science, technology & innovation
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REPUBLIC OF SOUTH AFRICA

NATIONAL INTELLECTUAL PROPERTY MANAGEMENT OFFICE
An initiative of the Department of Science, Technology and Innovation

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NIPMO INTERPRETATION NOTE 16

CLINICAL TRIALS AND INTELLECTUAL PROPERTY

The National Intellectual Property Management Office (NIPMO) is mandated to promote the objects[1] of the Intellectual Property Rights from Publicly Financed Research and Development Act, 51 of 2008 (IPR Act). One of the functions of NIPMO, according to section 9(4)(c)(ii)[2] of the IPR Act, is that NIPMO must provide assistance to institutions with intellectual property (IP) transactions.

NIPMO has received multiple queries regarding the applicability of the IPR Act, particularly in relation to clinical trials funded by philanthropic organisations. This NIPMO Interpretation Note (NIN) aims to clarify the principles governing the assignment and licensing of IP arising from such trials.

Should you have any questions or comments, please do not hesitate to contact NIPMO's Regulatory and Compliance Directorate:

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[1] Section 2(1) of the IPR Act: The object of this Act is to make provision that intellectual property emanating from publicly financed research and development is identified, protected, utilised and commercialised for the benefit of the people of the Republic, whether it be for a social, economic, military or any other benefit.
[2] Section 9(4)(c)(ii) of the IPR Act: NIPMO must, furthermore provide assistance to institutions with intellectual property transactions

1. INTRODUCTION

1.1 According to the IPR Act, the owner of IP emanating from publicly financed research and development (R&D) shall be the recipient[3], unless the said R&D is funded by a private entity or organisation[4] on a full cost basis in which case the provisions of the IPR Act will not apply[5].

1.2 This IP ownership provision appears to present a challenge for institutions conducting clinical trials, funded by philanthropic organisations not on a full cost basis, particularly when they insist on owning the resulting IP because of their obligation to provide humanitarian benefits to society.

1.3 To address this challenge, NIPMO facilitated a round table discussion on "*Clinical Trials and IP ownership*" on 22 August 2013 in Cape Town, bringing together various industry stakeholders to discuss challenges experienced during negotiations for clinical trials funding and IP ownership.

1.4 During these discussions, NIPMO was requested to consider granting a "general approval" on IP transactions for specific clinical trial outputs under specific instances.

1.5 On 7 March 2014, NIPMO published a notice granting approval on clinical trial outputs/ IP under certain instances. This authorisation was withdrawn on 12 July 2016, due to limited uptake/ reporting from institutions.

1.6 NIPMO recently received renewed requests to provide prior approval for clinical trials. In response, this NIN has been developed to address and provide NIPMO's position on clinical trials and the IPR Act.

2. CLINICAL TRIALS AND THE IPR ACT

2.1 The IPR Act applies to IP resulting from publicly financed R&D[6]. As the IPR Act does not define R&D, NIPMO aligns with the Organisation for Economic Co-operation and Development (OECD) Frascati Manual entitled "*Guidelines for Collecting and Reporting Data on Research and Experimental Development, The Measurement of Scientific, Technological and Innovation*" (2015).

2.2 The Frascati Manual states that "*clinical trials are divided into four standard phases, phases 1, 2 and 3 can be treated as R&D. Phase 4 clinical trials, which continue testing the drug or treatment after approval and manufacture, should only be treated as R&D if they bring about a further scientific or technological advance."*

[3] Section 4(1) of the IPR Act
[4] Section 15(5) of the IPR Act: For the purposes of this section, private entity or organisation includes a private sector company, a public entity, an international research organisation, an educational institution or an international funding or donor organisation.
[5] Section 15(4)(a) of the IPR Act: Any research and development undertaken at an institution and funded by a private entity or organisation on a full cost basis shall not be deemed to be publicly financed research and development and the provisions of this Act shall not apply thereto.
[6] Section 1 of the IPR Act: "**publicly financed research and development**" means research and development undertaken using any funds allocated by a funding agency but excludes funds allocated for scholarships and bursaries;

2.3 The IPR Act therefore applies to phases 1 to 3 clinical trials that are not funded on a full cost basis and may extend to certain phase 4 clinical trials.

3. GENERAL APPROVAL PROVISIONS AND REPORTING REQUIREMENTS

3.1 NIPMO hereby grants **upfront approval to institutions** that conduct clinical trials where all of the following four (4) conditions are met:

i The IP transaction applies to IP generated from a clinical trial (phases 1 to 3 and some phase 4).
- Although upfront approval is granted, recipients must still submit a motivation on why the selected IP transaction is in the public interest and why assignment (if selected) is necessary rather than an exclusive licence of the IP when reporting these IP transactions to NIPMO. If the IP transaction is a royalty-free licence for commercial purpose the recipient must ensure that the philanthropic funder finances 50% or more of direct cost for R&D)

ii The clinical trial is funded by a philanthropic organisation (or its intermediary) and funding is not on a full cost basis.

iii The clinical trial is for specific **infectious diseases** which include HIV/AIDS, Tuberculosis, Malaria and neglected diseases[7] as defined by the World Health Organization.

iv The objective of the trial is to make the tested drugs available at a preferential rate or at a reduced cost in South Africa or developing countries[8].

3.2 Reporting requirements and timelines

3.2.1 All IP4 to 6 and 8 forms related to clinical trials and fall within the prescribed provisions above must be submitted to NIPMO on a biannual basis. The submission dates will coincide with those of the IP7 form and are as follow:

Reporting date	Report period
30 April	IP transactions concluded between 1 October and 31 March under general approval provisions in paragraph 3.1
31 October	IP transactions concluded between 1 April and 30 September under general approval provisions in paragraph 3.1

3.2.2 The report to NIPMO must be on the relevant IP Form via the KIM system.
- Form IP4 for local assignment,
- Form IP5 for offshore assignment,
- Form IP6 for offshore exclusive licence, and
- Form IP8 for royalty-free provisions and collaborative clauses.

7 The World Health Organisation lists of Neglected Tropical Diseases https://www.who.int/health-topics/neglected-tropical-diseases#tab=tab_1. The list of neglected diseases includes: Buruli ulcer; Chagas disease; Dengue and Chikungunya; Dracunculiasis; Echinococcosis; Foodborne trematodiases; Human African Trypanosomiasis (sleeping sickness), Leishmaniasis; Leprosy; Lymphatic tilariasis; Mycetoma, Chromoblastomycosis and other deep Mycoses; Noma; Onchocerciasis; Rabies; Scabies and other Ectoparasitoses; Schistosomiasis; Soil-transmitted helminthiases; Snakebite envenoming; Taeniasis/cysticercosis; Trachoma; and Yaws.

8 List of developing countries by the International Statistical Institute: https://www.isi-web.org/low-and-middle-income-countries-and-regions

3.2.3 As part of the submission the cover letter must indicate that the submission relates to the upfront approval relating to clinical trial. Since approval is automatic, a short and concise motivation is required[9].

3.2.4 In the instance of serendipitous IP being generated during the clinical trials, not funded on a full cost basis, this general NIPMO approval will not be applicable. The institution generating the serendipitous IP will be the owner in accordance with the provisions of the IPR Act[10] and must report it accordingly. NIPMO will consider such applications on a case-by-case basis, taking into account the motivation provided and non-compliance "*will render such intellectual property transaction and relevant agreement void from the beginning*" [11].

4. CONCLUSION

4.1 NIPMO's upfront approval is granted for royalty-free licences for commercial purposes (local or offshore), offshore exclusive licences, and local or offshore assignments of clinical trial outputs meeting the criteria as set out in paragraph 3 above. NIPMO reminds institutions of its preference for institutions to enter into licences where possible rather than assignments and further of the institutions obligation to commercialise IP generated from publicly financed R&D, where applicable.

4.2 Please bear in mind that should an institution intend to conclude an offshore assignment; prior South African Reserve Bank approval would be required.

[9] Section 11 and 12 of the IPR Act
[10] Section 4(1) of the IPR Act: Subject to section 15(2), intellectual property emanating from publicly financed research and development shall be owned by the recipient. 8 Sections 11 and 12 of the IPR Act
[11] Regulation 17 of the IPR Act: Effect of non-compliance by a recipient. Failure by a recipient to obtain from NIPMO, approval for an intellectual property transaction for which approval is required in terms of the Act and these regulations, will render such intellectual property transaction and relevant agreement void from the beginning.