

**SOUTH AFRICAN  
MEDICAL RESEARCH  
COUNCIL**



**MANAGEMENT AND COMMERCIALISATION OF INTELLECTUAL  
PROPERTY POLICY**

## Document review and approval

### Revision history

Version	Author	Date	Revision
1	R Busang / Michelle Mulder / Tony Bunn	July 2011	
2	Contracted Employee	May 2012	
3	Policy Renewal Team	May 2012	
4	Michelle Mulder	January 2013	
5			
6			
7			

### This document has been reviewed by

	Reviewer	Date reviewed
1	Chief Financial Officer	November 2012
2	Executive Management Committee	15 January 2013
3	Acting President and Vice President Intramural Research	17 January 2013
4	Research and Development Committee	23 January 2013
5	Board	6 February 2013
6		
7		
8		
9		
10		

### This document has been approved by

	Subject matter experts and / or owners		
	Name	Signature	Date reviewed
1	Interim President: Prof. S Abdool Karim		
2	Research and Development Committee: Chairperson (See Resolution)		
3	Board: Chairperson (See Resolution)		
4			
5			

# Contents

1.	REGULATORY FRAMEWORK	4
2.	PURPOSE	4
3.	POLICY STATEMENT	4
4.	SCOPE	24
5.	DEFINITIONS APPLICABLE TO THE POLICY	24
6.	RELATED POLICIES	28
7.	POLICY AUTHORITY	29

## 1. REGULATORY FRAMEWORK

- 1.1. Section 51 (1)(a) of the Public Finance and Management Act No. 1 of 1999 (PFMA) requires the Accounting Authority of the public entity to exercise the duty of utmost care to ensure reasonable protection of the assets and records of the public entity.
- 1.2. Section 4(1)(r) of the MRC Act No. 58 of 1991:  
*"in addition to any function, power or duty that the MRC is required or empowered to do in terms of the provisions of this Act or in terms of any other law, do everything that is conducive to the achievement of its objects or is calculated, directly or indirectly, to enhance the value of or render profitable the property or rights of the MRC."*
- 1.3. The Intellectual Property Rights from Publicly Financed Research and Development Act No. 51 of 2008 (IPR Act).
- 1.4. The Patents Act No. 57 of 1978 and the Patents Amendment Act, No. 58 of 2002.
- 1.5. The Copyright Act No. 98 of 1978 and subsequent amendments.
- 1.6. The National Environmental Management: Biodiversity Act of 2004 (Biodiversity Act) and associated regulations.

## 2. PURPOSE

The purpose of this institutional policy is to –

- 2.1. reinforce and expand on the MRC Act No. 58 of 1991, with respect to intellectual property (IP);
- 2.2. provide for a fair, consistent and transparent system and procedures for the management of the MRC's intellectual assets in order to ensure compliance with the PFMA;
- 2.3. facilitate the effective identification, protection, utilisation and commercialisation of MRC intellectual property for the benefit of the people of South Africa; and
- 2.4. ensure that the relevant stakeholders are appropriately rewarded.

## 3. POLICY STATEMENT

### 3.1 General Statement

The mission of the South African Medical Research Council (MRC) is *"to improve the nation's health and quality of life by conducting and funding relevant and responsive health research, development, innovation and research translation."* In order to impact on health and quality of life, the MRC must ensure that its research is translated into new and/or improved health solutions. The aim of the MRC's policy on intellectual property is therefore to ensure that discoveries arising from MRC research are captured and translated into usable technologies and knowledge for the benefit of the MRC, MRC stakeholders and the people of South Africa, and to generate a return on investment for further investment in research.

This policy provides guidance on the ownership of and procedures for the disclosure, protection and commercialisation of any form of IP generated during the course of MRC supported research so as to make this available to industry

and others for public benefit. This policy recognises the need to achieve a balance between research excellence, academic freedom and capacity development and the need to commercialise inventions through innovative and entrepreneurial endeavour. Such applications of research findings should strive for the widest public benefit by including the IP Creator(s), the MRC, industry and society.

### 3.2. Rights and Obligations

This policy outlines the rights and obligations of the MRC and its members in disclosing, protecting and exploiting any form of IP generated during the course of research. In doing so, the MRC acknowledges that intellectual property is a key asset that requires effective and appropriate management and recognises that this policy needs to:

- 3.2.1. Promote sustainability with respect to capacity development, faculty retention, the attraction of new scientists into the system, research resource mobilisation and income generation;
- 3.2.2. Encourage research excellence and provide incentives for the development of IP and the commercialisation of resulting technologies for the best interest of the IP creator(s), the MRC, industry and society;
- 3.2.3. Promote the open dissemination and free exchange of research results and information among scholars after first ensuring that any IP is adequately protected;
- 3.2.4. Provide enabling guidelines and procedures for the disclosure, protection and commercialisation of IP and decision making thereon;
- 3.2.5. Clearly outline ownership rights of IP with respect to the MRC, its members and research partners and sponsors and the obligation for related costs and the division of related revenues;
- 3.2.6. Comply with the MRC Act, the IPR Act, the Copyright Act, the Patents Act, the Biodiversity Act, and the PFMA; and
- 3.2.7. Support and align with the National System of Innovation and the Essential National Health Research imperatives.

### 3.3. Intellectual Property Rights

The ownership rights for Intellectual Property (IP) created by members of the MRC and others participating in MRC programmes are as follows:

- 3.3.1. All newly created or discovered IP conceived or first reduced to practice by Members of the MRC in the normal course and scope of their duties or studies shall, subject to clauses 3.3.2-3.3.18, belong to the MRC, and MRC members shall assign such rights and interests to the MRC.
- 3.3.2. In cases where IP is generated by persons who have received External Capacity Development Awards from the MRC, ownership of the IP shall vest in the university at which the person is working or studying. Where the External Capacity Development Award includes a monetary contribution to the research costs then, notwithstanding IP ownership by the university, any income or benefits earned from that IP shall be shared proportionately with the MRC. Benefit sharing proportions will be determined on a case-by-case basis, depending on the relative contributions of the MRC and the university to the development and commercialisation of the IP in question.
- 3.3.3. In cases where IP is generated by MRC employees who have received Internal Capacity Development Awards from the MRC but are registered at a university or other educational institution for a higher

degree, ownership of the IP shall vest jointly in the MRC and the university. Any income or benefits earned from such IP shall be shared proportionately between the MRC and the university. Benefit sharing proportions will be determined on a case-by-case basis, depending on the relative contributions of the MRC and the university to the development and commercialisation of the IP in question.

- 3.3.4. IP developed by visiting researchers and students during the course of their visit, as a result of their use of the MRC's resources and facilities, or as a result of conducting work conceived and/or initiated by an MRC staff member, shall be jointly owned by the MRC and the employer of the visitor. The MRC's claim to IP ownership does not extend to any previously developed intellectual property. Visiting researchers and students must, prior to their visit, sign an agreement in terms of which they undertake to keep confidential all confidential information which may come to their attention during their visit to the MRC, and not to use it otherwise than as may be permitted by the MRC, and agree to comply with the terms of the MRC's IP policy. The participation of visiting researchers and students in the sharing of any income or benefits resulting from IP developed during their visit to the MRC or as a result of conducting work conceived and/or initiated by an MRC staff member shall be the responsibility of their employer.
- 3.3.5. In cases where IP is generated at external MRC Research Units, Groups, Lead Programmes or Centres located within universities, ownership of the IP shall vest in the university, except where an MRC-salaried person is involved in the invention as an IP Creator, in which case the IP will be co-owned by the MRC and the university. Notwithstanding IP ownership, benefits derived from exploitation of any IP developed in an external MRC Research Unit, Group, Lead Programme or Centre will be shared between the MRC and the university. For co-owned IP, the Technology Transfer Office of the MRC (TTO) and the Technology Transfer Office at the relevant university shall decide on a case-by-case basis on which of the offices shall take the lead (the lead organisation) in the protection and commercialisation of the IP and how costs will be apportioned. The proportions of benefit sharing will be determined on a case-by-case basis and will depend on the relative contributions of the MRC and the university to the development and commercialisation of the IP in question. In the event that the university is elected as the lead organisation, any contract to this effect shall also provide that, in the event of failure to adequately commercialise the IP, the MRC may act alone in exploiting the IP or appointing a different entity or organisation to do so.
- 3.3.6. Where the MRC provides Self-initiated Research Grants to non-MRC members, the MRC shall not claim ownership of any resulting IP. Such IP shall be dealt with in compliance with the IPR Act.
- 3.3.7. Except under the circumstances provided for in clauses 3.3.8 to 3.3.10, where IP is developed in the course of, or resulting from, Sponsored Research or Contract Research, such IP shall vest in the MRC. In the case of Sponsored Research or Contract Research conducted at an external MRC Research Unit, Group, Lead Programme or Centre, such IP shall vest in the university, except where an MRC-salaried person is involved in the invention as an IP Creator in which case the IP will be co-owned by the MRC and the university. The sponsor or contracting party may be granted an exclusive or a non-exclusive license to the IP, provided that it has the capacity to manage and commercialise the IP in a manner that benefits the people of South Africa.

- 3.3.8. Where the sponsor or contracting party has contributed resources, which may include financial or human resources, materials and infrastructure, equipment, facilities and/or relevant background IP, and where there is joint IP creatorship (i.e. where staff members of both the MRC and the sponsor or contracting party are included as inventors), the IP resulting from the sponsored research may be co-owned by the MRC and the sponsor or contracting party, provided that appropriate arrangements are made for benefit-sharing with IP Creators at the MRC, and an agreement is concluded between the MRC and the sponsor or contracting party for the commercialisation of the IP. Such agreement shall make provision for the MRC to act alone in exploiting the IP itself or appointing a different entity or organisation to do so in the event that the co-owner(s) does not satisfy the needs of the public in South Africa reasonably, or in the event that the co-owner(s) fails to exploit the invention adequately.
- 3.3.9. Where the research was sponsored or contracted on a Full Cost basis, ownership of the IP resulting from the Sponsored Research or Contract Research (contracted by third party and grant funding is received) shall vest in the MRC, unless otherwise negotiated between the MRC and the sponsor or contracting party. Where the IP vests in the MRC, the sponsor or contracting party may be granted an exclusive or a non-exclusive license to the IP, provided that it has the capacity to manage and commercialise the IP in a manner that benefits the people of South Africa. Negotiation of IP ownership or co-ownership by the sponsor or contracting party shall be on the condition that the IP Creators are not precluded from continuing with the research or using the results in further research and that the MRC is not prevented from protecting or commercialising IP that may be dependent on the IP owned or co-owned by the sponsor or contracting party.
- 3.3.10. Where the MRC conducts clinical research on a product on behalf of a sponsor or contracting party, any IP developed as a result of such research and all research results shall belong to the MRC. If the research is funded on a Full Cost basis by the sponsor or contracting party, the IP and research results shall vest in the MRC, unless otherwise negotiated between the MRC and the sponsor or contracting party. Notwithstanding ownership of the IP and research results by the MRC, the sponsor or contracting party shall be granted the right to use the IP and research results in any regulatory submissions anywhere in the world and may be granted an exclusive or a non-exclusive license to the IP, provided that it has the capacity to manage and commercialise the IP in a manner that benefits the people of South Africa.
- 3.3.11. Where IP is developed in the course of, or resulting from, a collaborative research and development agreement involving one or more local or international funding or donor organisations, or research institutions or organisations, or by any persons assisting the MRC with research, the MRC shall own any IP developed by its members and co-own any IP jointly developed by its members and collaborators. Where the IP is co-owned, the MRC shall ensure that the IP is commercialised to the benefit of the people of South Africa. Where a co-owner is authorised to use the IP, provision shall be made in the agreement for the MRC to act alone in exploiting the IP itself or appointing a different entity or organisation to do so in the event that the co-owner does not satisfy the needs of the public in South Africa reasonably, or in the event that the co-owner fails to exploit the invention adequately. Where the collaborative agreement requires that IP emanating from the collaborative research and development be made available to the

collaborators or other parties for commercialisation on a royalty-free basis, or should not be commercialised, the MRC shall refer such agreement to NIPMO for approval, prior to commencement of work under such agreement.

- 3.3.12. Where IP is developed by persons or organisations contracted by the MRC to undertake research or services during the course of or resulting from such research or services, such IP shall belong to the MRC, subject to any applicable laws and regulations or agreements that may be in place.
- 3.3.13. The MRC will, in general, refrain from claiming ownership of copyright in published academic works (not for profit), such as journal articles, theses, reports, conference papers, presentations and proceedings, posters, books, textbooks, and book chapters, provided that the MRC has been suitably acknowledged in such works and subject to the right of the MRC to have free, non-exclusive use of such materials indefinitely within the limits of any publication restrictions.
- 3.3.14. The MRC will claim ownership of original software (including source code), databases, electronic data, websites, training materials, games, and other works with commercial value that have been developed by MRC Members. Where the MRC has been contracted or commissioned by an outside party to develop original software, databases, websites, training materials, and other works on a Full Cost basis, ownership of the copyrights in such works as well as any data and information developed shall vest in the MRC, unless otherwise negotiated between the MRC and such outside party. Where co-ownership or ownership by the outside party is negotiated, the MRC shall retain the right to use the data, information and copyrighted works for internal research purposes. Where any copyright works developed by MRC members have commercial value, such works shall be owned by the MRC and may only be used by MRC members or outside parties with the written permission of the MRC. In order to protect the copyright, MRC-owned materials must be accompanied by the following statement: *Copyright © [year] Medical Research Council. All Rights Reserved.* The date should be the year in which the work was first published.
- 3.3.15. Where members of the MRC develop software in the course and scope of their employment, such software shall belong to the MRC. MRC members may not use, distribute, reproduce, remove or otherwise copy such software or associated development material, whether written, electronic or in any other format, without the express written consent of the MRC. The source code of such software belongs to the MRC and must be delivered to the head of Information Technology at the MRC for safekeeping on completion of the development of the software, and in the event of on-going development, on completion of each version thereof.
- 3.3.16. All Trade Marks and domain names developed by members of the MRC during the course and scope of their employment and related to their work shall be registered and owned by the MRC. Trade Marks must have printed in close proximity to the Trade Mark the legend <sup>TM</sup> to indicate that the Trade Mark is being used as a Trade Mark. In the event that it is known that the Trade Mark is registered then the legend ® should be used. The use of the MRC's Trade Marks for private purposes or gain by MRC members is strictly prohibited, unless the prior written consent of the MRC has been obtained.



- 3.3.17. In cases in which the MRC has an ownership interest in IP and either does not wish to or is unable to protect and/or commercialise the IP, the MRC is obliged to refer such IP to NIPMO. Should NIPMO decide not to acquire ownership of the IP on behalf of the State, the MRC shall, within 30 days of notification by NIPMO of such decision, offer the option to acquire ownership in the IP and to obtain statutory protection for the IP to the IP Creator(s), provided that in the case where a private entity or organisation has provided some funding, such private entity or organisation shall be offered such option before the IP Creator. Should the IP be offered to a private entity or organisation, this shall be subject to the rights of IP Creators to share in the benefits of commercialisation of the IP. In the case of NIPMO taking assignment of the IP, the MRC and the IP Creators will automatically be granted an irrevocable, non-transferable, royalty free license to use the IP for research and development and educational purposes.
- 3.3.18. Any IPRs resulting from MRC supported research that involve or make use of Indigenous Knowledge shall be dealt with in a manner that ensures due recognition of the indigenous community or individual from which the knowledge originated, including recognition as IP Creators or Enablers. Such individuals and communities shall also be entitled to equitable sharing in any benefits that may accrue from commercialisation of such IP. The development, protection and exploitation of such IPRs shall comply with the Patents Amendment Act of 2005, the Biodiversity Act of 2004 and associated regulations, and the Department of Science and Technology (DST)'s Indigenous Knowledge Systems (IKS) Policy.
- 3.3.19. The MRC may become involved in the evaluation, protection and commercialisation of IP that does not originate from MRC-funded research or an MRC member, provided that such IP has the potential to fulfill the mandate and mission of the MRC. In such cases, the MRC will participate in benefit sharing in any income that may result from the IP with the benefit sharing proportions to be decided on a case-by-case basis, depending on contribution. The MRC's involvement may include co-ownership of the IP, acquisition of equity and/or access to commercialisation rights.

#### 3.4. Responsibilities of MRC Members

- 3.4.1. Members of the MRC are obligated to disclose all newly created or discovered IP, whether or not it is considered patentable and including any copyright works that may have commercial and/or social value, to the TTO, and to cooperate with the TTO in all matters, including technical, marketing, patenting and commercialisation. Such disclosure shall be made within 90 days of identification of possible IP and before the IP is made public.
- 3.4.2. The form for disclosing newly generated IP is entitled "MRC Invention Disclosure Form" and is available from the MRC TTO. 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, Groups, Lead Programmes and Centres located within universities, members must submit an Invention Disclosure Form to the Technology Transfer Office or equivalent designated authority at the university. The mechanism for progressing the IP will be determined by mutual agreement between the TTO and the Technology Transfer Office of the university.

- 3.4.3. Members of the MRC are obligated to cooperate with and sign any documents necessary for the MRC to record itself as the owner or co-owner of the IP.
- 3.4.4. It is the responsibility of members of the MRC to maintain the confidentiality of any potential IP and to ensure that no public disclosure, including submission for publication or presentation to any parties, of any potential IP occurs prior to its having been submitted to the TTO and a clearance for publication or presentation having been obtained from the TTO.
- 3.4.5. 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 and other records associated with an invention patented by the MRC must be submitted for safekeeping to the unit director on ceasing to be a member of the MRC.
- 3.4.6. Members of the MRC who conduct research at other organisations or educational or research institutions for any reason, must, in consultation with the TTO and Legal Services, ensure that appropriate agreements regarding IP rights are concluded prior to the initiation of the research.
- 3.4.7. Members of the MRC who wish to transfer tangible materials such as monoclonal antibodies, genes, nucleic acid probes and promoters, clones, cell lines, plasmids, viruses, seeds, specially modified whole animals, and any other research material to any third party, whether for research or any other purpose, must inform the TTO of such proposed transfer. The TTO and Legal Services will arrange for the MRC and the receiving party to sign a Material Transfer Agreement governing the transfer and no such transfer shall take place until the necessary agreements are place.
- 3.4.8. No member of the MRC may conduct contract research for an outside organisation without the necessary agreements in place prior to commencement of the research. Such agreements must be approved by Legal Services and the TTO and signed by the MRC.
- 3.4.9. Any consulting work conducted by MRC members beyond normal working hours must be approved by the member's manager. Such consulting work must be done in a private capacity without association with the MRC and any agreement relating to such consulting work shall not include the MRC as a party.
- 3.4.10. Any consulting work conducted by MRC members during normal working hours must be approved by the member's manager. Such consulting work shall be subject to an agreement to which the MRC is a party and that has been approved by Legal Services. Any compensation received in consideration for such consulting work shall accrue to the MRC in the absence of any arrangement to the contrary approved by the member's manager.
- 3.4.11. No MRC member may proceed on their own initiative with the protection and/or commercialisation of IP arising in the normal course and scope of their employment or studies, without the prior written consent of the MRC.
- 3.4.12. MRC members may not use or exploit any IP owned by the MRC on a commercial basis without the written permission of the MRC.

3.4.13. IP Creators and IP Enablers who leave the employ of the MRC or otherwise become no longer MRC members may not make use of the IP they created without the express written permission of the MRC.

### 3.5. Responsibilities of the Technology Transfer Office

3.5.1. The administration of this Policy and the obligations of the MRC in terms of the IPR Act are the responsibility of the TTO.

3.5.2. The TTO is responsible for the identification, disclosure, evaluation, protection, development, management and commercialisation of IP, all benefit sharing arrangements in accordance with the MRC's Benefit Sharing Scheme, and appropriate capacity-building relating thereto. The TTO may, on behalf of the MRC and, where relevant, any co-owners, apply for a patent or any other form of IP registration in respect of any IP, and the MRC shall be regarded as the applicant or assignee of the patent or other form of IP protection. The filing of provisional, Patent Cooperation Treaty (PCT) and complete South African patent applications and the registration of designs and trademarks shall be at the discretion of the TTO. The TTO shall make a recommendation on the most appropriate commercialisation route to the Executive Management Committee (EMC), which shall make the final decision thereon on behalf of the MRC.

3.5.3. 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 will be advised by the TTO of the MRC entering into any contracts for the commercialisation, use or sale of that IP.

3.5.4. All invention disclosures and discussions on inventions with members will be subject to full confidentiality. The TTO shall, as soon as possible after disclosure, advise the IP Creators as to when they may publicly disclose such IP through publication and/or presentation or any other means. Clearance would normally be provided after any applications for the registration of the relevant IP have been filed.

3.5.5. The TTO may, with the approval of the EMC and consistent with the MRC's procurement systems, opt to use a technology transfer agency. In using any such agency, the TTO may enter into any commercially-reasonable arrangement for the sharing of royalties with such agencies. In such cases, only royalties payable to the MRC shall be subject to the MRC's Benefit Sharing Scheme.

### 3.6. Confidentiality

Where IP has been developed, in order to preserve the potential patentability, it is necessary to maintain the confidentiality of such IP. After the filing of provisional protection for the IP, the TTO will advise the IP Creators on whether it is necessary to continue to maintain the confidentiality of the IP in order to facilitate additional IP protection in the future or to preserve the commercial opportunity. Where an IP Creator wishes to disclose limited information on the creation or discovery of new IP to a third party, the IP Creator(s) must inform the third party of the confidential nature of such disclosure and arrange for the third party receiving such information to sign a non-disclosure agreement (NDA) in form and substance acceptable to the TTO before such disclosure. The TTO should be consulted before any disclosure of IP is made to third parties and will

advise on what may be disclosed without requiring a NDA. Even where an NDA has been signed, MRC members should refrain from making full disclosure of an invention or know-how to a third party.

### 3.7 Agreements

- 3.7.1 No member of the MRC may enter into any agreement on behalf of the MRC or any agreement relating to MRC IP. All agreements relating to MRC IP and/or to which the MRC is a party, including Material Transfer Agreements, must be drafted and/or reviewed and approved by Legal Services and signed by the President of the MRC or alternative designated authority. All IP related agreements and IP clauses in other types of agreements must, in addition, be reviewed and approved by the TTO.
- 3.7.2. All NDAs must be approved by Legal Services or the TTO and signed by the President of the MRC (or his/her designee), a member of Legal Services, or the Director of the TTO.
- 3.7.3. It is the responsibility of members of the MRC to be aware of IP clauses of research, collaboration and consortium contracts, and other clauses which place obligations on MRC members, and to ensure that they comply with the terms of such agreements.
- 3.7.4. Employees of the MRC may not enter into agreements related to outside employment, such as consulting agreements, that are in conflict with this IP Policy or may in any way affect the IP Rights of the MRC.
- 3.7.5. It is the policy of the MRC to ensure, in so far as is possible, the effective use of its IP for the benefit of the IP Creator(s), the MRC, and the people of South Africa and this aim is to be reflected in all IP contracts whereby IP of the MRC is to be exploited by an outside entity or organisation.

### 3.8. 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 from the TTO to avoid premature disclosure which will prevent any patent protection being sought.

### 3.9. Decision Making on IP and Commercialisation

- 3.9.1. The EMC is responsible for decisions on IP issues which have substantial long term financial commitments for the MRC as well as any transactions relating to the commercial use of MRC IP, based on recommendations from the TTO, including:
  - 3.9.1.1. Whether to enter national phase internationally for patents and in which countries
  - 3.9.1.2. Whether to spin out a company
  - 3.9.1.3. Whether the MRC should take equity in a spin-out company and how much

- 3.9.1.4. Whether the MRC should sell equity in a spin-out company and how much
  - 3.9.1.5. The involvement of inventors in spin-out companies as shareholders, directors, executive managers and/or consultants
  - 3.9.1.6. Who to appoint as a director to represent the MRC in spin-out companies
  - 3.9.1.7. Whether the MRC should enter into a joint venture and with whom
  - 3.9.1.8. Who to license MRC IP rights to and under what broad license terms
  - 3.9.1.9. Whether to place an invention in the public domain
  - 3.9.1.10. Whether to abandon an international patent or patent application
  - 3.9.1.11. Benefit sharing models with indigenous knowledge holders
- 3.9.2. The EMC is also responsible for settling any disputes that might arise in the application of this policy, and other IP-related decisions and for endorsing recommended changes to the MRC IP policy for ratification by the Board of the MRC.
- 3.9.3. When decisions are required by the EMC, the TTO will distribute a technology brief with recommendations to all EMC members and the Director of IC will present the brief at the EMC meeting. A person deemed to be an expert in the relevant technology or market under evaluation can be nominated by the TTO or the EMC to provide advice to the EMC in taking such decisions.
- 3.9.4. The TTO is responsible for the implementation of decisions made by the EMC.

### 3.10. Commercialisation

The MRC recognises that, as a public entity, it is required to manage its intangible assets in a fair, consistent and transparent manner and to ensure that they are applied for the benefit of the Republic of South Africa, in order to ensure compliance with the PFMA and the IPR Act. The MRC also recognises that identifying partners willing to take on the further development and commercialisation of IP is a challenge and, due to the specific expertise and infrastructure required, cannot be achieved through standard procurement processes. Thus decision making with respect to the commercialisation of the MRC's IP shall be based on the strategy and partner most appropriate to ensure the broadest application of the IP and the maximum benefit for the MRC and the people of South Africa, which benefit could include capacity development, technology transfer, job creation, enterprise development, social upliftment and the implementation of new products, processes and services.

The MRC may make use of one or more different means of commercialising its IP, including:

- Licensing
- Spin-out companies and subsidiary companies of the MRC
- Joint ventures
- Direct sale of products and services
- Providing open access to the IP
- Combinations of the above

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

Where IP is co-owned, any commercialisation shall be undertaken in consultation with and with the agreement of all co-owners, except in cases where the MRC has retained the right to act on its own with respect to commercialisation of the IP.

### 3.10.1. Licensing

3.10.1.1. License agreements will be negotiated with external parties to ensure commercialisation and the receipt of commercially reasonable royalties. Licenses may be exclusive (i.e. only one license is granted) or non-exclusive, in which instance a plurality of licenses may be granted. Licenses may be restricted to a particular geographic area, a particular market or manufacturing or processing sector or any other restricted sector, or a field of use.

3.10.1.2. The identification of potential licensees shall, in line with international best practice, be done on the basis of best fit for the IP in question and not through a tender process. The TTO will, through its due diligence process, identify potential licensees that have the necessary skills, expertise, networks and capacity to further develop and commercialise the IP. Where there is more than one party interested in acquiring a license to MRC IP, preference shall be given to BBBEE compliant entities, Small Enterprises, parties that seek to use the intellectual property in ways that provide optimal benefits to the people of South Africa, and parties that have made a material contribution to the research. Where appropriate, preference will also be given to non-exclusive licensing.

3.10.1.3. Where an exclusive license is required, minimum performance or diligence clauses will be included and provision will be made, where feasible, for the licensee to manufacture process and otherwise commercialise within South Africa. The prospective licensee will be required to furnish the TTO with a satisfactory development and marketing plan. The license will include any other appropriate terms to ensure that the benefits of the IP are reasonably accessible to the people of South Africa.

3.10.1.4. All exclusive licensees will be notified of the rights of NIPMO to intervene and/or for the license to be converted to a non-exclusive license where the licensee is not able to continue with the commercialisation of the IP in South Africa or where the IP is not commercialised within a reasonable period.

3.10.1.5. Each IP transaction that involves IP which falls within the IPR Act (i.e. all MRC IP except for that emanating from research that was funded by a sponsor on a Full Cost basis) will:

- provide the State with an irrevocable and royalty-free license authorising the State to use or have the IP used throughout the world for the health, security and emergency needs of the Republic;
- include provision for the State to have walk-in rights with respect to the IP in situations where a party fails to commercialise the IP to the benefit of the people of South Africa;

- include the following statement: *“The intellectual property properly under this transaction was created with support from the South African Government and is subject to the requirements of the South African Intellectual Property Rights from Publicly Financed Research and Development Act, 2008 and its regulations (“Act 51 of 2008”). The South African Government has certain rights to the intellectual property in terms of sections 3.10(1)(e), 3.10(2) and 14 of Act 51 of 2008.”*
- 3.10.1.6. Any licensing of MRC owned IP to parties outside of South Africa (offshore transactions) will be subject to the necessary statutory approvals, including approval from NIPMO, and will comply with all regulations and guidelines relating to the IPR Act. The MRC shall ensure that the people of South Africa will benefit from such transactions. An exclusive offshore license shall only be contemplated where there is insufficient capacity in South Africa to develop or commercialise the IP locally.
- 3.10.1.7. All licenses granted by the MRC shall reserve the right for the MRC and, where appropriate, other publicly funded entities in South Africa, to use the IP internally for research, development and educational purposes.
- 3.10.1.8. All licenses granted by the MRC that relate to new health solutions that may benefit developing country or poorer populations shall incorporate socially responsible licensing principles to ensure affordable access.
- 3.10.2. Spin-out Companies and Subsidiary Companies of the MRC
- 3.10.2.1. 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 and may be for-profit or not-for-profit companies.
- 3.10.2.2. Equity Holdings
- 3.10.2.2.1. The MRC may elect, subject to the approval of the Minister of Health and National Treasury, to take an equity stake in any spin-out company established to commercialise MRC IP. In such cases, MedRes (Pty) Ltd shall hold the shares in the spin-out company on the MRC’s behalf. Where MedRes holds a controlling equity stake in the company (>50% shareholding), the company shall be subject to the Public Finance Management Act.
- 3.10.2.2.2. 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.

- 3.10.2.2.3. IP Creators/Enablers responsible for the IP used in forming the spin-out company may own shares in the company. Where the IP Creators/Enablers are interested in establishing their own company to commercialise the IP, such company will be given first option to license the IP, provided that the company has the capacity and skills to commercialise such IP to the benefit of the people of South Africa, and providing that doing so shall not be at a significant cost to the MRC or the IP. The MRC may, at its own discretion and subject to the approval of the Minister of Health and National Treasury, elect whether or not to take equity in such company.
- 3.10.2.2.4. The allocation of equity in spin-out companies between the MRC and IP Creators/Enablers shall be negotiated on a case-by-case basis. The default position is that such equity shall be held in the following proportions, 51% MRC and 49% IP Creators/Enablers. Deviations from these proportions may be negotiated on a case-by-case basis. Where the MRC receives equity in a spin-out company as part of the IP transaction, i.e. as full or partial consideration for licensing or assignment of the IP to the company, a portion of such equity shall be allocated to the IP Creators/Enablers in line with the MRC's Benefit Sharing Scheme.
- 3.10.2.2.5. Shares owned by parties are subject to dilution in the event of investment by third parties e.g. venture capital investment.
- 3.10.2.3. Directorships, Management Positions and Consulting
  - 3.10.2.3.1. The MRC retains the right to appoint a non-executive director or observer at board meetings of companies in which it holds equity through MedRes.
  - 3.10.2.3.2. IP Creators/Enablers may act as non-executive directors and/or form part of the Scientific Advisory Board of the spin-out company, within the framework of the MRC's Conditions of Service. In doing so they will not serve as representatives of the MRC.
  - 3.10.2.3.3. In the event that a member of the MRC wishes to become involved in a spin-out company in an executive or a consulting capacity, such involvement must be approved by the member's manager and the EMC. Involvement of MRC members in spin-out companies shall, at the discretion of the EMC, be on one of the following bases: a.) reduction of the member's hours and remuneration in proportion to the amount of



time contributed to the spin-out company, in which case any remuneration received from the spin-out company shall accrue to the member; or b.) secondment of the member on a part-time or full-time basis to the company, in which case the MRC shall be remunerated for such time at a value equivalent to the salary of the member. In both cases, the MRC member shall be required to maintain existing benefits such as medical aid, pension and Group insurance in line with the rules of such benefit schemes. Any secondment arrangement shall be for a maximum period of one year, unless otherwise agreed by the member's manager and the EMC, after which the MRC member shall be required to leave the employ of the MRC if they wish to continue their involvement with the spin-out company.

3.10.2.4. Licensing or Assignment of IP to a Spin-out Company

3.10.2.4.1. The MRC may elect to license or assign IP to a spin-out company in return for shareholding, upfront payment or royalties. In general, the policy of the MRC is to refrain from assigning IP unless under exceptional circumstances. Any assignment of IP to a spin-out company shall be on the condition that the company is domiciled in South Africa and that, in the event of the liquidation of the spin-out company, the IP shall revert to the MRC prior to such liquidation. Any assignment of IP by the MRC shall be subject to the approval of NIPMO.

3.10.2.5. Responsibilities for Establishment of Spin-out Companies

3.10.2.5.1. The TTO shall be responsible for all procedures required for the establishment of new companies in which the MRC elects to take equity through MedRes, including company registration, company documentation, registration for income tax etc. Relevant agreements, such as Shareholder Agreements, shall be negotiated by the TTO in consultation with Legal Services.

3.10.2.5.2. The appointment of directors to act on behalf of the MRC in spin-out companies shall be the responsibility of the EMC.

3.10.2.5.3. The TTO shall incubate and provide on-going support and strategic advice to spin-out companies, as required. The MRC may negotiate a market related compensation or additional equity in the spin-out company in exchange for such services.

3.10.3. Joint Ventures

3.10.3.1. The MRC may elect, subject to the approval of the Minister of Health and National Treasury, to enter into a Joint Venture (JV) company with an outside entity or organisation for the exploitation of IP, the production of

products or the provision of services, in which instance MedRes shall become a shareholder in the JV company on the MRC's behalf.

3.10.3.2. The MRC may license or assign the IP to the JV company. Any assignment of IP to the JV company shall be on the condition that the company is domiciled in South Africa and that, in the event of the liquidation of the JV company, the IP shall revert to the MRC prior to such liquidation. Any assignment of IP by the MRC shall be subject to the approval of NIPMO.

3.10.4. Direct sale of products and services

3.10.4.1. In the event that an MRC member is able to sell products and/or services directly from their laboratory or premises without the assistance of the TTO, such members shall be permitted to do so, provided that the TTO is informed of all such activities.

3.10.4.2. Where such products and/or services are deemed by the TTO to involve IP that falls within the IPR Act, the TTO and Legal Services will ensure that the necessary agreements are in place to protect the MRC, the MRC member and the IP before the sales are executed. In such cases, a portion of the revenues received from the direct sales shall accrue to the IP Creators/Enablers, in line with the MRC's Benefit Sharing Scheme.

3.10.4.3. Revenues from the direct sale of copyright works on which the MRC would not normally exert IP ownership may accrue directly to the creator or author of such work, provided that significant use is not made of the MRC branding and MRC facilities to sell the work. Such works may not be sold within the MRC for personal gain. All transactions by MRC members in respect of copyright works owned by them must be concluded in their own name and will be for the account and responsibility of such MRC members only.

3.10.5. Providing Open Access to MRC IP

3.10.5.1. The MRC may, subject to the approval of NIPMO, decide to provide access to MRC 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.

3.10.5.2. Where the intention of a research project or collaboration involving MRC members is to place any resulting IP, including software, in the public domain through open-source or open-access systems, such action, and any agreement relating thereto, shall be subject to the approval of the TTO and NIPMO, prior to commencement of the research.

3.11. Conflicts of Interest and Commitment

3.11.1 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 potential conflict of interest does not necessarily imply wrongdoing on anyone's part. When conflicts of interest do arise, however, they must be recognised, disclosed and properly managed.

The following principles are among those that underlie the MRC policy on conflicts of interest as they pertain to IP and commercialisation:

- 3.11.1.1. MRC 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.
  - 3.11.1.2. MRC members should not seek to influence the MRC's technology transfer decisions in ways that could lead to improper personal gain; give improper advantage to their associates; or result in reduced income to the MRC.
  - 3.11.1.3. MRC members may 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.
  - 3.11.1.4. MRC members who are involved in a spin-out company shall not compete with such enterprise or be involved in any other entity that competes with such enterprise by providing similar goods or services without prior authorisation from the MRC.
- 3.11.2. Conflict of Commitment
- 3.11.2.1. MRC members are expected to accord the MRC their primary professional loyalty, and to arrange outside obligations, financial interests and activities so as not to conflict with this overriding commitment. Members of the MRC are also 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 recognised 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 and require the approval of the relevant line manager.
  - 3.11.2.2. Professional effort may be directed to outside work resulting from IP generated at the MRC. For example, the IP Creator(s) may be required to offer consultancy services to a licensee or spin-out company in order to facilitate transfer of the technology and know-how or they may wish to become involved in an executive capacity in a spin-out company. Such involvement shall be in accordance with clause 3.10.2.3.3. of this policy.

## 3.12. MRC Benefit Sharing Scheme

The MRC wishes to share with IP Creator(s)/Enabler(s) whatever material benefits that may arise from the beneficiation of MRC IP. As such, IP Creator(s)/Enabler(s) and their heirs are granted a right to a portion of the revenues that accrue to the MRC from their IP for as long as revenues are derived from such IP and accrue to the MRC.

#### 3.12.1. Beneficiaries from the Exploitation of Intellectual Property

There are four possible beneficiaries from the exploitation of MRC IP:

- the IP Creator(s)/Enabler(s)
- the Unit/Programme/Centre/Group (the Entities) or Department of which the IP Creator(s)/Enabler(s) are members
- the MRC TTO
- the MRC – corporate contributions

3.12.1.1. All IP Creator(s)/Enabler(s) and Units / Programmes / 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 TTO 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 TTO. This declaration will determine the sharing of the IP Creator(s)/Enabler(s)’s and Unit’s portions of benefits. Any changes to these contributions or the inclusion of 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 benefits. The same applies where more than one Unit / Programme / Centre / Group is involved. In the absence of an agreement, benefits will be shared equally between IP Creators / Enablers and their respective units.

3.12.1.2. 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 Committee Member and the Dean of Faculty (where applicable) will decide on the matter(s). If the dispute is still unresolved, the EMC will make a final decision on the matter(s).

#### 3.12.2. 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:

- Licence fees
- Evaluation fees
- Milestone payments
- Royalty income
- Outright sale of IP
- Sale of commercial ventures built around MRC IP
- Sale of shares in such commercial ventures
- Dividends derived from such commercial ventures
- Commissions
- Direct sale of products or services

#### 3.12.3. MRC Benefit Sharing Scheme

- 3.12.3.1. Subject to clauses 3.12.3.2. - 3.12.3.6., any income that accrues to the MRC as a result of the implementation of IP developed by an MRC member shall be shared with the beneficiaries as follows:

For the first R1 million of income where there are no expenses, the income shall be split as follows: 35% to the inventors, 35% to the unit, and 30% to the MRC.

For the first R1 million of income where there are expenses to be deducted, the income shall be split as follows: 25% of gross income or 35% of net income, whichever is greater, shall be paid to the inventors. Expenses incurred will be deducted from the remaining amount and reimbursed to the TTO or relevant unit and any surplus thereafter will be split as follows: 50% to the unit and 50% to the MRC.

For any income received over and above R1 million, the net income (after deduction of any remaining expenses) shall be split as follows: 35% to the inventors, 35% to the unit, and 30% to the MRC.

- 3.12.3.2. This Benefit Sharing Scheme will apply for all IP that produces income. An IP Creator/Enabler may therefore be able to benefit from more than one invention. Beneficiaries are entitled to share in benefits for as long as the MRC continues to receive benefits
- 3.12.3.3. The MRC's Benefit Sharing Scheme shall not apply to research grants or other monetary and non-monetary contributions which are provided to support research or to income from the direct sale of products or services that it has been agreed will accrue directly to MRC members or MRC Units/Programmes/Groups/Centres, for example books, handbooks, databases etc.
- 3.12.3.4. Where the IP Creators/Enablers own equity in a spin-out company in which the MRC also owns a corresponding share, any dividend or sale of equity income earned by the MRC as a result of such equity shall not be subject to the MRC's Benefit Sharing Scheme. However, any income earned by the MRC as a result of licensing or assignment of the IP to the spin-out company is subject to the MRC's Benefit Sharing Scheme.
- 3.12.3.5. Where the MRC owns equity in a spin-out company but the IP Creators/Enablers have elected not to take equity, then both dividend and sale of equity income earned by the MRC as a result of such equity and any income earned by the MRC as a result of licensing or assignment of the IP to the spin-out company shall be subject to the MRC's Benefit Sharing Scheme.
- 3.12.3.6. Where the IP Creators/Enablers own equity in a spin-out company but the MRC has elected not to take equity, then the sharing of income earned by the MRC as a result of licensing or assignment of the IP to the spin-out company shall be determined on a case-by-case basis.

- 3.12.3.7. The benefits to IP Creators/Enablers and their heirs shall be a first call on the applicable income ahead of any institutional distribution.
- 3.12.3.8. After death, benefits 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).
- 3.12.3.9. Benefits 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.
- 3.12.3.10. The TTO shall ensure that IP Creators/Enablers receive their portion of the benefits referred to above within 120 days of receipt of any revenue by the MRC, or such extended period of time as may be agreed upon in writing by the MRC and the IP Creators/Enablers.
- 3.12.3.11. If the MRC is unable to affect payment because of incorrect or inadequate banking details, the MRC will keep the relevant amounts in trust for a maximum period of 3 (three) years after which all rights of IP Creators/Enablers to receive such payments will be forfeited and the money will be taken out of trust. If the MRC pays an amount into an incorrect account as a result of information supplied to it being outdated or incorrect, the MRC will not have any further obligation or liability in respect of such payment, which will be deemed to have been duly and properly made.
- 3.12.3.12. At least a portion of the awards received by the Unit/Programme/Group/Centre must be used to fund further research and development. At least a portion of the funds accruing to the MRC shall be used to fund the operations of the TTO and the protection and commercialisation of MRC IP.
- 3.12.3.13. In cases where IP is shared with universities and the parties decide to reward inventors and their respective units before splitting the income between the institutions, any remaining income accruing to the MRC shall accrue to the MRC corporate. The rewarding of inventors and their respective units shall be in accordance with the IP Policy of the relevant university or the MRC, whichever is more favourable for the IP Creators/Enablers. Payments to MRC members shall be made by the MRC and are subject to normal employee taxes.
- 3.12.3.14. The MRC reserves the right to modify the Benefit Sharing Scheme for IP beneficiaries in accordance with international best practice in the best interest of firstly, the IP Creator(s)/Enabler(s) and thereafter the other beneficiaries, subject to compliance with the IPR Act.

3.12.3.15. Where IP owned or co-owned by the MRC results from indigenous knowledge, the MRC shall enter into a benefit sharing arrangement with the indigenous knowledge holder(s) to ensure fair and equitable sharing of any resulting benefits. Such benefit sharing arrangement shall be in compliance with the Patents Amendment Act of 2005, the Biodiversity Act of 2004 and associated regulations, and the DST's IKS Policy, shall be determined on a case-by-case basis, and may include the establishment of a trust fund.

#### 3.12.4. Non-monetary Benefits Derived from the Exploitation of Intellectual Property

3.12.4.1. The MRC will as far as possible refrain from accepting non-monetary benefits from the commercialisation of MRC IP.

3.12.4.2. Where non-monetary benefits, such as new equipment or facilities, do accrue to the MRC as a result of commercialisation of MRC IP, the sharing of such benefits shall be dealt with as follows:

3.12.4.2.1. The monetary value of the benefit shall be determined upfront and used to calculate the proportion which should accrue to the IP Creators/Enablers in terms of the MRC's Benefit Sharing Scheme.

3.12.4.2.2. Where sufficient funds are available to reimburse the IP Creators/Enablers for their share of the non-monetary benefit, such funds shall be paid to the IP Creators/Enablers in cash.

3.12.4.2.3. Where sufficient funds are not available to reimburse the IP Creators/Enablers for their share of the non-monetary benefit, the MRC shall hold such non-monetary benefit in co-ownership with the IP Creators/Enablers until such time as the MRC is able to purchase the IP Creators/Enabler's share of the benefit, or the value of the benefit is realised, e.g. the equipment or sold or leased or otherwise commercially exploited, at which point the IP Creators/Enablers will receive their portion of such value in cash. The MRC will be solely entitled to determine possession, use and commercial exploitation of all such co-owned non-monetary benefits. If the MRC elects to purchase the IP Creators/Enabler's share of the co-owned benefit, the MRC will seek to agree the purchase price of the share with the IP Creators/Enablers. Failing such agreement, the MRC may have the share valued by independent auditors, whose valuation will be final and binding.

#### 3.13 Dispute Resolution

3.13.1. 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 should be brought to the attention of the TTO.

3.13.2. The TTO 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 TTO Director, the EMC will be asked to resolve the dispute. If such a dispute cannot be resolved by the EMC, the MRC President will be asked to resolve the dispute. Failing resolution, the MRC President 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 and any decision of the arbitrator shall be binding on the parties. At any point, if any party chooses to seek legal remedy and to proceed in law, the mediative role of the TTO, the EMC, and the MRC President shall end.

### 3.14 Electronic Communications and Transactions

All MRC members and the TTO must ensure that all electronic communications and transactions are in accordance with the Electronic Communications and Transactions Act, 2002.

### 3.15. Implementation

This policy complies with and expands on the South African Medical Research Council Act 58 of 1991, and shall apply from the date of Board approval. All IP conceived or first reduced to practice between the 22 May 1991 and the approval date of this policy shall be subject to the previous MRC IP Policy, except where this has a negative effect on the rights of the inventors and where it is in conflict with the IPR Act.

Waivers of the provisions of this policy may be granted by the EMC 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, whether the waiver would result in a conflict of interest, and subject to approval from NIPMO, where required.

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.

## 4. SCOPE

This policy applies to all members of the MRC as defined in 5.20 and all MRC-funded research.

## 5. DEFINITIONS APPLICABLE TO THE POLICY

### 5.1. BBBEE –

Broad-based black economic empowerment means the economic empowerment of all black people including women, workers, youth, people with disabilities and people living in rural areas through diverse but integrated socio-economic strategies that include, but are not limited to -

- a) increasing the number of black people that manage, own and control enterprises and productive assets;
- b) facilitating ownership and management of enterprises and productive assets by communities, workers, cooperatives and other collective enterprises;
- c) human resource and skills development;
- d) achieving equitable representation in all occupational categories and levels in the workforce;
- e) preferential procurement; and
- f) investment in enterprises that are owned or managed by black people (as defined in section 1 of the Broad-Based Black Economic Empowerment Act No. 53 of 2003).



- 5.2. Commercialisation – means the process of gaining financial and/or social benefit from the IP generated by members of the MRC. It includes protecting, managing and developing the commercial value of IP and research, most commonly through the creation of linkages with industry and the creation of commercial enterprises linked by formal legal agreements to the MRC.
- 5.3. Conflict of Interest – means an instance in which the relevant individual is involved in more than one employment position (including one of self-employment) wherein one employment position could possibly adversely influence the motivation for action or inaction in the other.
- 5.4. Consulting Work – refers to private work conducted by an MRC member in which he/she makes his/her knowledge and expertise available to a third party or applies his/her knowledge and expertise to solve a problem for a third party in exchange for compensation, without any substantial use being made of the MRC's facilities, infrastructure or other staff.
- 5.5. Contract Research – refers to research that is commissioned by an outside organisation (contracting party) and that makes use of the MRC's staff, facilities and/or infrastructure.
- 5.6. Economic Interest – means a shareholding, a management position or board membership or any other fiduciary relationship held by an MRC member with an entity or organisation other than the MRC.
- 5.7. Expenses – means out-of-pocket costs, fees and expenses that the MRC incurs, including filing, prosecuting, developing and maintaining any statutory protection of intellectual property; defense, validation and enforcement of intellectual property rights; legal advice and services; auditing, recovery or collection of gross revenues; business research, business development, marketing, advertising, promotion or sales activities or services, reasonable travel, subsistence and administrative expenses, but excluding costs associated with prior research and development.
- 5.8. External Capacity Development Awards – means monetary awards provided by the MRC to individuals working or studying at universities and/or medical facilities for the purposes of capacity development. Such awards include, but are not limited to, bursaries for Masters and Doctoral studies, research training internships for black students, research training scholarships for Allied Health Professionals, post-doctoral awards, MRC career awards, post MBChB and BChD grants, overseas doctoral scholarships, research development grants, travel grants and grants for conference attendance.
- 5.9. Full-Cost Sponsored Research – refers to research, training and instructional projects in which the full cost of undertaking the research and development, as determined in accordance with the MRC's Full Cost Model and including all applicable direct costs (including staff salaries, bursaries, equipment and other running costs) and indirect costs (which cover buildings, rent, services and other overheads, etc.), are covered by the sponsor.
- 5.10. Indigenous Knowledge – refers to the knowledge, innovations and practices of indigenous and local communities. Developed from experience gained over the centuries and adapted to the local culture and environment, indigenous knowledge is transmitted orally

from generation to generation. It tends to be collectively owned and takes the form of stories, songs, folklore, proverbs, cultural values, beliefs, rituals, community laws, local language, and agricultural practices, including the development of plant species and animal breeds. Indigenous knowledge is mainly of a practical nature, particularly in such fields as agriculture, fisheries, health, horticulture, and forestry.

- 5.11. Intellectual Property (IP) – for the purposes of this policy, Intellectual Property is defined as any new or useful method, process, machine, device, composition of matter, life form, article of manufacture, software, database, data set, copyrighted work, and know-how and information associated with the above. It includes but is not restricted to such things as new or improved devices, circuit layouts, chemical compounds, drugs, genetically engineered biological organisms, data sets, databases, software, or unique and innovative uses of existing inventions. Innovations in the social sciences are also considered to be intellectual property, provided that they are novel and have social and/or economic application. Intellectual Property may or may not be protectable under legislation, and may be tangible (e.g. biological organisms, plant varieties, computer software, engineering drawings etc.) or intangible (e.g. patents, copyrights, ideas, tacit knowledge etc.). There are broadly two types of Intellectual Property, those that require formal registration and those that do not.

*Forms of IP that require registration:*

- 5.11.1. *Patent* – a grant by the patent office to an IP Creator of the right to exclude others from making, using, or selling their creation or invention. A patent confers the right to exclude others from a precisely defined scope of invention in return for full disclosure of the details of the creation or invention to the public so that others can understand it and use it to further develop the technology. Once the patent expires, the public is entitled to make and use the invention and is entitled to a full and complete disclosure of how to do so. To be patentable, an invention must be novel, have utility, and differ from what skilled users might expect (non-obvious).
- 5.11.2. *Trademark* – a distinctive word, design or graphic symbol or combination of word and design that distinguishes and identifies the goods and services of one party from those of another.
- 5.11.3. *Plant Breeders' Rights* – exclusive commercial rights to a registered plant variety. The rights are a form of Intellectual Property and are administered under the Plant Breeders' Rights Act of 1976. To be eligible for protection, a plant variety must adhere to three broad criteria, i.e. distinctiveness, uniformity and stability.

*Forms of IP that do not require registration:*

- 5.11.4. *Confidential Information* – includes trade secrets, know-how or other information that involves an obligation of confidentiality. There is no legislation available to protect confidential information; however, common law principles apply and protection depends on the relationship between the parties and any contracts that may be in place.
- 5.11.5. *Copyright* – provides legal rights to, including but not limited to, literary works, artistic, musical and dramatic works, computer programmes and software, films, sound recordings, broadcasts, published editions and performances. Copyright confers an exclusive right on the creator to exclude others from reproducing, adapting, distributing, performing or displaying their works in public. To be valid, a copyrighted work must have originality and be reduced to material form. Copyrights arise automatically and generally do not have to be registered. There is only provision in South Africa for the registration of copyright in cinematograph films. In some other countries it is possible to register copyright.

- 5.12. Intellectual Property (IP) Creators/Inventors – refers to individuals who are deemed to have made an intellectual contribution to the creation and/or development of IP arising from MRC supported research. They do not include individuals that have only carried out the tasks or supplied materials. IP Creators should be identified at the outset (usually as part of the invention disclosure) and are not necessarily those appearing as authors on a scientific publication. To be recognised legally, a co-inventor must have conceived of an essential element of the invention or contributed substantially to the general concept.
- 5.13. Intellectual Property (IP) Enablers – refers to assistants, technicians and other individuals who have indirectly contributed to the creation of Intellectual Property arising from MRC sponsored research and without whose intellectual or practical contribution commercial application would not have been possible.
- 5.14. Intellectual Property Rights (IPR) – give legal recognition to the ownership of intellectual property.
- 5.15. Internal Capacity Development Awards – means monetary awards provided by the MRC to individuals who are on the MRC payroll and are studying towards additional qualifications at an educational institution for the purposes of capacity development. Such individuals include MRC trainees and interns.
- 5.16. Invention – means a novel and useful idea relating to processes, machines, manufactures, and compositions of matter. It may cover such things as new or improved devices, systems, circuits, chemical compounds, mixtures, etc. It is probable that an invention has been made when something new and useful has been conceived or developed, or when unusual, unexpected, or non-obvious results have been obtained and can be exploited. An invention may be the product of a single individual or a group of individuals who have collaborated on a project.
- 5.17. Legal Services – means the office of the MRC responsible for all legal and contractual matters.
- 5.18. Medical Research Council (MRC) – means the statutory body established in terms of the South African Medical Research Council Act 58 of 1991.
- 5.19. MedRes – means the company MedRes (Pty) Ltd with registration number 1988/000511/07 which is a for-profit entity wholly owned by the MRC and through which commercial activities of the MRC may be undertaken.
- 5.20. Members of the MRC - includes
- 5.20.1. all permanent, contract, full-time, part-time, and consulting employees of the MRC, i.e. all persons on the MRC payroll who are funded from either baseline or contract funding
  - 5.20.2. all recipients of Internal Capacity Development Awards that are on the MRC payroll
  - 5.20.3. any persons using MRC research facilities, including but not limited to outside contractors, students and visiting faculty
  - 5.20.4. persons working in external MRC Research Units, Groups, Lead Programmes or Centres located within universities who are on the MRC payroll (MRC-salaried persons)
- 5.21. Net Income –

means gross royalties, license fees or other payments made to the MRC as a consideration in respect of an IP transaction, less any out-of-pocket Expenses incurred for intellectual property protection and commercialisation.

- 5.22. NIPMO –  
the National Intellectual Property Management Office established in terms of the IPR Act of 2008.
- 5.23. Open Source Software –  
refers to software that is developed, tested, or improved through public collaboration and distributed with the idea that it must be shared with others, ensuring open future collaboration. The underlying programming code (the source code) of the open source software is made available under a license that gives users the freedom to access, modify and run the program for any purpose, and to redistribute copies of either the original or modified program, without having to pay royalties to previous developers.
- 5.24. Research –  
means the creation, preservation, accumulation and improvement of knowledge by means of scientific investigations and methods in the field of the medical and related sciences as well as those sciences the application of which is important for the promotion of health or the combating of disease, and includes the acquisition, development and transfer of expertise and technology, and “researcher” has a corresponding meaning (as defined in the MRC Act No 58 of 1991).
- 5.25. Self-Initiated Research Grants –  
means research grants awarded on a competitive basis by the MRC to researchers working at or associated with universities in South Africa.
- 5.26. Small Enterprise –  
means a separate and distinct business entity, together with its branches or subsidiaries, if any, including co-operative enterprises, managed by one owner or more predominantly carried on in any sector or subsector of the economy mentioned in column 1 of the Schedule and classified as a micro-, a very small, a small or a medium enterprise by satisfying the criteria mentioned in columns 3, 4 and 5 of the Schedule (as defined in section 1 of the National Small Enterprise Act No. 102 of 1996).
- 5.27. Sponsored Research –  
means research, training and instructional projects involving funds, materials or other compensation from outside sources, including private sector companies, public entities, international research organisations, educational institutions and local and international funding or donor organisations, under agreements between the sponsoring agent and the MRC.
- 5.28. Subsidiary Companies of the MRC –  
means companies under the ownership control of the MRC.
- 5.29. The TTO –  
means the Technology Transfer Office of the MRC, which is responsible for intellectual property management and technology transfer, for the implementation of the MRC’s Intellectual Property Policy and for the obligations of the MRC in terms of the IPR Act.

## **6. RELATED POLICIES**

- 6.1. Code of Business Ethics Framework Policy  
6.2. Fraud Prevention Policy

6.3. Delegation of Authority Framework Policy

7. **POLICY AUTHORITY**

The Executive Management Committee

<b>Category:</b>	Level 1
<b>Risk:</b>	Strategic
<b>Effective Date:</b>	May 2012
<b>Review Date:</b>	May 2015
<b>Policy Owner:</b>	Technology Transfer Office
<b>Policy Manager / Cognisant Person:</b>	Director: SHIP / Division Manager: Technology Transfer
<b>Board Approval:</b>	February 2013

**Confirmation of Approval**

  
.....  
Prof S Abdool Karim  
President

18 February 2013  
.....  
Date