NIPMO NOTICE

Dear NIPMO Stakeholder

CLINICAL TRIALS AND INTELLECTUAL PROPERTY OWNERSHIP

1. INTRODUCTION

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

1.2 In terms of the IP ownership requirement according to the IPR-PFRD Act, it is provided that intellectual property emanating from publicly financed research and development (hereinafter “R&D”) shall be owned by the recipient\(^2\), unless said R&D is funded by a private entity or organisation\(^3\) on a full cost basis in which case the provisions of the IPR-PFRD Act will not apply\(^4\).

1.3 The above IP ownership provisions appear to present a challenge for institutions that conduct specific philanthropical clinical trials, which are not funded on a full cost basis, but where the private entity or organisation insists on owning the IP generated because of its humanitarian benefit to society.

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1 Section 2(1) of the IPR-PFRD 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 4(1) of the IPR-PFRD Act

3 Section 15(5) of the IPR-PFRD 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.

4 Section 15(4)(a) of the IPR-PFRD 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.
1.4 It is against this background that NIPMO facilitated a Round Table Discussion on "Clinical Trials and IP ownership" on 22 August 2013 in Cape Town. The discussion was held in order to establish the challenges experienced by practitioners during negotiations for the funding of clinical trials and the ownership of subsequent IP generated during these trials.

1.5 The Round Table Discussion was attended by personnel from Offices of Technology Transfer (OTT), researchers who conduct clinical trials, the National Health Laboratory Service and a representative from the Health Innovation sub-programme of the Department of Science and Technology.

1.6 During discussions, NIPMO was requested to give consideration to the provision of "general approval" for the ownership of specific IP outputs from clinical trials under very specific instances. NIPMO undertook to give consideration to this request and, as part of this process, to seek advice from the NIPMO Advisory Board.

2. GENERAL APPROVAL PROVISIONS AND REPORTING REQUIREMENTS

This process is now complete and NIPMO hereby advises as follows:

2.1 General approval provisions

NIPMO hereby grants upfront approval for institutions that conduct clinical trials where the following four conditions are met:

(a) For IP transactions (including royalty-free non-exclusive licences, offshore exclusive licences, or local and offshore assignments) on IP generated following a clinical trial (phase 1 to 3);

(b) wherein the clinical trial is for specific infectious diseases which include HIV/AIDS, Tuberculosis, Malaria and neglected diseases\(^5\), which neglected diseases are: Buruli ulcer disease, Chagas disease, Dengue, Dracunclusiasis (guinea-worm disease), Echinococcosis, Endemic treponematoses, Foodborne trematodiases, Human African Trypanosomiasis (sleeping sickness), Leishmaniases, Leprosy, Lymphatic filariasis,

Onchocerciasis (river blindness), Rabies, Schistosomiasis (bilharzia), Soil-transmitted helminthiases, Taeniasis/cysticercosis, and Trachoma;

(c) and the clinical trial is funded by a philanthropic organisation (or its intermediary) which funding is not on a full cost basis;

(d) and wherein the objective is to make the tested drugs available at a preferential rate or at a reduced cost in developing countries⁶.

NIPMO grants this approval to institutions for a specific review period of 3 years, after which this general approval will be reviewed. The approval period is from 1 September 2013 to 30 August 2016.

Please note that the approval provisions are subject to amendment which amendments will be communicated to stakeholders six months prior to the reporting date (see below).

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 thereof in terms of the provisions of the IPR-PFRD Act⁷ and will report on it accordingly.

2.2 Reporting Requirements

Kindly note that although upfront approval is granted, ALL eligible IP transactions must still be reported to NIPMO on the relevant IP Form (Form IP4 for local assignment, Form IP5 for off-shore assignment, Form IP6 for off-shore exclusive licence, and Form IP8 for non-exclusive royalty free provisions). Submission of the Forms will merely be a formality to ensure compliance as per the provisions of the IPR-PFRD Act⁸ and an extensive motivation is therefore not required.

All IP4 to 6 and 8 Forms which fall within the prescribed provisions of paragraph 2.1 above must be submitted to NIPMO on a biannual basis. The submission dates will coincide with those of the IP7 Forms “Intellectual Property Status and Commercialisation Reports” and are as follows:

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⁶ List of developing countries by the International Statistical Institute: [http://www.isi-web.org/component/content/article/5-root/root/81-developing](http://www.isi-web.org/component/content/article/5-root/root/81-developing)

⁷ Section 4(1) of the IPR-PFRD 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-PFRD Act
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<thead>
<tr>
<th>Reporting date</th>
<th>Report period</th>
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<tbody>
<tr>
<td>30 April</td>
<td>For IP transactions concluded between 1 September and 31 March in terms of the general approval provisions set out in paragraph 2.1 above</td>
</tr>
<tr>
<td>31 October</td>
<td>For IP transactions concluded between 1 April and 30 September in terms of the general approval provisions set out in paragraph 2.1 above</td>
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In instances where only some of the provisions for the clinical trial outputs are met (provided in paragraph 2.1 above), institutions have to follow the normal procedures in obtaining NIPMO approval under the IPR-PFRD Act and regulations. NIPMO will consider such applications on a case-by-case basis, taking into account the motivation provided. We remind you that non-compliance "will render such intellectual property transaction and relevant agreement void from the beginning".  

3. CONCLUSION

3.1 Please bear in mind that should the institution conclude an off-shore assignment, prior National Treasury approval would be required. Regulation 10(1)(c) of the Exchange Control Regulations of 1961 provides that prior National Treasury permission must be obtained before entering into any transaction whereby capital or any right to capital is directly or indirectly exported from the Republic. The amended National Treasury Exchange Control Regulations\(^9\) defines "capital" to include both registered and unregistered IP rights\(^10\).

3.2 Kindly note that NIPMO approval is granted for royalty-free non-exclusive licences, offshore exclusive licences, and local and offshore assignments of clinical trial outputs complying with the above stated provisions. The NIPMO reminds institutions of its preference for institutions to enter into licences rather than assignments and further of the institutions obligation to commercialise IP generated from publicly financed R&D, where applicable.\(^12\)

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\(^9\) Regulation 17 of the IPR-PFRD 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.

\(^10\) 8 June 2012, Amended the Exchange Control Regulations (Government Gazette No. 35430)

\(^11\) Regulation 10(4) of the Currency and Exchanges Act (9 of 1993) For the purposes of sub-regulation (1)(c)-
(a) 'capital' shall include, without derogating from the generality of that term, any intellectual property right, whether registered or unregistered; and
(b) 'exported from the Republic' shall include, without derogating from the generality of that term, the cession of, the creation of a hypothetic or other form of security over, or the assignment or transfer of any intellectual property right, to or in favour of a person who is not resident in the Republic.

\(^12\) Section 5(1)(a) & (g) of the IPR-PFRD Act: A recipient must
Please do not hesitate to contact Jetane Weyers (Jetane.weyers@nipmo.org.za) should you have any queries or comments on this matter.

Kindly acknowledge receipt of this correspondence and the contents thereof by return mail by no later than Thursday 20 March 2014.

We look forward to receiving your first batch of Forms IP4 to 6 and 8 for all IP transactions concluded during the period 1 September 2013 to 31 March 2014 by 30 April 2014 as per the granted approval.

Warm regards

Kerry Faul
Head: NIPMO

(a) put in place mechanisms for the identification, protection, development, management of intellectual property, intellectual property transactions and, where applicable, the commercialisation of intellectual property and appropriate capacity-building relating thereto;

(g) negotiate and enter into intellectual property transactions with third parties on intellectual property belonging to the recipient.