

EQUITABLE TECHNOLOGY ACCESS FRAMEWORK (ETAF)

Every health technology developed by publicly-funded research or at a publicly-funded institution (hereinafter “publicly-funded research institution” “PFRI”) with the potential for further development into a medicine, vaccine, medical device, procedure and system¹ (hereinafter “health technology”) should be transferred with a concrete and transparent strategy to make affordable versions equitably available for patients. This document acts as a framework for this process to be adapted based on the context. Technology transfer is complex and occurs through different modalities, hence each case will be unique. PFRI should therefore implement concrete Global Access Strategies that adhere to all of the following 3 Goals.

GOALS:

- I. Improve global equitable access
Equitable access² refers to the global availability and affordability of health technologies and should be the primary purpose of technology transfer. Maximising equitable access includes both promoting the availability of health technologies while protecting affordability.
- II. Promote further development of health technologies
Technology transfer should promote utilisation and further development of the health technology, while ensuring that intellectual property does not act as a barrier to further research. Therefore, intellectual property must be managed in a way that is conducive to the dissemination and sharing of knowledge and the benefits of scientific progress.
- III. Improve transparency of health technology transfer
Technology transfer agreements, the nature of technology transfer negotiations, and the patent status of health technologies should be transparent to ensure effective evaluation of the PFRI’s strategies. In addition, all funding sources and amounts should be made public.

¹ WHO. *What is a health technology?* Available from: <https://www.who.int/health-technology-assessment/about/healthtechnology/en/?fbclid=IwAR3HxOaemMMiXwpTDRfwA2F2fddCh4thD3DqFsZKSONnR1NtrZEDMDIsZcg> [Accessed 03 July 2020]

² WHO. *Accessibility.* Available from: [who.int/gender-equity-rights/understanding/accessibility-definition/](https://www.who.int/gender-equity-rights/understanding/accessibility-definition/) [Accessed 24 February 2020]

GENERAL PRINCIPLES OF GLOBAL ACCESS TECHNOLOGY TRANSFER

These principles are applicable to all technology transfer modalities.

- I. As publicly and charitably funded bodies, *publicly funded research institutions* (PFRI) have a responsibility to act in the interest and to the benefit of the public. Throughout the entire research and technology transfer processes the primary objective must be to ensure a return on public investment by maximising availability, accessibility and affordability to the health technology.
- II. Monopolies are an important barrier to facilitating affordable access to health technologies in all countries. Therefore, such barriers should be reduced to allow for competition. Issuing non-exclusive licenses is one way to achieve this.
- III. PFRI should, wherever possible, retain intellectual property (IP) rights as this maximises their influence over the management of health technologies.
 - A. Any transfer of rights should be contingent on the attachment of conditions that promote access, in accordance with the *ETAF Goals and Principles*. This includes, but is not limited to, agreements relating to licensing of health technologies, cooperation with other parties, and employment of researchers.
 - B. In the event that the PFRI does not retain ownership over the IP developed by researchers employed or funded by the PFRI, all principles in this document should still apply to the transfer of IP from the PFRI to a third party.
- IV. Step-in rights are a necessary tool to ensure affordable access to health technologies. They should therefore be included in all agreements involving the transfer of health technologies, and should be actively enforced if the default strategies taken to promote access are found to be ineffective.
 - A. Examples of step-in rights may include, but are not limited to:
 1. Partial or full revocation of technology transfer agreements.
 2. Retention of rights to unilaterally issue non-exclusive sub-licenses under a licensing agreement.
 3. Application of field-of-use limitations in technology transfer agreements.
- V. All technology transfer agreements should feature 'reach through' clauses. These ensure that future utilisations of transferred technologies are subject to the same access protections conveyed by the original transfer agreements.
- VI. PFRI should always waive market and/or data exclusivities in jurisdictions where this is possible, and should refrain from applying for further extensions to market and data protections. PFRI should mandate that subsequent patent owners or licensees honour this same principle.
- VII. PFRI should commit to full sharing of all data and research findings to promote further research and scientific progress. This includes the publishing of all clinical trials regardless of its outcome or completion.

- VIII. PFRIs should commit to ensure transparency of all public funding sources and amounts for the entire research and development process of a health technology and commit to ensure the same disclosure from the end producers.

- IX. PFRIs should implement robust accountability and transparency mechanisms. It should commit to continuous evaluation of the success of the strategies applied in achieving sustainable affordable access to the health technology.
 - A. Any deviation from the principles and strategies set out in this document should be justified by the PFRI in a publicly available statement, alongside a strategy to promote access to the health technology.

MODALITIES OF TECHNOLOGY TRANSFER AND CORRESPONDING STRATEGIES

A: LICENSING

Where licensing is the mechanism of technology transfer, the following licensing strategies should be employed:

1. The preferred mode of technology transfer should always be **non-exclusive licensing, whereby as many licensees as possible are actively sought out** (Principle II)
In instances where there are justifiable reasons why this is not possible, one or more of the following strategies should be employed:
 - 1.1. Non-exclusive licensing of the health technology, without active seeking of multiple licensees.
 - 1.2. Limit exclusive licenses to high-income countries, as defined in the World Bank's List of Economies³, and grant non-exclusive licenses in low- and middle-income countries.
2. The licensee and licensor should commit to disclosing all sources of public funding for the health technology (Principle VIII).
3. To prevent downstream compromise of Principles I and II, licensors should waive rights to regulatory monopolies such as data and market-exclusivities (Principle VI).
4. Licensing agreements should include step-in rights that become active if the default strategies are found to be ineffective in providing affordable access to the health technology. (Principle IV).
5. Licensing agreements should include 'reach through' clauses (Principle V), that require the following:
 - 5.1. Any future health technology developed from the original licensed health technology is subject to the same access protections conveyed by the original transfer agreements.
 - 5.2. Any further sub-licenses related to the original licensed technologies are subject to the same access mechanisms included in the original publicly funded research institutions (PFRI) license.
6. All of the strategies chosen by the PFRI must be justified in a publically available statement (Principle IX).

³ World Bank Country and Lending Groups, World Bank Data. Online source: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>. [Accessed 3 October 2019].

B: SPIN-OFF COMPANY

Where a spin-off company is established as a means of health technology transfer, the following strategies should be employed:

1. For all research conducted, the publicly funded research institution (PFRI) should adhere to Principle III in its management of all intellectual property (IP) generated by faculty members, staff, and students affiliated with the PFRI.
 - 1.1. If the PFRI is unable to retain full IP rights, this must be justified. Furthermore, the broadest possible rights attainable should be retained, and effective step-in rights to guarantee access to the health technology should be implemented (Principles III, IV).
2. As a condition of the transfer of IP from the PFRI to faculty members, staff, and students affiliated with the PFRI, prior to the creation of a spin-off company, commitment to protecting affordable access to the health technology should be included in the contractual agreements covering “in kind contributions” of the spin-off company, and Memorandums of Understanding between the PFRI and the spin-off company (Principle I).
3. As part of these commitments, the spin-off company should commit to the following concrete steps to protect access to the health technology (Principle II):
 - 3.1. Commit to issuing non-exclusive licenses permitting generic production of the health technology.
 - 3.2. Commit to not enforce monopolies in any country.
 - 3.3. Commit to limit monopolies to high-income countries, as defined in the World Bank's List of Economies¹, and grant non-exclusive licenses in low- and middle-income countries.
4. The spin-off company and PFRI should commit to disclosure of all public funding for the health technology (Principle VIII).
5. The PFRI should produce, separately to the contractual agreements and Memorandums of Understanding, a publicly-available statement detailing and justifying the manner in which commitment to access was guaranteed by the spin-off company, and the strategies chosen to enact this (Principles I and IX).
6. To prevent downstream compromise of Principles I and II, the spin-off company should waive rights to regulatory monopolies such as data and market-exclusivities (Principle VI).
7. In the case of a merger or acquisition involving the spin-off company, all commitments to the *ETAF Goals and Principles* set out in this document should be retained in all agreements and legally binding contracts.
8. Technology transfer agreements from a PFRI to a spin-off company should include ‘reach through’ clauses (Principle V), that is, clauses requiring that:



- 8.1. Any future health technology developed from the original transferred health technology are subject to the same access protections conveyed by the original transfer agreements.
- 8.2. Any further technology transfer agreements between the spin-off and a third party related to the original transferred IP are subject to the same access mechanisms included in the original PFRI-spin-off licence.

C: PRODUCT DEVELOPMENT PARTNERSHIP (PDP)

When the publicly funded research institution (PFRI) enters into a Product Development Partnership - including partnerships with private entities, public entities, and other PFRI - the following strategies should be employed:

1. Where possible, PFRI should enter research partnership agreements with third parties which adhere to existing principles on accessibility, affordability, and transparency of health technologies in alignment with those outlined in this framework (Principle I).
2. The PFRI should ensure that intellectual property (IP) rights resulting from the cooperation are either shared or retained by the PFRI, and that decisions over enforcement of shared IP are jointly discussed (Principle III). This may be achieved through:
 - 2.1. A prior contractual agreement with the partner before initiating the PDP.
 - 2.2. Jointly submitting funding applications with the partner.
3. Management of jointly held IP rights should prioritise the following strategies for promoting access (Principle II):
 - 3.1. Commit to issuing non-exclusive licenses permitting generic production of the health technology.
 - 3.2. If there is a justifiable reason why a monopoly is unavoidable, these should be limited to high-income countries, as defined in the World Bank's List of Economies¹, with provisions allowing non-monopolistic competition in low- and middle-income countries.
4. To prevent downstream compromise of Principles I and II, partners should waive rights to use and enforce regulatory monopolies such as data and market-exclusivities (Principle VI).
5. The partners should commit to disclosing all sources of public funding for the health technology (Principle VIII).
6. Product development partnership agreements should include 'reach through' clauses (Principle V), that is, clauses requiring that:
 - 6.1. Any future health technology developed from the original transferred health technology by any partners or sub-licensees are subject to the same access mechanisms included in the original agreement.
 - 6.2. Any further technology transfer agreement between the product development partner and a third party related to the original IP are subject to the same access mechanisms included in the original agreement.
7. All steps taken to promote affordable access to the health technology throughout the product development partnership process, along with all formal outcomes of agreements with partners, should be published and justified (Principle IX).

D: COMMISSIONED RESEARCH

When the publicly funded research institution (PFRI) is being commissioned by a third party to conduct research, the following strategies should be employed:

1. Wherever possible, PFRI should enter research partnership agreements with private and public entities which adhere to existing principles on accessibility, affordability, and transparency of health technologies in alignment with those outlined in this framework ([Principle I](#)).
2. In cases where the research partner does not have existing principles on affordable access in all countries, the PFRI should include provisions in the commission contract that ensure global availability and protection of affordable access to the health technology through the following strategy:
 - 2.1. Limitation of any monopolies to high-income countries, as defined in the [World Bank's List of Economies](#), with provisions allowing non-monopolistic competition in low- and middle-income countries ([Principle II](#)).
3. To prevent downstream compromise of [Principles I and II](#), all partners should waive rights to use and enforce regulatory monopolies such as data and market-exclusivities ([Principle VI](#)).
4. All partners should commit to disclosure of all public funding sources for the health technology ([Principle VIII](#)).
5. If none of the above provisions can be achieved in negotiations with potential partners, the PFRI should not enter into partnership with the partners ([Principle I](#)).
6. The following additional steps should be taken to preserve the effectiveness of the above strategies:
 - 6.1. The PFRI should communicate with any other institutions commissioned by the partner, such that these institutions also include the above provisions in any contracts with the partner.
 - 6.2. Inclusion of the above provisions in all contracts made between the partner and the PFRI.
7. Commissioned research agreements should include 'reach through' clauses, that is, clauses requiring that ([Principle V](#)):
 - 7.1. Any future health technology developed from the original health technology transferred by the partner is subject to the same access mechanisms included in the original research partnership agreements
 - 7.2. Any further technology transfer agreement between the PFRI or partner and a third party related to the original IP are subject to the same access mechanisms included in the original agreement.

MECHANISMS FOR ACCOUNTABILITY

To ensure accountability with regard to the strategies set out in each of the above modalities, the following mechanisms should be implemented (Principle IX):

1. The publicly funded research institution (PFRI) should make information public concerning when it is in negotiations regarding technology transfer with a third party, the specific health technology concerned, and the identity of the third party.
2. The PFRI should publish technology transfer agreements in full for all health technologies on the PFRI's website as soon as they are finalised. If there is a justifiable reason why the full technology transfer agreement cannot be made publicly available, the following strategies should be employed :
 - 2.1. The PFRI should publish a redacted version of the technology transfer agreement, which should contain, as a minimum, unredacted text relating to access to and affordability of the health technology.
 - 2.2. The PFRI should publish and justify the exact language used during the transfer process to promote access to and affordability of the health technology.
3. The PFRI should release a publicly available annual report, or maintain a page on the PFRI's website, detailing the transfer processes for all health technologies which took place in the previous year. This report/page should contain the following information for each technology transfer:
 - 3.1. To whom the technology was transferred, with specific reference to:
 - 3.1.1. The current owners of all intellectual property (IP) related to the health technology in question.
 - 3.1.2. All parties to whom rights to use any IP have been licensed or transferred.
 - 3.1.3. What the mode of transfer was, with reference to the modalities and conditions set out above.
4. All universities, being PFRI's with an attached student body, should additionally implement the following strategies:
 - 4.1. Establishment of a committee composed of existing university staff, from both academic and non-academic backgrounds and including representation from the university's Ethics Committee, alongside student representatives.
 - 4.1.1. This committee should be endowed with the responsibility and relevant powers for regular monitoring and promotion of adherence to the strategies committed to by the university in all of its health technology transfer processes.
 - 4.1.2. If the university does not adhere to its committed strategies, this committee can make recommendations to a higher body, such as the University Board, including recommending the utilisation of step-in rights (Principle V).

- 4.1.3. The activities and findings of this committee should be publicly accessible, and actively shared with the staff and student-body through appropriate channels, including Students' Unions, student representatives, and/or relevant student societies.
- 4.2. Assignment of the responsibilities and powers set out in *Accountability 4.1.* to an existing relevant body within the university, such as (Faculty) Ethics Committees which must also include university students on a volunteer basis.
5. In the implementation of *Accountability 4.1.* all members of the committee should declare all potential conflicts of interest publicly available.
6. In the implementation of *Accountability 4.1.* the selected university students should ideally be members of Universities Allied for Essential Medicines, as the original proposers of this framework.
 - 6.1. Alternatively, or in addition, the students should be chosen by the wider student body.