1. SCOPE
This Policy applies to all staff, students and visiting researchers at the London School of Hygiene and Tropical Medicine (LSHTM) including the MRC Unit The Gambia at LSHTM, and the MRC/UVRI and LSHTM Uganda Research Unit. LSHTM expects the principles, policies and procedures set out in this Policy to be understood, observed and followed by all staff, students and visiting researchers.

2. PURPOSE AND OVERVIEW
This policy provides a framework and guidance for the effective identification, protection and translation of LSHTM intellectual property (IP) to ensure that LSHTM’s research activities deliver societal impact and patient benefit in an ethical and socially responsible manner.

Employees and Students of LSHTM consistently produce research with a focus on delivering real-world impact. Impact can be achieved by dissemination of research findings widely to the research community or society as a whole. Translation, or technology transfer, can also play a vital role in realising impact from academic research, facilitating development of therapeutics, diagnostics or other products and services arising from academic research findings, allowing them to reach patients and wider communities.

IP generated from innovation and translation must be managed effectively so that industrial partners can be attracted to progress the development and commercialisation of products and services arising from academic discoveries made at LSHTM, and to ensure such inventions are translated in a manner consistent with LSHTM’s mission and status as a socially responsible higher education and research institution. Any revenue generated from commercialisation of LSHTM IP is invested back into funding further research and/or education as well as into supporting further technology transfer activities.

3. POLICY

3.1. Terminology

Awards to Inventors (ATI) means LSHTM’s scheme for the distribution of Distributable Payments to eligible Originators (refer to section 3.6.7).
Commercialisation means all forms of commercialisation or exploitation by LSHTM, alone or in conjunction with a Third Party, including licensing or any other means of disposal of any rights vested in LSHTM in return for any form of Consideration. Commercialisation in this context does not include the delivery of courses by LSHTM in the course of its role as a higher education institution.

Confidential Information means all information of LSHTM or a Third Party that is not already in the public domain.

Consideration means any payments, income or revenue received from Commercialisation, including, but not limited to, cash, payment in kind and equity.

Distributable Payments means all monetary Consideration received by LSHTM after the deduction of costs incurred by LSHTM for the protection and Commercialisation of the relevant IP such as patent-related costs and external lawyer’s fees.

Employee means an employee of LSHTM.

Finance and Development Committee means the committee of that name, or its successor committee, to which LSHTM’s Council has delegated responsibility for the evaluation and approval of Commercialisation of its Intellectual Property.

Incidental Use of LSHTM Resources shall refer only to very insignificant use of LSHTM’s general resources, such as computers or office equipment. If there is any doubt as to whether an activity constitutes more than an Incidental Use of LSHTM Resources, the matter should be referred to the Innovation Committee.

Innovation Committee means a committee comprising of one representative from each faculty, LSHTM’s Chief Operating Officer, representation from LSHTM’s Strategic Research Office, representation from LSHTM’s Research Operations Office a representative(s) from LSHTM’s Technology Transfer team. Where additional or independent expertise is required, external advisors will join LSHTM Innovation Committee meetings.

IP (Intellectual Property) means all research results and data generated through research programmes conducted at LSHTM (including with Third Party collaborators), as well as all other outputs of work conducted by Originators, such as Teaching Materials, and all intellectual property rights associated with or arising from such results and outputs. Intellectual property rights mean patents and utility patents, including all divisionals, continuations and supplementary protection certificates, copyright, database rights, topography rights, design rights, whether registered or not, trademarks, whether registered or not, rights to prevent passing off, plant breeders rights and know-how, including any inventions in such know-how and all applications for any of the foregoing, including the right to claim priority. IP should also be interpreted to include all other intellectual or industrial property rights (whether registered or unregistered / registrable or un-registrable) and including applications or rights to apply for them, all extensions and renewals of them, and in each case all rights having equivalent or similar effect anywhere in the world.

Originator means any Employee, individuals treated as an Employee as defined in this policy, such as a visiting worker and honorary appointee, or Student that creates or contributes to the creation of research results and data, inventions, copyright (including software) and designs (whether registered or unregistered / registrable or un-registrable); compiles, presents or verifies a database; generates or develops new plant varieties, Research Materials, Teaching Materials, know-how or any other IP (as defined above).
Physical Manifestations of IP shall mean all documents, including lab books, electronic files/documents or other tangible materials that comprise of or otherwise record LSHTM IP.

Research Materials shall include, but not be limited to, all biological materials, non-biological materials, chemical entities, compounds, samples, formulae, models, processes, instructions, graphic representations, technical specifications, designs and drawings, databases, computer software, prototype devices and equipment, diagnostic and research-use kits as well as any associated research results.

Research Operations means the team concerned with the management of LSHTM's portfolio of research grants.

Research Publications Team means the team concerned with research publications within the Library & Archives Service.

LSHTM means the London School of Hygiene and Tropical Medicine.

Senior Leadership Team means the decision making body which takes a collective overview of and responsibility for School-wide issues.

Student means any individual registered as a postgraduate student at LSHTM or applying for a PhD by Prior Publication in lieu of a thesis, or any individual following a course of study at LSHTM as if they were a Student.

Teaching Materials shall include all present materials for teaching, such as lecture notes, slides and other audio-visual teaching aids, course guides and instruction manuals, lecture handouts, recorded lectures, examination questions, online materials and virtual learning environments and physical materials, such as apparatus for practical and experimental work and models for demonstration.

Technology Disclosure Form means the appended form, intended to aid the disclosure to LSHTM of inventions, technologies or other IP with potential for Commercialisation, via its Technology Transfer team.

Technology Transfer team means any external service provider or internal team, including LSHTM's IP manager, engaged in the future to assist with the protection, translation and exploitation of LSHTM IP.

Third Party means any legal entity that is not directly or indirectly controlled by or under common control of LSHTM, such as companies, government bodies, funders and charities or any other entity or individual that is not an Employee.

3.2. Ownership of IP and Research Materials created by Employees

3.2.1. Ownership of IP/Research Materials created by Employees

All IP created and/or developed by an employee in the course of their employment will belong to their employer as a matter of law (Copyright, Designs and Patents Act 1988 and the Patents Act 1977).

As provided under their employment contract with LSHTM, all IP and Research Materials created and/or developed by an Employee during the course of their employment duties, or that might reasonably be expected to result from the Employee carrying out their duties, will vest in LSHTM. The latter instance arises, for example, if the subject matter of such IP is materially
similar to the subject of their employment and is therefore not severable from their employment duties. In the event that such IP and/or Research Materials are created and/or developed by an Employee only partly during the course of their employment duties or that might reasonably be expected to result from the Employee carrying out their duties, LSHTM will own the part of IP/Research Materials corresponding to the proportional contribution.

If any IP or Research Materials such as software and databases are created and/or developed with more than an Incidental Use of LSHTM Resources, even if outside the scope of an Employee’s normal employment duties, the Employee will assign ownership of such IP to LSHTM and will do so upon the request of LSHTM.

These provisions in 3.2.1 above shall apply to all Employees, including Students that are also Employees.

3.2.2. Employee Technology Disclosure
Employees are expected to disclose all technologies, inventions, research discoveries, or other IP they create and/or develop, including Teaching Materials and Research Materials, which have the potential for Commercialisation to LSHTM’s Technology Transfer team.
Employees are encouraged to make all such disclosures to LSHTM’s Technology Transfer team using the Technology Disclosure Form [see appendix 1].

3.2.3. Honorary Appointments and Visiting Workers
In instances where an Employee of LSHTM wishes to enter into an honorary academic appointment at another institution, a contract must be entered into between LSHTM and the institution in question governing the terms of the appointment before initiating that honorary appointment. Such agreement will include terms that set out, among other things, the ownership of all arising IP/Research Materials and provisions for access to any existing LSHTM IP or Research Materials. In all such instances, the Employee should discuss this arrangement with Research Operations and any contract will be negotiated by Research Operations in consultation with the Technology Transfer Team on behalf of LSHTM.

In instances where an individual is not an Employee or a Student of LSHTM but has an honorary appointment with or is a visiting worker at LSHTM, such individuals will adhere to the provisions of this policy as if they were Employees of LSHTM and will only commence their appointment once a contract has been entered into between LSHTM and that individual, and/or their employer where applicable, which governs the terms of that appointment. All arrangements in 3.2.3 above will be made by Research Operations and any contract will be negotiated and signed by Research Operations on behalf of LSHTM.

Unless explicitly stated to the contrary in any agreement referenced in the preceding paragraph, all honorary appointees or visiting workers at LSHTM will, when requested, assign to LSHTM the ownership of all IP, Research Materials and Teaching Materials created and/or developed during the course of their activities at LSHTM and/or all IP, Research Materials and Teaching Materials such as software and databases created and/or developed with more than an Incidental Use of LSHTM Resources. In return for this assignment, such honorary appointees and visiting workers will be treated as if they were Employees with respect to Awards to Inventors and be eligible to receive ATI (please refer to section 3.6.7 for further detail).

3.2.4. Deposit of Physical Manifestations of IP and Materials
Upon LSHTM’s request each Employee must deposit with a person to be nominated by the Innovation Committee all Physical Manifestations of IP, Research Materials and Teaching Materials owned by LSHTM. In all instances, an Employee must deposit all such Physical Manifestations of IP, Research Materials and Teaching Materials prior to leaving LSHTM’s
employment. Author Accepted Manuscripts of research papers, and where possible final published versions, should be deposited in LSHTM Research Online via the Elements publications system. Research data should be signposted from and where appropriate deposited in LSHTM Data Compass.
3.3. Ownership of IP and Research Materials – Students

3.3.1. Assignment of Student IP
Students who are not also Employees shall assign the ownership of IP and Research Materials to LSHTM if any of the following apply:

- they are conducting their studies as part of a sponsored studentship or sponsored research programme, to the extent that the agreements regulating said sponsoring require said assignment or grants any rights to IP or research Materials to third parties;
- they are working on a project that derives from the IP of an Employee or involves substantial collaboration with an Employee, unless there is no intellectual contribution by the Employee.
- they create and/or develop IP or Research Materials such as software and databases with more than an Incidental Use of LSHTM Resources;
- they create and/or develop Teaching Materials.

Where a Student is undertaking any of the above-mentioned activities, they will sign the Student IP Letter of Understanding before commencing work on the project [see appendix 2]. Students, however, shall not be required to assign the ownership of copyright in any thesis or report submitted to LSHTM for the award of an academic degree, and nothing beyond legal and contractual obligations relating to confidentiality will prevent a Student from submitting a thesis or report for examination.

If a student conducting any of the above-mentioned activities does not assign their rights in the IP, Research Materials and Teaching Materials they create and/or develop to LSHTM, LSHTM may choose not to allow them to conduct such activities.

3.3.2. Students and Awards to Inventors policies
In instances where the ownership of IP, Research Materials and Teaching Materials created and/or developed by a Student is assigned to LSHTM, such IP will be subject to all other provisions in this policy in relation to the management of LSHTM IP. For clarity, Students will be eligible to receive Awards to Inventors (please refer to section 3.6.7 for further detail).

3.3.3. Student Technology Disclosure
Students are expected to disclose all technologies, inventions, research discoveries, or other IP they create and/or develop, including Teaching Materials and Research Materials, which have the potential for Commercialisation to LSHTM’s Technology Transfer team. Students are encouraged to make all such disclosures to LSHTM’s Technology Transfer team using the Technology Disclosure Form [see appendix 1]. Disclosures under this section will be without prejudice to any of the Students rights as set in this Policy.

3.3.4. Grant of rights to LSHTM
Students conduct a broad range of activities at LSHTM, and some activities may result in the Student, as opposed to LSHTM, owning the resulting IP. Examples may include, the copyright in theses, reports, non-research based course work and certain creative works they may develop, provided that they do not conform to the provisions set out in 3.3.1. Upon the creation and/or development of any such IP, each Student shall provide LSHTM with a worldwide, non-exclusive, perpetual and irrevocable right to use such IP for all purposes, including but not limited to; teaching, education and promotional purposes. This will include the right to grant rights in such IP to Third Parties where appropriate.
Should the student submit a thesis or dissertation in the course of their studies, LSHTM will be required to place the document in the public record via LSHTM Research Online. There may be the need to delay the public disclosure of any thesis or dissertation in order to protect patentable IP, third-party IP, or sensitive data. All students are expected to deposit their thesis in accordance with LSHTM's Electronic Doctoral Degree Theses Submission Policy but in justified cases could request to restrict access for a maximum two-year embargo.

3.3.5. Deposit of Physical Manifestations of IP and Materials
Upon LSHTM's request, each Student must deposit with their supervisor all Physical Manifestations of IP, Research Materials and Teaching Materials. In all instances a Student must have deposited all such Physical Manifestations of IP, Research Materials and Teaching Materials prior to completing their studies.

3.4. Material Transfer
No Research Materials shall be transferred outside of LSHTM or to any Third Party unless an appropriate Material Transfer Agreement(s) is in place, such arrangements to be negotiated by Research Operations or LSHTM's Technology Transfer team and signed by Research Operations. In all instances, such agreements shall be first discussed with Research Operations. No data shall be transferred outside of LSHTM or to any Third Party unless an appropriate Data Transfer Agreement(s) is in place, such arrangements to be negotiated by the Research Data Manager in the Library & Archives Service. Research data should be signposted from and where appropriate deposited in LSHTM Data Compass.

All Employees shall make LSHTM aware of any Research Materials that they may wish to bring with them at the time of initiating their employment with LSHTM. If any of these Research Materials were generated during their previous employment or may belong to any other Third Party, they will only be permitted to do so once LSHTM’s Research Operations Office puts in place an appropriate Material Transfer Agreement(s) accessing the necessary Third Party rights to such materials. If Employees wish to bring with them commercially available or purchased materials they can do so if they can provide evidence that they have the ongoing right to use such materials and permission to transfer them.

In the event that a Student wishes to use Research Materials that belong to or are provided by a Third Party, the Student shall notify their supervisor and Research Operations, so that the necessary agreements are put in place prior to initiation of their project.

3.5. Teaching Materials

3.5.1. Ownership of IP in Teaching Materials
All IP in Teaching Materials created and/or developed by an Employee or Student will be owned by LSHTM.

All Employees shall make LSHTM aware of any Teaching Materials created under their previous employment that they wish to bring with them at the time of initiating their employment and will only be permitted to do so if they can provide evidence that they have the ongoing right to use such materials.

3.5.2. Commercialisation of Teaching Materials
LSHTM is free to Commercialise or freely disseminate all Teaching Materials an Employee or Student creates and/or develops as it sees fit, including as part of a package of other Teaching Materials owned by LSHTM.

LSHTM may at its sole discretion permit continuing use of Teaching Materials when the Originator leaves the employment of LSHTM or ceases to be a registered Student of LSHTM.
3.6. Protection and Commercialisation of IP & Publication of Research

3.6.1. Confidentiality and publication
It is consistent with LSHTM’s mission that research findings should be promptly published, however, short delays to publication are required when:

- the publication relates to potentially patentable IP (see 3.6.2 below) or would otherwise compromise the validity of related patent applications owned in whole or part by LSHTM, or;
- There exist contractual obligations to consult Third Parties prior to publication.

In cases of potentially patentable IP, maintaining confidentiality until a patent application has been filed at the patent office is vital to secure valid patent protection. Disclosure in any form, including publications, abstracts, posters, presentations, and all forms of public engagement, can preclude patent protection. It is the responsibility of all Employees and Students to ensure that potentially patentable IP is kept confidential until measures to protect such IP have been put in place or until a decision has been taken that patent protection should not be progressed.

All Employees and Students should disclose IP which has the potential for Commercialisation to LSHTM’s Technology Transfer team, as set out in 3.2, 3.3 and 3.5 of this policy, in a timely manner and before any disclosure of the information to a Third Party, either directly or through publication and any other form of dissemination, such as abstracts, posters and presentations. If in doubt as to whether patentable IP will be disclosed, please consult with LSHTM’s Technology Transfer team before proceeding with any disclosure.

A delay in disclosure may be necessary in order to protect potentially patentable inventions, however, the delay will be the minimum necessary to allow for the filing of a patent application. It may also be the case that omitting some details of a technology from a disclosure may allow the disclosure to proceed without delay. This should, however, be discussed and agreed with LSHTM’s Technology Transfer team before proceeding.

When publishing, all Students and Employees must comply with LSHTM’s Open Access Publishing Policy, LSHTM’s Research Data Management Policy, and the open access and data policies of their funders. As far as possible, Students and Employees should not assign their rights in any copyright to publishers. All Students and Employees should consult with the Research Publications Team within the Library & Archives Service and/or the Technology Transfer team as appropriate in advance of publication. It is acceptable for Students and Employees to retain their moral rights (which include the right to attribution) in any published copyright if they wish to do so.

Before Employees or Students embark upon discussions with a Third Party(ies) where unpublished information may be exchanged, contractual arrangements to protect Confidential Information, such as Confidential Disclosure Agreements, should be put in place by Research Operations, with input from LSHTM’s Technology Transfer team. If there is any doubt as to whether such contractual arrangements are required, all Employees or Students should first discuss the matter with Research Operations (contracts team).

3.6.2. IP protection
LSHTM shall be responsible at its sole discretion for deciding if IP protection is required for Commercialisation of any LSHTM-owned IP and LSHTM will be responsible for all costs relating to IP protection where appropriate. Following instruction by LSHTM, patent filing and prosecution will be conducted by LSHTM’s Technology Transfer team.
LSHTM’s Innovation Committee will be the forum for making all material decisions relating to IP protection in consultation with LSHTM’s Technology Transfer team, following consultation with the Originator.

3.6.3. Routes of Commercialisation
LSHTM shall be responsible for determining at its sole discretion the Commercialisation route of all LSHTM-owned IP. LSHTM’s Innovation Committee will be the forum for providing recommendations on all material decisions relating to the Commercialisation route in consultation with LSHTM’s Technology Transfer team, following consultation with the Originator. Recommendations will be ratified by the Senior Leadership Team. LSHTM’s Finance and Development Committee will receive regular updates from the committee and where appropriate will be involved in decision making. The route of Commercialisation will typically be via licencing to an existing commercial entity or via creation of a new spin-out company.

All contracts required to support the Commercialisation of LSHTM IP entered into with Third Parties will be at the sole discretion of LSHTM. Licence terms and conditions will be negotiated and agreed upon with Third Parties by LSHTM’s Technology Transfer team in consultation with LSHTM’s Innovation Committee and Research Operations.

3.6.4. Originator Assistance and Obligations
Originators will provide all reasonable assistance necessary for the protection and/or Commercialisation of IP, Research Materials or Teaching Materials, including completing all documentation required within necessary timelines, providing any support needed to patent attorneys in the prosecution or defence of patent rights, and reasonable support in the Commercialisation of IP, such as the provision of information, results, Research Materials or Teaching Materials, as required.

3.6.5. Patent abandonment
Should LSHTM elect not to seek patent or similar protection for a technology or choose to cease supporting a patent or other registered IP right, the Originator(s) may seek approval from the Innovation Committee to obtain assignment of ownership of said IP. LSHTM, via a recommendation by the Innovation Committee, may choose at its sole discretion to assign ownership of such IP to the Originator(s), provided that a suitable agreement is put in place to provide an indemnity from the Originator(s) to LSHTM against all Third Party claims arising from Originator’s use/disposal/Commercialisation of said IP. The Originator will be requested to provide evidence of an appropriate insurance policy that will adequately cover the indemnity granted to LSHTM.

If the above condition is satisfied, the assignment contract that will be put in place may also set out obligations for reimbursement of past patent cost borne by LSHTM and the agreed distribution of income arising between the Originator(s) and LSHTM in the event of successful Commercialisation of the technology by the Originator(s). In the event of assignment of LSHTM IP to Originator(s) all patent or other registered IP right-related costs will be borne directly by the Originator(s).

3.6.6. Social Responsibility
LSHTM will not support a Commercialisation strategy that is not in keeping with their mission as a socially responsible institution or that could lead to reputational risk.

LSHTM will refuse to contract with or commercialise IP in partnership with a tobacco company.
LSHTM may include provisions in commercial agreements that promote the availability of treatments at affordable prices in low income countries and may adopt an IP strategy that promotes access to such products in low income countries.

Where appropriate, LSHTM will agree to waive its right to receive revenue from the Commercialisation of treatments in low income countries, in order to promote affordable access.

3.6.7. Awards to Inventors (ATI)

In recognition for their contribution, Originators will be eligible for a share of revenues (Distributable Payments) received by LSHTM from the Commercialisation of IP, Research Materials and Teaching Materials they have created and/or developed. All Distributable Payments are distributed in accordance with LSHTM’s Awards to Inventors (ATI) scheme, as set out in the table below. LSHTM reserves the right to amend its ATI scheme from time to time including the proportions distributed between Originator(s), Departments and LSHTM.

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<th>£0-£4000 (net):</th>
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<tr>
<th>£4,000 (net) - £15,000 (net):</th>
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<th>£15,000 (net) - £75,000 (net):</th>
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All Student and Employee Originators of LSHTM-owned IP/Research Materials are eligible for the Awards to Inventors scheme. Where there is more than one Originator, the Originator(s) share will be distributed among all individuals in a proportion discussed and agreed by all Originator(s), to reflect the relative contribution of all Originator(s) in creating or developing the commercialised technology. This information shall be captured in the Technology Disclosure Form. The form will then be countersigned for final approval by the Dean of Faculty.

In instances where the chosen Commercialisation route is via creation of a spin-out company, the Originator(s) may choose to hold equity in the company. Originators may choose to take an equity holding in a spin-out or choose to be rewarded via the ATI scheme. Originators who chose to be rewarded via shareholding will waive their right to receive ATI from any Distributable Payments received by LSHTM in relation to that particular spin-out company.

3.6.8. Conflicts of Interest

Each Employee and Student has an obligation to act in the best interests of LSHTM in relation to their duties as an Employee or Student of LSHTM.
The existence of conflict of interest, or potential conflict of interest, does not necessarily imply any wrongdoing, however, it is an Employee and Student’s duty to recognise and disclose any conflict of interest (actual or perceived) to LSHTM, in order for the conflict of interest to be appropriately managed or eliminated in a manner consistent with LSHTM’s policy on conflict of interest.

Potential conflict of interest may arise where an Employee has or seeks to enter into a separate consultancy agreement with a company (including a spin-out) which has taken a licence to develop/commercialise IP created by that Employee, where the Employee or Student is engaged in a research collaboration with that company, or where an Employee or Student wishes to hold any position in a spin-out which is a vehicle for developing and commercialising IP which they helped create. Conflict may also arise in instances where the Employee or Student may have other interests in such a company or where a relative, spouse or partner of that Employee or Student may have interests in the company.

In all situations such as those described above, as well as any other situation in which potential/perceived conflict of interest exists, the matter should be declared promptly using LSHTM’s Declaration of Interest procedure, available at https://lshtm.sharepoint.com/governance/Pages/Declaration-of-Interest.aspx. LSHTM, at its sole discretion, will decide if any Employee will be permitted to engage in any of the activities described above and whether the conflict of interest could be or has adequately been resolved or mitigated.