

**SOUTH AFRICAN MEDICAL
RESEARCH COUNCIL**



**MANAGEMENT AND COMMERCIALISATION OF
INTELLECTUAL PROPERTY POLICY**

Document review and approval

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1. REGULATORY FRAMEWORK

- 1.1. Section 51 (1)(a) of the Public Finance 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 states that:
"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 and associated regulations (IPR Act).
- 1.4. The Patents Act No. 57 of 1978, as amended.
- 1.5. The Copyright Act No. 98 of 1978, as amended.
- 1.6. Trademarks Act 194 of 1993, as amended.
- 1.7. Designs Act 195 of 1993, as amended.
- 1.8. Competition Act 89 of 1998, as amended.
- 1.9. Companies Act 71 of 2008, as amended.
- 1.10. The National Environmental Management: Biodiversity Act of 2004 (Biodiversity Act), as amended.

2. PURPOSE

The purpose of this policy is to –

- 2.1. outline the rights and obligations with respect to Intellectual Property (IP) of the SAMRC, its Employees and others making use of SAMRC facilities and/or receiving funding from the SAMRC;
- 2.2. align the management of IP at the SAMRC with the relevant legislation and, using instruments provided by statutory as well as common law, set out the process the SAMRC would follow in product conception, development, evaluation, protection/ registration, prosecution, commercialization, assertion/enforcement and disposal;
- 2.3. fulfil the requirements of the IPR Act with respect to IP policy;
- 2.4. provide for a fair, consistent and transparent system and procedures for the management of the SAMRC's intellectual assets in order to ensure compliance with the PFMA;
- 2.5. facilitate the effective identification, protection, utilisation and commercialisation of SAMRC IP for the benefit of the people of South Africa; and
- 2.6. 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 through promoting and conducting relevant and responsive health research.”* In order to impact on health and quality of life, the SAMRC must ensure that its research is translated into new and/or improved health solutions. The primary aim of the SAMRC’s policy on Intellectual Property is therefore to ensure that discoveries arising from SAMRC research are effectively managed and translated into usable technologies and knowledge for the benefit of the SAMRC, SAMRC stakeholders and the people of South Africa, and, where possible, to generate income for further investment in research and development.

This policy provides guidance on the ownership, disclosure, protection and commercialisation of any form of IP generated during the course of SAMRC 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 IP through innovative and entrepreneurial endeavour. Such applications of research findings should strive for the widest public benefit by including the IP Creator(s), the SAMRC, industry and society.

3.2 Intellectual Property Rights

3.2.1 The ownership rights for IP created by SAMRC Employees and others making use of MRC facilities are as follows:

3.2.1.1. All newly created or discovered IP conceived or first reduced to practice by Employees of the SAMRC in the normal course and scope of their duties or studies shall, subject to clauses 3.2.1.2-3.2.1.14, belong to the SAMRC, and SAMRC Employees shall assign their rights and interests in such IP to the SAMRC.

3.2.1.2. Where IP is generated by SAMRC Employees who have received Internal Capacity Development Awards from the SAMRC but are registered at a university or other educational institution for a higher degree, ownership of the IP shall either vest in the SAMRC or shall vest jointly in the SAMRC and the university, in accordance with IP Creatorship.

3.2.1.3. IP developed by visiting researchers and students during the course of their visit, as a result of their use of the SAMRC’s resources and facilities, and/or as a result of conducting work conceived and/or initiated by an SAMRC Employee, shall be jointly owned by the SAMRC and the employer and/or host institution of the visitor, provided that all requirements for joint ownership in terms of the IPR Act are met. The SAMRC’s claim to IP ownership does not extend to any previously developed IP. Visiting researchers and students and their employers and/or host institution must, prior to the visit, sign an agreement in terms of which they agree to these IP ownership terms and undertake to keep confidential all confidential information which may come to their attention during their visit to the SAMRC, and not to use it otherwise than as specifically permitted by the SAMRC. The participation of visiting researchers and students in the sharing of any income or benefits resulting from IP developed during their visit to the SAMRC and/or as a result of conducting work

conceived and/or initiated by an SAMRC staff member shall be the responsibility of their employer and/or host institution.

- 3.2.1.4. Except under the circumstances provided for in clauses 3.2.1.5 to 3.2.1.7, where IP is developed in the course of, or resulting from, Sponsored Research or Contract Research conducted by the SAMRC, such IP shall vest in the SAMRC. 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 and provided that such exclusive licensing is not in violation of the Competition Act, 2008.
- 3.2.1.5. 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 between employees of the SAMRC and the sponsor or contracting party, the IP resulting from the Sponsored Research may be co-owned by the SAMRC and the sponsor or contracting party, provided that appropriate arrangements are made for benefit-sharing with IP Creators at the SAMRC, and an agreement is concluded between the SAMRC and the sponsor or contracting party for the commercialisation of the IP.
- 3.2.1.6. Where the research referred to in 3.2.1.4 was sponsored or contracted on a Full Cost basis, ownership of the IP resulting from the Sponsored Research or Contract Research shall vest in the SAMRC, unless otherwise negotiated between the SAMRC and the sponsor or contracting party. Where the IP vests in the SAMRC, 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 SAMRC 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.
- 3.2.1.7. Subject to 3.2.1.5, where the SAMRC 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 SAMRC. 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 SAMRC, unless otherwise negotiated between the SAMRC and the sponsor or contracting party. Notwithstanding ownership of the IP and research results by the SAMRC, 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.
- 3.2.1.8. 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 and the SAMRC, the

SAMRC shall own any IP developed by its Employees and co-own any IP jointly developed by its Employees and collaborators, provided that all requirements for joint ownership in terms of the IPR Act are met. 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 SAMRC shall refer such agreement to NIPMO for approval, prior to commencement of work under such agreement.

- 3.2.1.9. Where IP is developed by persons or organisations contracted by the SAMRC to undertake research or services during the course of or resulting from such research or services, such IP shall belong to the SAMRC, subject to any applicable laws and regulations or agreements that may be in place and provided that the SAMRC is deemed to have paid the full cost for such research or services.
- 3.2.1.10. The SAMRC 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 SAMRC has been suitably acknowledged in such works and subject to the right of the SAMRC to have free, non-exclusive use of such materials indefinitely within the limits of any publication restrictions.
- 3.2.1.11. The SAMRC will claim ownership of original databases, electronic data, websites, training materials, games, and other works with commercial value that have been developed by SAMRC Employees in the course and scope of employment. Such works may only be used by outside parties with the written permission of the SAMRC. Where the SAMRC has been contracted or commissioned by an outside party to develop original databases, websites, training materials, and other works, ownership of the copyrights in such works as well as any data and information developed shall vest in the SAMRC. If the contract is funded on a Full Cost basis, ownership of the copyrights in such works as well as any data and information developed shall vest in the SAMRC, unless otherwise negotiated between the SAMRC and such outside party. Where co-ownership or ownership by the outside party is negotiated, the SAMRC shall retain the right to use the data, information and copyrighted works for internal research purposes. In order to protect the copyright, SAMRC-owned materials must be accompanied by the following statement: *Copyright © [year] South African Medical Research Council. All Rights Reserved.* The date should be the year in which the work was first published.
- 3.2.1.12. Where SAMRC Employees develop software in the course and scope of their employment, such software shall belong to the SAMRC. SAMRC Employees 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 SAMRC. The source code of such software belongs to the SAMRC and must be delivered to the head of Information Technology at the SAMRC for safekeeping on completion of the development of the software, and in the event of on-going development, on completion of each version thereof.

- 3.2.1.13. All Trade Marks and domain names developed by SAMRC Employees during the course and scope of their employment and related to their work shall be registered and owned by the SAMRC. Trade Marks must have printed in close proximity to the Trade Mark the legend ™ 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 SAMRC's Trade Marks for private purposes or gain by SAMRC Employees is prohibited, unless the prior written consent of the SAMRC has been obtained.
- 3.2.1.14. In cases in which the SAMRC has an ownership interest in IP and either does not wish to or is unable to protect and/or commercialise the IP, the SAMRC is obliged to refer such IP to NIPMO. Should NIPMO decide not to acquire ownership of the IP on behalf of the State, the SAMRC 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 sponsor or contracting party has provided some funding, such sponsor or contracting party shall be offered such option before the IP Creator. Should the IP be offered to a sponsor or contracting party, 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 or a sponsor or contracting party taking assignment of the IP, the SAMRC 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.
- 3.2.2 The ownership rights for IP created by persons or institutions receiving funding from the SAMRC (Host Institutions) are as follows:
- 3.2.2.1. Where IP is generated by persons working within Extra Mural Units, persons who have received External Capacity Development Awards from the SAMRC, or persons who have received any other SAMRC funding awards, including but not limited to Self-initiated Research, Strategic Health Innovation Partnership and Flagship grants, such IP shall, subject to 3.2.2.2-3.2.2.3, be owned by the Host Institution and shall be dealt with in accordance with the IPR Act and the Host Institution's IP Policy.
- 3.2.2.2 Where an SAMRC Employee is involved in the creation of any of the IP referred to in 3.2.2.1 as an IP Creator, such IP will be co-owned by the SAMRC and the Host Institution, provided that all requirements for joint ownership in terms of the IPR Act are met. For co-owned IP, the Technology Transfer Office of the SAMRC (TTO) and the Technology Transfer Office at the relevant Host Institution shall decide on a case-by-case basis 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.
- 3.2.2.3 Notwithstanding IP ownership by the Host Institution pursuant to 3.2.2.1, in certain circumstances the SAMRC may require that any income or benefits earned from such IP are shared proportionately with the SAMRC in recognition of the SAMRC's contribution and/or that consultation with the SAMRC on the protection and commercialisation of such IP are required, as determined by the relevant funding agreement. Benefit sharing proportions will be determined on a case-by-case basis, depending on the relative

contributions of the SAMRC and the Host Institution and any other parties to the development and commercialisation of the IP in question.

3.2.3 In all cases where the requirements for joint IP ownership in terms of the IPR Act and this IP Policy are met, the proportional ownership between the qualifying entities and the SAMRC shall be determined on a case-by-case basis, depending on the relative contributions of the SAMRC and the other entity(ies) to the development and commercialisation of the IP in question. Any income or benefits earned from such IP shall be shared proportionately between the IP co-owners in accordance with the IP ownership proportions unless agreed otherwise between the co-owners. Any agreement for the management and commercialization of co-owned IP shall make provision for the SAMRC 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.

3.2.4 Any IPRs resulting from SAMRC 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 Innovation (DSI)'s Indigenous Knowledge Systems (IKS) Policy.

3.2.5. The SAMRC may become involved in the evaluation, protection and commercialisation of IP that does not originate from SAMRC-funded research or an SAMRC Employee, provided that such IP has the potential to fulfill the mandate and mission of the SAMRC. In such cases, the SAMRC 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 SAMRC's involvement may include co-ownership of the IP, acquisition of equity and/or access to commercialisation rights.

3.3. Responsibilities of SAMRC Employees

3.3.1. SAMRC Employees are required 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, protection and commercialisation. Such disclosure shall be made within 90 days of identification of possible IP and before the IP is made public and shall also be made to the director of the relevant intra-mural unit or division.

3.3.2. SAMRC Employees are obligated to cooperate with and sign any documents necessary for the SAMRC to record itself as the owner or co-owner of the IP.

3.3.3. It is the responsibility of SAMRC Employees 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 it having been submitted to the TTO and

a clearance for publication or presentation having been obtained from the TTO. Where the disclosure of confidential information by an SAMRC Employee to a third party is required for any reason, he or she must inform the third party of the confidential nature of such disclosure and work with Legal Services to ensure that a non-disclosure agreement (NDA) is in place between the SAMRC and the third party before such disclosure. Even where an NDA has been signed, SAMRC Employees should refrain from making full disclosure of an invention or confidential know-how to a third party.

- 3.3.4. It is the responsibility of SAMRC Employees 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 SAMRC must be submitted for safekeeping to the director of the relevant intra-mural unit or division on ceasing to be an SAMRC Employee.
 - 3.3.5. SAMRC Employees 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 that are consistent with the provisions of this IP Policy are concluded prior to the initiation of the research.
 - 3.3.6. SAMRC Employees 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 SAMRC 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 in place. Such transfer shall transfer possession and not ownership of the material, unless a contrary intention is specifically and patently set out.
 - 3.3.7. No SAMRC Employee 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 signed by the SAMRC and must be consistent with the provisions of this IP Policy.
 - 3.3.8. No SAMRC Employee 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 SAMRC.
 - 3.3.9. SAMRC Employees may not use or exploit any IP owned by the SAMRC on a commercial basis without the written permission of the SAMRC.
 - 3.3.10. IP Creators and IP Enablers who leave the employ of the SAMRC or otherwise become no longer SAMRC Employees may not make use of the IP they created without the express written permission of the SAMRC.
- 3.4. Responsibilities of the Technology Transfer Office
- 3.4.1. The administration of this Policy and the obligations of the SAMRC in terms of the IPR Act are the responsibility of the TTO.

- 3.4.2. The TTO is responsible for the identification, evaluation, protection, (with the exception of opposition to applications, prosecution or defending Infringements and drafting of relevant contracts, which are the domains of the Legal and Compliances Services), management and commercialisation of IP, all benefit sharing arrangements in accordance with the SAMRC's Benefit Sharing Scheme, and appropriate capacity-building relating thereto. The TTO may, on behalf of the SAMRC and, where relevant, any co-owners, apply for a patent or any other form of IP registration in respect of any IP, and the SAMRC shall be regarded as the applicant or assignee of the patent or other form of IP protection. The filing of all 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 SAMRC.
- 3.4.3. The SAMRC 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 SAMRC entering into any contracts for the commercialisation, use or sale of that IP.
- 3.4.4. All invention disclosures and discussions on inventions with SAMRC Employees 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.
- 3.4.5. The TTO may, with the approval of the EMC and consistent with the SAMRC'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 SAMRC shall be subject to the SAMRC's Benefit Sharing Scheme.

3.5 Agreements

- 3.5.1 No SAMRC Employee may enter into any agreement on behalf of the SAMRC or any agreement relating to SAMRC IP. All agreements relating to SAMRC IP and/or to which the SAMRC is a party, including Material Transfer Agreements and NDAs, must be drafted and/or reviewed and approved by Legal and Compliance Services and signed by the President of the SAMRC in her capacity as the Accounting Officer or such other official as may be capacitated by the Delegation of Authority instrument of the SAMRC. All IP related agreements and, where required by Legal and Compliance Services, IP clauses in other types of agreements must, in addition, be reviewed and approved by the TTO.
- 3.5.2. It is the responsibility of SAMRC Employees to be aware of IP clauses of research, collaboration and consortium agreements, and other clauses which place obligations on SAMRC Employees, and to ensure that they comply with the terms of such agreements.
- 3.5.3. SAMRC Employees may not enter into agreements related to outside employment, such as consulting agreements, that are in conflict with this IP Policy or may adversely affect the IP Rights of the SAMRC.

3.5.4. It is the policy of the SAMRC to ensure, in so far as is possible, the effective use of its IP for the benefit of the IP Creator(s), the SAMRC, and the people of South Africa and this aim is to be reflected in all IP contracts whereby IP of the SAMRC is to be exploited by an outside entity or organisation.

3.6. Decision Making on IP and Commercialisation

3.6.1. The EMC or the Board, as the Delegation of Authority may confer the relevant authority in respect of subject matter and monetary value, is responsible for decisions on any transactions relating to the commercial use of SAMRC IP, based on recommendations from the TTO, including:

- Whether to spin out a company
- Whether the SAMRC should take equity in a spin-out company and how much
- Whether the SAMRC should sell equity in a spin-out company and how much
- The involvement of inventors in spin-out companies as shareholders, directors, executive managers and/or consultants
- Who to appoint as a director to represent the SAMRC in spin-out companies
- Whether the SAMRC should enter into a joint venture and with whom
- Who to license SAMRC IP rights to and under what broad license terms
- Whether to place an invention in the public domain

3.6.2. Any of the above transactions requiring additional approvals in terms of the PFMA or the SAMRC's Delegation of Authority Policy shall be referred to the SAMRC Board for approval, prior to any additional approvals that may be required.

3.6.3. The EMC, after consulting with the Legal and Compliance Services, 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 SAMRC IP policy for ratification by the Board of the SAMRC.

3.6.4. The TTO is responsible for the implementation of decisions made by the EMC referred to in 3.6.1.

3.7. Commercialisation

The SAMRC 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 SAMRC 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 in most cases be achieved through standard procurement processes. Thus the selection of partners for the commercialisation of the SAMRC'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 SAMRC 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 SAMRC may make use of one or more different means of commercialising its IP, including:

- Licensing
- Spin-out companies and subsidiary companies of the SAMRC
- Joint ventures
- Direct sale of products and services
- Assignment
- 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 SAMRC has retained the right to act on its own with respect to commercialisation of the IP.

3.7.1. Licensing

- 3.7.1.1. 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.
- 3.7.1.2. 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. 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 SAMRC 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.
- 3.7.1.3. 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/or 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.
- 3.7.1.4. 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.
- 3.7.1.5. Each IP transaction that involves IP which falls within the IPR Act (i.e. all SAMRC IP arising after 2 August 2010, 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 created 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.”*
- 3.7.1.6. Any licensing of SAMRC owned IP to parties outside of South Africa (offshore transactions) will be subject to the necessary statutory approvals, including approval from NIPMO and the South African Reserve Bank, and will comply with all regulations and guidelines relating to the IPR Act. The SAMRC 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 or commitment in South Africa to develop or commercialise the IP locally.
- 3.7.1.7. All licenses granted by the SAMRC shall reserve the right for the SAMRC and, where appropriate, other publicly funded entities in South Africa, to use the IP internally for research, development and educational purposes.
- 3.7.1.8. All licenses granted by the SAMRC that relate to new health solutions that may benefit developing country or poorer populations shall incorporate socially responsible licensing principles to ensure affordable access.
- 3.7.2. Spin-out Companies and Subsidiary Companies of the SAMRC
- 3.7.2.1. The SAMRC supports the formation of companies that can develop SAMRC IP into useful products and move them into the market, subject to the Public Finance Management Act. These may be independent companies or subsidiary companies of the SAMRC and may be for-profit or not-for-profit companies.
- 3.7.2.2. Equity Holdings
- 3.7.2.2.1. The SAMRC 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 SAMRC IP. In such cases, MedRes (Pty) Ltd shall hold the shares in the spin-out company on the SAMRC’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.
- 3.7.2.2.2. No SAMRC Employee in a position to influence the relationship between the SAMRC 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 SAMRC’s nominee. This clause does not apply in cases where such SAMRC Employees are deemed to be IP Creators/Enablers.

- 3.7.2.2.3. IP Creators/Enablers responsible for the IP on which the spin-out company is based 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 SAMRC or the IP. The SAMRC 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.
 - 3.7.2.2.4. The allocation of equity in spin-out companies between the SAMRC 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% SAMRC and 49% IP Creators/Enablers. Deviations from these proportions may be negotiated on a case-by-case basis. Where the SAMRC 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 SAMRC's Benefit Sharing Scheme.
 - 3.7.2.2.5. Shares owned by parties are subject to dilution in the event of investment by third parties e.g. venture capital investment.
- 3.7.2.3. Directorships, Management Positions and Consulting
- 3.7.2.3.1. The SAMRC retains the right to appoint a non-executive director or observer at board meetings of companies in which it holds equity through a subsidiary such as MedRes.
 - 3.7.2.3.2. 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 SAMRC's Conditions of Service. In doing so they will not serve as representatives of the SAMRC.
 - 3.7.2.3.3. In the event that an SAMRC Employee wishes to become involved in a spin-out company in an executive or a consulting capacity, such involvement must be approved by the Employee's manager and the EMC. Involvement of SAMRC Employees in spin-out companies shall, at the discretion of the EMC, be on one of the following bases: a.) reduction of the Employee'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 Employee; or b.) secondment of the Employee on a part-time or full-time basis to the company, in which case the SAMRC shall be remunerated for such time at

a value equivalent to the salary of the Employee. In both cases, the SAMRC Employee 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 Employee's manager and the EMC, after which the SAMRC Employee shall be required to leave the employ of the SAMRC if they wish to continue their involvement with the spin-out company.

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

3.7.2.4.1. The SAMRC may elect to license or assign IP to a spin-out company in return for shareholding, upfront payment and/or royalties. In general, the policy of the SAMRC 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 SAMRC prior to such liquidation. Any assignment of IP by the SAMRC shall be subject to the approval of NIPMO.

3.7.2.5. Responsibilities for Establishment of Spin-out Companies

3.7.2.5.1. The TTO shall be responsible for all procedures required for the establishment of new companies in which the SAMRC elects to take equity through a subsidiary, such as 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.

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

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

3.7.3. Joint Ventures

3.7.3.1. The SAMRC may elect, subject to the approval of the Minister of Health and National Treasury where the significance and materiality framework require such approval, 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 a subsidiary, such as MedRes, shall become a shareholder in the JV company on the SAMRC's behalf.

3.7.3.2. The SAMRC 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

SAMRC prior to such liquidation. Any assignment of IP by the SAMRC shall be subject to the approval of NIPMO.

3.7.4. Direct sale of products and services

3.7.4.1. In the event that an SAMRC Employee is able to sell products and/or services that embody SAMRC IP directly from their laboratory or premises without the assistance of the TTO, such Employee shall be permitted to do so, provided that the TTO is informed of all such activities. The TTO and Legal Services will ensure that the necessary agreements are in place to protect the SAMRC, the SAMRC Employee and the IP before the sales are executed.

3.7.4.2. Where such products and/or services are deemed by the TTO to involve IP that falls within the IPR Act, , a portion of the revenues received from the direct sales shall accrue to the IP Creators/Enablers, in line with the SAMRC's Benefit Sharing Scheme.

3.7.4.3. Revenues from the direct sale of copyright works on which the SAMRC 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 SAMRC branding and SAMRC facilities to sell the work. Such works may not be sold within the SAMRC for personal gain. All transactions by SAMRC Employees 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 SAMRC Employees only.

3.7.5. Providing Open Access to SAMRC IP

3.7.5.1. The SAMRC may, subject to the approval of NIPMO, decide to provide access to SAMRC 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.

3.7.5.2. Where the intention of a research project or collaboration involving SAMRC Employees 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.

3.8. Conflicts of Interest and Commitment

3.8.1 Conflict of Interest

A conflict of interest will exist when an SAMRC Employee, an Employee's direct family or associated legal entity (such as companies owned by Employees 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 SAMRC. 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 SAMRC policy on conflicts of interest as they pertain to IP and commercialisation:

- 3.8.1.1. SAMRC Employees 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 SAMRC's Conditions of Service.
- 3.8.1.2. SAMRC Employees should not seek to influence the SAMRC'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 SAMRC.
- 3.8.1.3. SAMRC Employees may not participate directly in the negotiation of research agreements, license agreements or other arrangements between the SAMRC and external organisations in which the Employee has a significant economic interest.
- 3.8.1.4. SAMRC Employees shall not compete with SAMRC spin-out companies or be involved in any other entity that competes with such companies by providing similar goods or services without prior authorisation from the SAMRC.

3.8.2. Conflict of Commitment

- 3.8.2.1. SAMRC Employees are expected to accord the SAMRC their primary professional loyalty, and to arrange outside obligations, financial interests and activities so as not to conflict with this overriding commitment. SAMRC Employees are also expected to satisfy all the requirements of their employment, and should not permit outside activities to interfere with the performance of their SAMRC 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 SAMRC activities. Time allocated to external activities should be defined in the annual performance management systems and require the approval of the relevant line manager.
- 3.8.2.2. Professional effort may be directed to outside work resulting from IP generated at the SAMRC. 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 3.7.2.3.3. of this policy.

3.9. SAMRC Benefit Sharing Scheme

The SAMRC wishes to share with IP Creator(s)/Enabler(s) whatever material benefits that may arise from the beneficiation of SAMRC 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 SAMRC from their IP for as long as revenues are derived from such IP and accrue to the SAMRC.

- 3.9.1. Beneficiaries from the Exploitation of Intellectual Property
There are three possible beneficiaries from the exploitation of SAMRC IP:
 - the IP Creator(s)/Enabler(s)

- the unit(s) or division(s) of which the IP Creator(s)/Enabler(s) are a member
- the SAMRC

3.9.1.1. All IP Creator(s)/Enabler(s) and their respective units or divisions 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 "SAMRC 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/division'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 or division is involved. In the absence of an agreement, benefits will be shared equally between IP Creators / Enablers and their respective units or divisions.

3.9.1.2. Should any dispute on any of the above-mentioned matters arise, the director of the unit or division 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 EMC will decide on the matter(s).

3.9.2. 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 SAMRC, including:

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

3.9.3. SAMRC Benefit Sharing Proportions

3.9.3.1. Subject to clauses 3.9.3.2. - 3.9.3.6., any income that accrues to the SAMRC as a result of the implementation of IP developed by an SAMRC Employee 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 IP Creators/Enablers, 35% to the unit(s)/division(s), 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 IP Creators/Enablers. Expenses incurred will be deducted from the remaining amount and reimbursed to the TTO or relevant

unit(s)/division(s) and any surplus thereafter will be split as follows: 50% to the unit(s)/division(s) and 50% to the SAMRC.

Notwithstanding the above, the SAMRC shall ensure that the IP Creators receive at least 20% of the first R1 million of income as required by Section 10 of the IPR Act.

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 IP Creators/Enablers, 35% to the unit(s)/division(s) and 30% to the SAMRC.

- 3.9.3.2. 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 SAMRC continues to receive benefits
- 3.9.3.3. The SAMRC'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 SAMRC Employees or unit(s)/division(s), for example books, handbooks, databases etc.
- 3.9.3.4. Where the IP Creators/Enablers own equity in a spin-out company in which the SAMRC also owns a corresponding share, any dividend or sale of equity income earned by the SAMRC as a result of such equity shall not be subject to the SAMRC's Benefit Sharing Scheme. However, any income earned by the SAMRC as a result of licensing or assignment of the IP to the spin-out company is subject to the SAMRC's Benefit Sharing Scheme.
- 3.9.3.5. Where the SAMRC 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 SAMRC as a result of such equity and any income earned by the SAMRC as a result of licensing or assignment of the IP to the spin-out company shall be subject to the SAMRC's Benefit Sharing Scheme.
- 3.9.3.6. Where the IP Creators/Enablers own equity in a spin-out company but the SAMRC has elected not to take equity, then the sharing of income earned by the SAMRC as a result of licensing or assignment of the IP to the spin-out company shall be determined on a case-by-case basis.
- 3.9.3.7. The benefits to IP Creators/Enablers and their heirs shall be a first call on the applicable income ahead of any distribution to the SAMRC.
- 3.9.3.8. 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 SAMRC of any changes in contact details after death of the IP Creator(s)/Enabler(s).
- 3.9.3.9. 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 SAMRC. It is the responsibility of the IP Creator/Enabler to notify the SAMRC of any changes in contact details after termination of employment.

- 3.9.3.10. 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 SAMRC, or such extended period of time as may be agreed upon in writing by the SAMRC and the IP Creators/Enablers.
- 3.9.3.11. If the SAMRC is unable to affect payment because of incorrect or inadequate banking details, the SAMRC will keep the relevant amounts in reserve 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 reserve. If the SAMRC pays an amount into an incorrect account as a result of information supplied to it being outdated or incorrect, the SAMRC will not have any further obligation or liability in respect of such payment, which will be deemed to have been duly and properly made.
- 3.9.3.12. At least a portion of the awards received by the unit(s)/division(s) must be used to fund further research and development. At least a portion of the funds accruing to the SAMRC shall be used to fund the operations of the TTO and the protection and commercialisation of SAMRC IP.
- 3.9.3.13. In cases where IP is shared with universities and the parties decide to reward inventors and their respective unit(s)/division(s) before splitting the income between the institutions, any remaining income accruing to the SAMRC shall accrue to the SAMRC corporate. The rewarding of inventors and their respective unit(s)/division(s) shall be in accordance with the IP Policy of the relevant university or the SAMRC, whichever is more favourable for the IP Creators/Enablers. Payments to SAMRC Employees shall be made by the SAMRC and are subject to normal employee taxes.
- 3.9.3.14. The SAMRC 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.
- 3.9.3.15. Where IP owned or co-owned by the SAMRC results from indigenous knowledge, the SAMRC 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 DSI's IKS Policy, shall be determined on a case-by-case basis.
- 3.9.4. Non-monetary Benefits Derived from the Exploitation of Intellectual Property
- 3.9.4.1. The SAMRC will as far as possible refrain from accepting non-monetary benefits from the commercialisation of SAMRC IP.
- 3.9.4.2. Where non-monetary benefits, such as new equipment or facilities, do accrue to the SAMRC as a result of commercialisation of SAMRC IP, the sharing of such benefits shall be dealt with as follows:

- 3.9.4.2.1. 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 SAMRC's Benefit Sharing Scheme.
- 3.9.4.2.2. 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.
- 3.9.4.2.3. Where sufficient funds are not available to reimburse the IP Creators/Enablers for their share of the non-monetary benefit, the SAMRC shall hold such non-monetary benefit in co-ownership with the IP Creators/Enablers until such time as the SAMRC 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 is sold or leased or otherwise commercially exploited, at which point the IP Creators/Enablers will receive their portion of such value in cash. The SAMRC will be solely entitled to determine possession, use and commercial exploitation of all such co-owned non-monetary benefits. If the SAMRC elects to purchase the IP Creators/Enabler's share of the co-owned benefit, the SAMRC will seek to agree the purchase price of the share with the IP Creators/Enablers. Failing such agreement, the SAMRC may have the share valued by independent auditors, whose valuation will be final and binding.

3.10 Dispute Resolution

- 3.10.1. 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 and Legal and Compliance Services.
- 3.10.2. The Head of the TTO 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 Head of the TTO, the EMC will be asked to resolve the dispute. If such a dispute cannot be resolved by the EMC, the SAMRC President will be asked to resolve the dispute. Failing resolution by the President, the Legal and Compliance Services shall attend to advise on, and manage implementation of, the correct dispute forum and dispute rules. Where the parties have opted for a private (arbitration, adjudication, mediation) dispute mechanism, the SAMRC President shall, after consultation with the General Counsel, appoint an arbitrator, adjudicator or mediator as the case may be, acceptable to the parties, to investigate and make a determination (arbitrator / adjudicator) or make a recommendation (mediator). Where the parties cannot agree on the arbitrator / adjudicator or mediator, the chair of LSSA/ GCB / NBCSA / AFSA / HIROs, as the case may be, will be approached to recommend a suitable person of no less than 8 years' experience in relevant dispute subject area. Disputes submitted to arbitration/adjudication 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 SAMRC President shall end.

3.11 Electronic Communications and Transactions

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

3.12. Implementation

This policy 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 SAMRC 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 SAMRC 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 SAMRC, whether the waiver would result in a conflict of interest, and subject to approval from NIPMO, where required.

The SAMRC 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 SAMRC Employees as defined in 5.21, persons making use of SAMRC facilities, and all SAMRC-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 IP, most commonly through the creation of linkages with industry and the creation of commercial enterprises linked by formal legal agreements to the SAMRC.

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) and/or position on a committee, forum, professional body, board of directors etc., wherein one such position could possibly adversely influence the motivation for action or inaction in another and/or an instance in which the relevant individual, their direct family or associated legal entity (such as companies owned by the individual or their direct family) has an economic interest that could influence his or her actions or decisions.

- 5.4. Consulting Work – refers to private work conducted by an SAMRC Employee 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 SAMRC'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 SAMRC'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 SAMRC Employee with an entity or organisation other than the SAMRC.
- 5.7. Expenses – means out-of-pocket costs, fees and expenses that the SAMRC incurs, including for 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 SAMRC 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, scholarships for Masters and Doctoral studies, research training internships career development awards, National Health Scholars Programme awards, travel grants and grants for conference attendance.
- 5.9. Extra Mural Unit – means an SAMRC unit situated within an existing scientific faculty at a university, research organisation or science council in South Africa under the leadership of a director which is established to conduct health research.
- 5.10. Full-Cost Sponsored Research – refers to research projects in which the full cost of undertaking the research and development, as determined in accordance with the SAMRC'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.
- 5.11. Host Institution – refers to a university, research organisation, science council or other entity that hosts an Extra Mural Unit and/or a researcher and/or a research project that has been awarded funding by the SAMRC.

- 5.12. 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.
- 5.13. Intellectual Property (IP) – for the purposes of this policy, Intellectual Property is defined as any creation of the mind that can be applied for social and/or commercial benefit. It includes creations that can be protected by, as well as any resulting, patents, trade marks, registered designs, plant breeders rights, copyrights, and trade secrets (including applications for any of them and all extensions and renewals anywhere in the world), strains of micro-organisms, genetically modified micro-organisms, rights in databases and other protectable lists of information, protocols, standard operating procedures, rights in confidential information, and all know-how associated therewith.
- 5.14. 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. 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, an inventor must have conceived of an essential element of the invention or contributed substantially to the general concept.
- 5.15. IP Creatorship – refers to the collection of individuals and their respective host institutions or employers who have made an intellectual contribution to the creation and/or development of IP
- 5.16. Intellectual Property (IP) Enablers – refers to assistants, technicians and other individuals who have indirectly contributed to the creation of IP and without whose intellectual or practical contribution commercial application would not have been possible.
- 5.17. Intellectual Property Rights (IPR) – give legal recognition to the ownership of intellectual property.
- 5.18. Internal Capacity Development Awards – means monetary awards provided by the SAMRC to individuals who are on the SAMRC payroll (SAMRC Employees) and are studying towards additional qualifications at an educational institution for the purposes of capacity development. Such individuals include SAMRC students, trainees and interns.
- 5.19. Legal and Compliance Services – means the office of the SAMRC responsible for all legal, compliance, public policy, governance, litigation and contractual matters, which office is headed by the General Counsel of the SAMRC.
- 5.20. South African Medical Research Council (SAMRC) – means the statutory body established in terms of the South African Medical Research Council Act 58 of 1991.
- 5.21. MedRes –

means the company MedRes (Pty) Ltd with registration number 1988/000511/07 which is a for-profit entity wholly owned by the SAMRC and through which commercial activities of the SAMRC may be undertaken.

- 5.22. SAMRC Employees – refers to all permanent, contract, full-time, part-time, and consulting employees of the SAMRC, i.e. all persons on the SAMRC payroll, whether they are funded from baseline or contract funding and whether or not they conduct their work on SAMRC premises, including all recipients of Internal Capacity Development Awards and persons who are jointly appointed / employed by the SAMRC and another entity.
- 5.23. Net Income – means gross royalties, license fees or other payments made to the SAMRC as a consideration in respect of an IP transaction, less any out-of-pocket Expenses incurred for intellectual property protection and commercialisation.
- 5.24. NIPMO – the National Intellectual Property Management Office established in terms of the IPR Act of 2008.
- 5.25. 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.
- 5.26. 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 SAMRC Act No 58 of 1991).
- 5.27. 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, 5 and 5 of the Schedule (as defined in section 1 of the National Small Enterprise Act No. 102 of 1996).
- 5.28. Sponsored Research – means research 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 SAMRC.
- 5.29. Subsidiary Companies of the SAMRC – means companies under the ownership control of the SAMRC.
- 5.30. The TTO –

means the Technology Transfer Office of the SAMRC, which is responsible for intellectual property management and technology transfer, for the implementation of the SAMRC's Intellectual Property Policy and for the obligations of the SAMRC 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
- 6.4. Contract Management Policy
- 6.5. Guidelines on Research Conduct Policy

7. POLICY AUTHORITY

The Executive Management Committee

Category:	Level 1
Risk:	Strategic
Effective Date:	January 2022
Review Date:	February 2025
Policy Owner:	Technology Transfer Office
Policy Manager / Cognisant Person:	Executive Director: GIPD / Head: Technology Transfer Office
Board Approval:	December 2021

Confirmation of Approval



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Prof Glenda Gray
President

12 May 2022

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Date