IP Committee, Awards for IP Beneficiaries will continue to be paid to an IP Creator/Enabler after the IP Creator/Enabler has left the employ of the MRC or the Institution where the invention was made. It is the responsibility

of the IP Creator/Enabler to notify the MRC of any changes in contact details after termination of employment.

The agreement between the IP Creator/Enabler and the MRC in the event of death of the IP Creator/Enabler will continue to apply.

15. DISPUTE RESOLUTION

Disputes that arise as a result of the operation of the IP Policy or as to any matter on which the operation of this policy hinges, with the exception of disputes discussed in 14.1.1, should be brought to the attention of the IC.

The IC Director will arrange a meeting of the parties to discuss the substance of the dispute and the possibility of negotiating a resolution. If such a dispute cannot be resolved through the assistance of the IC Director, the IP Committee will be asked to resolve the dispute. Failing resolution, the IP Committee must appoint an arbitrator, acceptable to the parties, to investigate and decide upon the matters in dispute. Disputes submitted to arbitration will be administered in accordance with Arbitration Rules of South Africa. At any point, if any party chooses to seek legal remedy and to proceed in law, the mediative role of the IC and the IP Committee shall end.

16. IP POLICY AGREEMENT

All members of the MRC, as defined in section 4.1, must sign the MRC's IP Policy Agreement. In doing so, the member acknowledges that he/she is aware of and understands the MRC's policy with respect to the disclosure and assignment of intellectual property, and that he/she undertakes to adhere to the policy. The agreement shall also bind the IC and the IP Committee to the confidentiality of invention disclosures and discussions with members regarding inventions. Unit Directors or the equivalent are responsible for ensuring that the IP Policy Agreement is signed by all members of the unit.

17. IMPLEMENTATION

This policy complies with and expands on the South African Medical Research Council Act 58 of 1991, and shall apply retrospectively to all intellectual property conceived or first reduced to practice on or after the 22 May 1991, except where this has a negative effect on the rights of the inventors. Waivers of the provisions of this policy may be granted by the IP Committee on a case-by-case basis, giving consideration among other things to MRC obligations to sponsors, whether the waiver would be in the best interest of technology transfer, whether the waiver would be in the best interest of the MRC and whether the waiver would result in a conflict of interest.

The MRC reserves the right to modify or add to this policy at any time provided that any such policy change will in normal circumstances only apply to works, inventions and other subject matter in which IP rights subsist that come into being after the effective date of the change. In exceptional cases or unforeseen circumstances, the IP Committee in consultation with those parties who have a direct interest in such a case, may vary or depart from the terms of this policy if, in its judgement, doing so would better achieve the overall objectives of the policy.

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