

### **COLLABORATION AGREEMENT**

**THIS AGREEMENT dated** <sup>1st June 2020</sup> is made **BETWEEN**:

- UNIVERSITY OF KEELE, a university established by the University of Keele Act 1962 (10 &11 Eliz. 2 Ch Xv) and the granting of a Royal Charter in 1962, of Keele, Staffordshire ST5 5BG (*Keele*); and
- FEDERAL UNIVERSITY OF BAHIA, a federal public institution of higher education with its main administrative offices at Rua Basílio da Gama, s / n - Canela, Salvador - BA, 40110-040, Brazil (UFBa), represented by its Dean João Carlos Salles Pires da Silva, BRAZIL (Bahia);
- 3. **MEKELLE UNIVERSITY**, Mekelle University is a federal higher education institution established by the Council of Ministers Regulations No. 61/1999 with its main administrative offices in Mekelle, Tigray, ETHIOPIA (Mekelle); and
- 4. **RAJARATA UNIVERSITY OF SRI LANKA,** a university established on 7th November 1995 under section 21 of the university Act No. 16 of 1978, Mihintale, 50300, SRI LANKA (Rajarata);

each a "Party" and collectively "the Parties".

#### RECITALS

- A. Keele was the lead applicant in an application to the Secretary of State for Health and Social Care for Research and Innovation for Global Health Transformation (RIGHT) call 1, for a research project called "Empowering people with Cutaneous Leishmaniasis: Intervention Programme to improve patient journey and reduce Stigma via community Education (ECLIPSE)".
- B. The Award has been made to Keele and will be administered by Keele on behalf of all Parties. This Agreement sets out the terms of the collaboration.

#### It is agreed by the Parties:

#### 1. **DEFINITIONS**

1.1. The following expressions shall have the following meanings in this Agreement including its recitals, unless the context requires otherwise:

"Agreement"	means this collaboration agreement and the schedules annexed to and forming part of this agreement;		
"Allocated Tasks"	means the tasks relating to the Research Project to be performed by the Parties as set out more specifically in the Application and Schedule 5;		
"Application"	means the application made by the Parties to the Funder in relation to the Research Project application NIHR200135 and as incorporated in the Main Contract as set out in Schedule 2;		
"Background Intellectual Property"	means any Intellectual Property excluding Foreground Intellectual Property owned or controlled by any Party prior to commencement of, or independently from the Research Project, and which the owning Party contributes or uses in the course of performing the Research;		
"Co-investigator(s)"	means each of the co-investigators of the Research Project as set out in Schedule 1 (and any agreed successors);		
"Collaborator(s)"	means all parties to this Agreement, excluding Keele, referred to collectively as the "Collaborators" and individually as a "Collaborator";		
"Confidential Information"	<ul> <li>means information of any form, however conveyed and irrespective of the media on which it is stored that is:</li> <li>a) information which has been designated as confidential by a Party at the time of disclosure; or</li> <li>b) information that reasonably ought to be considered as confidential including information which relates to the business, affairs, properties, assets, trading practices, goods/services, developments, trade secrets, Intellectual Property, know-how, personnel, customers and suppliers and commercially sensitive information of a Party; or</li> <li>c) Personal Data and Sensitive Personal Data within the meaning of the Data Protection Act 2018, as amended from time to time;</li> <li>d) the Research Data.</li> </ul>		
"Contractor"	University of Keele;		
"Data Protection Legislation"	means the Data Protection Act 2018 and the General Data Protection Regulation (EU) 2016/679 in addition to any other applicable laws relating to the processing of personal data and privacy;		

"Foreground Intellectual Property"	means any Intellectual Property which is generated or first reduced to practice by any Party or Parties directly as a result of the work undertaken in accordance with this Agreement;		
"Fraud"	means any offence under English law or equivalent local laws creating offences in respect of fraudulent acts or at common law in respect of fraudulent acts in relation to the Agreement, the facilitation or performance of the Research Project, or defrauding or attempting to defraud or conspiring to defraud the Crown;		
"Funder"	means the Secretary of State for Health and Social Care;		
"Intellectual Property"	means any intellectual property rights of any description including but not limited to patents, copyright, design rights, trade marks, data rights, database rights, know-how, trade secrets, and related rights whether registerable or not and including any applications and all similar rights in inventions, computer programs, designs, semiconductor topography rights, and any other intellectual property rights;		
"Lead Applicant"	means Keele or any agreed successor who has primary responsibility for the design, conducting and reporting of the Research Project;		
"Main Contract"	means the Contract between the Funder and Keele, annexed in Schedule 2;		
"IP Policy"	means the policy to be prepared by Keele and reviewed by the Funder;		
"Research Data"	means information or data which is not Personal Data that is collected or generated in the performance of the Research Project and includes (but is not limited to) information that is collated or stored in searchable form. For the avoidance of doubt, Research Data does not include information that has been analysed.		
"Research Outputs"	means the conclusions of the Research Project, including any part of the Results of the Research Project, or any Foreground Intellectual Property or data or matters arising from the Results or data;		
"Research Period"	means the period from 1 <sup>st</sup> November 2019 to 31 <sup>st</sup> October 2023;		
"Research Project"	means the research project: NIHR200135 "Empowering people with Cutaneous Leishmaniasis: Intervention Programme to improve patient journey and reduce Stigma via community Education (ECLIPSE)" which is		
11906-7664_ECLIPSE Collaboration Agt_17.10.19	Page 3 of 32		

more particularly described in Section 3 of the Main Contract and further detailed in the Application, together with any modifications or deletions as agreed in writing by Keele and the Funder in consultation with the Collaborators;

"Results" means the results, materials, data, information and Foreground Intellectual Property created or generated by a Party during the Research Project;

"Sponsor" means the organisation that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project as defined in the UK Policy Framework for Health and Social Care Research. For the purposes of this Agreement and the Research Project, Keele will be the Sponsor;

- "Study Management Group" means the study management group responsible for managing the Research Project as more particularly 'described in Schedule 4;
- "Study Steering Committee" means the oversight committee for the Research Project as more particularly described in Schedule 4;

In this Agreement, references to Clauses and Schedules refer to clauses and schedules of this Agreement; and the singular form of any word includes the plural, and vice versa, as required by the context.

#### THE PARTIES HEREBY AGREE:

#### 2. THE PROJECT

- 2.1 The Parties will each use their reasonable endeavours to collaborate on the Research Project as described in the Application and the Main Contract, both detailed in Schedule 2, including any modifications, deletions or expansions approved in writing by the Parties.
- 2.2 The Parties to this Agreement shall be bound *mutatis mutandis* by the terms and conditions of the Main Contract, the IP Policy, which form part of this Agreement; except that provisions of the Main Contract that are particular to the Contractor shall apply only to the Contractor. In the event of any conflict between the terms of this Agreement and the terms of the Main Contract, then the terms of the Main Contract will prevail.
- 2.3 The Collaborator(s) shall assist Keele in complying with the terms of the Main Contract and the IP Policy.
- 2.4 The Collaborator(s) shall comply with those aspects of the Main Contract and the IP Policy that are relevant to the Collaborator(s) as detailed in Clause 3.11. of the Main Contract.

- 2.5 The Research Project shall be performed by or under the direction and supervision of the Lead Applicant and Co-investigator(s) as listed in Schedule 1.
- 2.6 In respect of the Allocated Tasks, each Party will use its reasonable endeavours to provide adequate facilities; to obtain any requisite materials, equipment and personnel; and to carry out the work diligently within the scope allowed by its funding. Although each Party will use its reasonable endeavours to perform the Research Project, no Party undertakes that work carried out under or pursuant to this Agreement will lead to any particular result, nor is the success of such work guaranteed. For the avoidance of doubt, nothing in this clause purports to permit any Party to reverse engineer or otherwise analyse any of the materials provided to it under this Agreement except in accordance with the provisions of this Research Project and to the extent applicable by law.
- 2.7 The Parties shall establish a Study Management Group; the roles and responsibilities of which are set out in Schedule 4 as may be amended by agreement of the Parties from time to time.
- 2.8 The Lead Investigator, on behalf of Keele, shall appoint a Study Steering Committee and a Financial Monitoring Committee to provide oversight of the entire Research Project, as well as Study Management Group; the roles and responsibilities of which are set out in Schedule 4 as may be amended from time to time.
  - 2.9 Each Collaborator is obliged to perform the Research Project in accordance with the Main Contract, and where Research Data vests in the Collaborator(s), each Collaborator irrevocably agrees in writing that any Research Data it retains will be subject to and be managed by that Collaborator in accordance with the provisions of the Main Contract as if such Collaborator were a party to the Main Contract.
  - 2.10 Each Collaborator will translate all the required Research Data into English and submit on a regular and timely manner these translated data to the Contractor, data that is required in the research activities included in the Schedule 5 (Allocated Tasks) and the milestones and objectives detailed in the NIHR-approved MD1 form (attached to this Agreement, Appendix 4).
  - 2.11 Each Collaborator, shall at the request of the Contractor, deposit qualitative, quantitative and evaluation Research Data (including but not limited to written transcripts and surveys, field notes, images, recorded material and interventions) in a relevant data archive subject to any reasonable delay necessary to enable the protection or exploitation of Results. The Contractor shall be entitled to inspect, take and be supplied with copies on the Research Data in a non-anonymised form.
  - 2.12 The Contractor will review periodically the progress of the Research of each of the Collaborators, with site visits taking place up to twice annually in a similar manner as the Funder's requirements for the Contractor included in Clause 13 (Monitoring and reporting) and Clause 15 (Site Visit Group) of the Main contract.

#### 3. PAYMENT AND FINANCIAL REPORTING

- 3.1 The Funder has undertaken to provide funding for the Research Project (the "Funding") which is managed by Keele or the Parties in accordance with the Main Contract. The sole financial obligation of Keele under this Agreement shall be to forward the payments allocated to the other Parties, in accordance with Schedule 3 of this Agreement. Other parties agree to using funds in accordance with the Funder's guidance and this will be monitored by the Contractor within the monthly reporting regime per Clause 3.8.
- 3.2 Payment will be made by Keele to the Collaborators within 30 days of receipt of a valid invoice requesting payment on account, subject to the requirements stated in this Agreement . A valid invoice must quote the related Keele purchase order. The first payment will be made immediately on signature of this Agreement by all Parties, without any conditions of reporting. All following payments on account for a valid invoice will not be made until the collaborator has adequately demonstrated through the template reporting document (List of Transactions (LOTs) see Appendix 1) and associated copies of invoices, receipts and timesheets (Timesheet template and guidance see Appendix 2) that all previous payments on account have been fully exhausted and Keele is content that the Collaborator has properly accounted for expenditure relating to these previous payments on account.
- 3.3 In the event that the Funder requires the reimbursement by Keele of any sums paid under this Agreement, then to the extent that such requirement arises from the acts or omissions of a Collaborator, the relevant Collaborator agrees to reimburse Keele the associated sum received by that Collaborator.
- 3.4 Similarly the Collaborator agrees to return all unspent payments that have been received on account by them at the end of the Research Project.
- 3.5 Each Collaborator shall maintain proper financial records relating to its Allocated Tasks at all times during the period of the Research Project and for six (6) years after the end of the Research Project, and shall provide copies of such records to Keele, as it is a requirement for Keele to provide the same to the Funder.
- 3.6 Expenditure on the project will be made in accordance with the Collaborator's agreed budget and in accordance with the Funder's (NIHR) terms and conditions for the project.
- 3.7 All payments will be in GBP sterling. The Collaborator will be responsible for any costs incurred which arise due to currency exchange fluctuations or local withholding tax. For the purpose of financial reporting of monthly expenditure, the currency rate of conversion between GBP sterling and the Collaborator local currency will be that relating to the previous payment on account. This will be applied using the first in first out (FIFO) principle in section 6 (I) a) of the Financial Guidance for NIHR Global Health Research Programme Contract Holders: Exchange Rates (attached to this Collaboration Agreement, see Appendix 3).
- 3.8 The collaborator agrees to provide calendar monthly accounts of expenditure by the 15<sup>th</sup> calendar day of each month to enable the Contractor to comply with the reporting deadlines stipulated by the Funder.
- 3.9 The Contractor may suspend or reduce its payments of amounts due under Schedule 3 to any of the Collaborator at any time if in the view of the Contractor:

3.9.1 reasonable progress on the work undertaken in accordance with this Agreement and the Main Contract has not been maintained

3.9.2 Research Data (as described in clause 2.11 and, translated as per clause 2.10), was not supplied on a timely manner in accordance to Schedule 5, and working towards the milestones and objectives detailed in the active version of the NIHR-approved MD1 form (see Appendix 3)

3.9.3 any of the Collaborators has substantially failed to comply with the terms of this Collaboration Agreement or the Main contract

#### 4. CONFIDENTIALITY AND PUBLICATION PROCEDURES

#### **Confidentiality:**

- 4.1 Subject to the remainder of this clause 4, each Party agrees to use reasonable endeavours to keep confidential any Confidential Information and not to disclose to any third party any Confidential Information nor use for any purpose except as expressly permitted by this Agreement.
- 4.2 The obligation in clause 4.1 shall continue without limit of time, but will not apply to information which:
  - 4.2.1 is known to the receiving Party before the start of the Research Period, and not impressed already with any obligation of confidentiality to the disclosing Party; or
  - 4.2.2 is or becomes publicly known without the fault of the receiving Party; or
  - 4.3.3 is obtained by the receiving Party from a third party in circumstances where the receiving Party has no reason to believe that there has been a breach of an obligation of confidentiality owed to the disclosing Party; or
  - 4.2.4 is independently developed by the receiving Party; or
  - 4.2.5 is approved for release in writing by an authorised representative of the disclosing Party; or
  - 4.2.6 the receiving Party is specifically required to disclose in order to fulfil an order of any Court of competent jurisdiction, or is required to disclose by law or regulatory authority provided that, in the case of a disclosure under the Freedom of Information Act 2000, none of the exemptions in that Act applies to the Confidential Information.
- 4.3 If any Party receives a request under the Freedom of Information Act 2000 ("FOIA") and the Environmental Information Regulations 2004 ("EIR") to disclose any Confidential Information, it will notify and consult with the other Parties whose Confidential Information may be threatened with the disclosure. The other Parties will respond within five (5) working days after receiving notice if the notice requests assistance in determining whether or not an exemption in the EIR and/or FOIA applies. The final decision as to whether any Confidential Information shall be disclosed in response to a request under EIR or FOIA rests with the party in receipt of the request.

- 4.4 Each of the Parties undertakes that, in relation to the performance of this Agreement and/or as required for the proper and lawful operation of this Agreement, it will comply with all applicable laws, regulations, orders and codes of practice from time to time in force relating to data protection.
- 4.5 Each Party shall defend, fully indemnify and keep indemnified each of the other Parties, its officers, employees and agents from and against any and all liabilities, losses, costs, charges and expenses incurred (either directly or indirectly) as a result of any claims, demands, actions and proceedings made or brought against that other Party by any third party in respect of any loss or distress suffered by the loss or unauthorised disclosure of Personal Data, or Special Categories of Personal Data as defined in the Data Protection Legislation, or medical records by the indemnifying Party, or any employees, agents or person within its control.

#### Publication:

- 4.6 In accordance with the Main Contract the Parties through Keele must notify the Funder prior to publication or dissemination (whether in oral, written or other form) of the Research Outputs. Keele on behalf of all publishing Parties shall send one draft copy of the proposed publication to the Funder's representative at the same time as submission for publication, or at least twenty-eight (28) days before the intended publication date, whichever is earlier.
- 4.7 This Agreement shall not prevent or hinder registered students of any Party from submitting for degrees of that Party theses based on results obtained during the course of work undertaken as part of the Research Project; or from following that Party's procedures for examinations and for admission to postgraduate degree status.
- 4.7.1 Any requests to use anonymous patient data collected during the Research Project shall be submitted in writing to the Lead Applicant along with a study protocol before release of the data shall be considered. The Lead Applicant will communicate a decision for the data request within 30 days of receiving the request.
- 4.8 Prior to publication of the Research Outputs the Parties will ensure that such publications will include open, transparent, standardised and structured information regarding the contribution of the Parties.
- 4.9 In accordance with normal academic practice, all employees, students or agents of the Parties (including those who work on the Research Project) shall be permitted:-
- 4.9.1 following the procedures laid down in Clause 4.10 and 4.11, to publish results, jointly where applicable, obtained during the course of work undertaken as part of the Research Project; and
- 4.9.2 in pursuance of the Parties' academic functions, to discuss work undertaken as part of the Project in internal seminars and to give instruction within their organisation on questions related to such work.

- 4.10 The Collaborators shall submit any material relating the Research Project intended for publication to Keele in writing not less than twenty eight (28) days in advance of the submission for publication.
- 4.11 The publishing Party may be required to delay submission for publication if:
- 4.11.1The Funder requires any revision of elements of detail in such proposed publications; or
- 4.11.2 in any other Party's reasonable opinion such delay is necessary in order for that other Party to seek patent or similar protection for material in respect of which it is entitled to seek protection, or to modify the publication in order to protect its Confidential Information. A delay imposed on submission for publication as a result of a requirement made by the other Party shall not last longer than is absolutely necessary to seek the required protection; and therefore shall not exceed three (3) months from the date of receipt of the material by such Party, although the publishing Party will not unreasonably refuse a request from the other Party for additional delay in the event that property rights would otherwise be lost. Notification of the requirement for delay in submission for publication must be received by the publishing Party within thirty (30) days after the receipt of the material by the other Party, failing which the publishing Party shall be free to assume that the other Party has no objection to the proposed publication.
- 4.12 Where material relating to the Research Project intended for publication is co-written by two or more authors who are employed by different Parties in circumstances where the copyright is owned by the employing Party, the following provisions shall additionally apply:
- 4.12.1 any publication requires the consent of all relevant Parties; and
- 4.12.2 any journal publication fees (or similar) shall be payable by the Party who at the time of publication is employing the lead author, unless the relevant Parties agree otherwise.
- 4.13 The provisions of clauses 4.8, 4.10, 4.11 and 4.12 shall survive expiry or termination of this Agreement. The provisions of clause 4.13 shall survive whilst the relevant Parties remain owners of the relevant copyright.

#### 5. RESEARCH GOVERNANCE

- 5.1 The Parties agree to comply with all relevant laws, regulations and codes of practice applicable to a Party as a consequence of this Agreement or arising from its or their performance of the Research Project. To the extent applicable to their respective obligations, the Parties agree to comply with the following:
  - 5.1.1 The Health Research Authority guidance "UK Policy Framework for Health and Social Care Research", as revised or reissued from time to time;
  - 5.1.2 The Human Tissue Act 2004;
  - 5.1.3 The Mental Capacity Act 2005;
  - 5.1.4 The Data Protection Legislation;
  - 5.1.5 ICH Harmonised Tripartite Guideline for Good Clinical Practice E6;

- 5.1.6 Orders, rules and requirements made by governmental or regulatory bodies having the force of law (including applicable directions received from a regulatory authority and/or ethics committee) all as may be updated or amended from time to time.
- 5.2 Keele may, on reasonable notice, monitor and audit the conduct of any work by a Collaborator relating to the Research Project including the right to inspect, during office hours, any facilities being used for the Research Project and to examine any procedures or records relating to any part of the Research Project.

#### 6. INTELLECTUAL PROPERTY RIGHTS

- 6.1 For the avoidance of doubt all Background Intellectual Property used in connection with the Research Project shall remain the property of the Party introducing the same (or its licensors). No Party will make any representation or do any act which may be taken to indicate that it has any right, title or interest in or to the ownership or use of any of the Background Intellectual Property of the other Parties except under the terms of this Agreement. The Parties agree that any improvements or modifications to a Party's Background Intellectual Property arising from the Research Project which are not severable from that Background Intellectual Property.
- 6.2 Each Party grants the other Parties, subject to restrictions in Clause 4 an irrevocable, royaltyfree, non-exclusive licence for the duration of the Research Project to use its Background Intellectual Property (provided it is free to licence the Background Intellectual Property in question) for the sole purpose of carrying out the Research Project. No Party may grant any sub-licence over or in respect of any other Party's Background Intellectual Property.
- 6.3 Subject to clauses 6.4 and in accordance with the Main Contract, all Foreground Intellectual Property shall vest in Keele.
- 6.4 Each Party shall promptly disclose to the other Parties all Foreground Intellectual Property conceived, exemplified, developed, generated or first reduced to practice by it. A written record of Foreground Intellectual Property shall be created and updated as necessary by the Study Management Group. The Parties agree that in accordance with normal practice inventors shall be named as such on any patent applications regardless of ownership of Foreground Intellectual Property.
- 6.5 In the event that any profit accrues to Keele as a result of any commercial exploitation of Foreground Intellectual Property, Keele will by separate written agreement share such profits as are fair and reasonable in all the circumstances with the relevant Parties taking account (a) any revenue share due to the Funder under the Main Contract and (b) the intellectual and/or inventive contribution of each Party in the generation of the Foreground Intellectual Property in question. Any arrangements will be subject to the approval of the Funder.
- 6.6 Keele grants to the Collaborators a non-exclusive, irrevocable, non-transferable, royalty-free licence to use the Foreground Intellectual Property for:

6.1.1 the purposes of the Research Project; and

- 6.1.2 academic, clinical and non-commercial teaching and research purposes, including research involving projects funded by third parties provided that those parties gain no claim or rights to such Results or Foreground Intellectual Property.
- 6.7 If Keele reasonably requires the use of Background Intellectual Property of any Collaborator in order to exercise its rights in Foreground Intellectual Property then, provided the relevant Collaborator is free to license the Background Intellectual Property in question, the Collaborator will not unreasonably refuse to grant or delay granting a licence to Keele for that purpose provided always that all licences granted under this clause 6.7 are agreed in writing and signed by duly authorised representatives of Keele and the relevant Collaborator.
- 6.8 No Party shall enter into a third-party agreement that:

6.8.1 Limits or restricts the use of Research Data held by Keele and/or Collaborator; and/or

6.8.2 Grants any form of exclusivity to a third party.

#### 7. ASSIGNMENT

No Party will assign this Agreement without the prior written consent of the other Parties, such consent not to be unreasonably withheld, denied or delayed.

#### 8. DURATION AND TERMINATION

- 8.1 This Agreement will be deemed to have taken effect from 1<sup>st</sup> November 2019 and shall continue in full force and effect until 31<sup>st</sup> October 2023 unless terminated earlier in accordance with this Clause 8 or Clause 20.3 of the Main Contract.
- 8.2 Any Party ("the Withdrawing Party") may terminate its involvement in the Research Project and its status as a Party to this Agreement on three (3) months' written notice to the other Parties. The Withdrawing Party shall not from the date of withdrawal be entitled to recover any of its costs incurred in connection with the Allocated Tasks and shall, from the date of withdrawal, comply with any conditions that may be imposed by Keele in consultation with the remaining Collaborators which shall include (without limitation), unless otherwise agreed:
  - 8.2.1 rights granted to the other Parties in respect of the Withdrawing Party's Background Intellectual Property shall continue for the duration of the Research Project solely for the purposes of carrying out the Research Project, subject to the restrictions contained in this Agreement;
  - 8.2.2 to the extent that exploitation by Keele of Foreground Intellectual Property is dependent upon the Withdrawing Party's Background Intellectual Property, then the Withdrawing Party shall, to the extent that it is free to do so, grant to Keele a non-exclusive licence to such Background Intellectual Property on fair and reasonable terms to be agreed;

- 8.2.3 all rights acquired by the Withdrawing Party to the Background Intellectual Property of the other Parties and Foreground Intellectual Property of Keele shall cease immediately.
- 8.3 In the event that a Party is in material breach of this Agreement (the "Breaching Party") then any other Party (each a "Non-Breaching Party") may at any time serve notice on the Breaching Party to remedy the breach. If the breach is capable of remedy and the Breaching Party has not remedied or taken such steps as are reasonable in the circumstances to begin to remedy it within thirty (30) days of receiving written notice of such breach, then the Breaching Party's involvement in the Research and status as a party to the Agreement shall be terminated immediately. For the avoidance of doubt, the Non-Breaching Parties shall remain parties to the Agreement and continue to be bound by the terms of this Agreement.
- 8.4 Each Party agrees to notify the other Party(s) promptly if at any time their key members of staff are unable or unwilling to continue the direction and supervision of the Allocated Tasks. Within thirty (30) days after such incapacity or expression of unwillingness that Party shall nominate a successor to replace any key members of staff. The other Party(s) will not decline unreasonably to accept the nominated successor. However, if the successor is not acceptable on reasonable and substantial grounds, then either (i) such party may be required to withdraw from the Research Project by the Study Management Group or (ii) this Agreement may be terminated by the Study Management Group giving thirty (30) days' written notice to the other Party(s).
- 8.5 Keele may terminate this Agreement with immediate effect by giving written notice to the Collaborator(s) in the event that the Funder terminates the Main Contract (as defined in clause 3.1).
- 8.6 In the event of early termination of this Agreement, Keele shall reimburse each of the nonbreaching Parties for all costs properly charged in accordance with this Agreement and incurred or committed up to the date of termination, providing such funds have been or are able to be recovered from the Funder except in the event that non receipt of funds is as a result of an act or omission of Keele, in which case, the Collaborator shall receive recompense of applicable costs from Keele. For the avoidance of doubt, no Party shall be required to contribute to any losses suffered by another Party in circumstances where costs have not been recovered from the Funder.
- 8.7 In the event that any Party compounds or makes arrangements with its creditors or goes into liquidation (voluntarily or otherwise) other than for the purpose of a bona fide reconstruction or a receiver, administrative receiver or administrator is appointed in respect of the whole or any part of its business or assets or if any similar or analogous event occurs the remaining Parties shall meet to either suspend or terminate that Party's involvement in the Research Project. Any removal of the defaulting Party shall be effective as of the date of the receipt of such notice whereupon the provisions of Clause 8.2 shall apply to the defaulting Party (as if deemed to be a Withdrawing Party).

8.8 Subject to earlier termination in accordance with its terms, this Agreement shall remain in force until the expiry of the Research Period whereupon it shall automatically terminate. Termination of this Agreement for whatever reason shall not affect the accrued rights of the Parties arising in any way out of this Agreement as at the date of termination, and any provisions which are expressly stated or impliedly understood to survive this Agreement shall remain in full force and effect including without limitation Clauses 4, 6, 9, 10, 11, 13.8 and 13.9. Clause 4.13 shall survive whilst the relevant Parties remain owners of the relevant copyright.

#### 9 LIMITATION OF LIABILITY

- 9.1 No Party makes any representation or warranty that advice or information given by any of its employees, students, agents or appointees who work on the Research Project, or the content or use of any materials, works or information provided in connection with the Research Project, will not constitute or result in infringement of third-party rights.
- 9.2 Subject to Clause 9.3, no Party accepts any responsibility for any use which may be made of any work carried out under or pursuant to this Agreement, or of the results of the Research Project, nor for any reliance which may be placed on such work or results, nor for advice or information given in connection with them.
- 9.3 The Parties undertake to make no claim in connection with this Agreement or its subject matter against any employees, students, agents or appointees of the other Parties (apart from claims based on fraud or wilful misconduct). This undertaking is intended to give protection to individual researchers: it does not prejudice any right which a Party might have to claim against any other Party.
- 9.4 The liability of any Party for any breach of this Agreement, or arising in any other way out of the subject-matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses.
- 9.5 In any event, the maximum liability of any Collaborator under or otherwise in connection with this Agreement or its subject matter shall, subject to clause 9.6, not exceed the monies received by that Collaborator under this Agreement as detailed in Schedule 3.
- 9.6 The maximum liability of Keele in aggregate under or otherwise in connection with this Agreement or its subject matter (subject to clause 9.7) shall not exceed the monies received Keele, from the Funder under the Main Contract for the Research Project.
- 9.7 Nothing in this Agreement limits or excludes either Party's liability for:
  - 9.7.1 death or personal injury resulting from negligence; or
  - 9.7.2 wilful misconduct or fraud or fraudulent misrepresentation; or
  - 9.7.3 any other liability which, by law, cannot be limited or excluded.
  - 9.8 If any sub-clause of this Clause 9 is held to be invalid or unenforceable under any applicable statute or rule of law then it shall be deemed to be omitted, and if as a result

any Party becomes liable for loss or damage which would otherwise have been excluded then such liability shall be subject to the remaining sub-clauses of this Clause 9.

9.9 Each Party shall throughout the term of this Agreement effect and maintain with a reputable insurance company or underwriters at Lloyds of London, a policy or policies of insurance providing an adequate level of cover in respect to all risks which may be incurred by the Parties arising out of Parties' performance out of this Agreement and shall provide documentary evidence of such insurance on reasonable demand by any other Party.

#### 10 NOTICES

Keele's representative for the purpose of receiving reports and other notices shall until further notice be:

Head of Legal and Information Compliance Directorate of Student and Academic Services Tawney Building Keele University Staffordshire ST5 5BG

The Collaborators' representatives for the purpose of receiving reports and other notices shall until further notice be:

For Bahia:

Named role: Executive Director of THE FOUNDATION OF SUPPORT TO RESEARCH AND EXTENSION (FAPEX), Antonio Fernando de Souza Queiroz Adress: Avenida Manoel Dias da Silva, 1784, Edifício Comercial Pituba, Pituba, CEP: 41.830-001, Salvador, Bahia, Brazil For Mekelle: Named role: Chief Executive Director of the College of Health Sciences Address: Mekelle University, Mekelle, Tigray, ETHIOPIA

For Rajarata: Named role: Dr Batagalle Ananda Karunarathne ,Vice Chancellor Address: Mihintale, 50300, SRI LANKA

#### 11 FORCE MAJEURE

- 11.1 A Party shall not be liable for failure to perform its obligations under this Agreement, nor be liable to any claim for compensation or damage, nor be deemed to be in breach of this Agreement, if such failure arises from an occurrence or circumstances beyond the reasonable control of that Party (excluding an obligation to make payment).
- **11.2** If a Party affected by such an occurrence causes a delay of three (3) months or more, and if such delay may reasonably be anticipated to continue, then the Parties shall, in

consultation with the Funder, discuss whether continuation of the Research Project is viable, or whether the Research Project and this Agreement should be terminated.

#### 12 EQUALITY, ANTI-BRIBERY AND MODERN SLAVERY

- 12.1 In carrying out its obligations under this Agreement each Party will:
  - 12.1.1 comply with all laws, statutes, regulations, case law and regulatory guidance which apply to it or its activities and which relate to:
    - 12.1.1.1 Fraud, anti-bribery and anti-corruption, including the Bribery Act 2010;
    - 12.1.1.2 equality, including the Equality Act 2010;
    - 12.1.1.3 modern slavery, including the Modern Slavery Act 2015;
  - 12.1.2 adopt, maintain and follow appropriate policies and procedures to secure such compliance. If the activity is occurring outside of the UK, Collaborators must ensure that the Research Project is conducted to an equivalent standard to those listed in 12.2.1.
  - 12.1.3 ensure that its employees, students, group companies, subcontractors, agents and their respective employees comply with the terms imposed by these provisions.
- 12.2 The Collaborator(s) shall, for the duration of the Research Project, maintain information relating to the gender of their staff and supply Keele with the relevant information that can then be reported to the Funder as required under the Main Contract.

#### 13 SAFEGUARDING PROVISIONS

- 13.1 In carrying out its obligations under this Agreement each Party will:
  - 13.1.1 take all reasonable steps to prevent actual, attempted or threatened Sexual Exploitation, Abuse or Harassment (as defined in the Main Contract) by its employees or any other persons engaged and controlled by it to perform any activities under this Agreement; and
  - 13.1.2 adopt robust procedures for the reporting of suspected misconduct, illegal acts or failures to investigate.
- 13.2 Each Party shall take all reasonable steps to ensure that the Key Staff (as defined in the Main Contract) and others employed, retained or contracted to perform any activities under this Agreement do not engage in sexual activity with any individual under the age of 18, even if the age of majority or age of consent is lower in the relevant territory.

#### 13.3 Each Party shall:

- 13.3.1 report any complaints or concerns regrading possible Sexual Exploitation, Abuse or Harassment by its employees or any other persons engaged and controlled by it to perform any activities under this Agreement to the relevant authorities (including Keele and local law enforcement or other agencies); and
- 13.3.2 take all reasonable steps to ensure that individuals are enabled to report concerns and complaints through supportive, confidential and accountable mechanisms.
- 13.4 Each Party shall take all reasonable steps to investigate allegations or suspicions of Sexual Exploitation, Abuse or Harassment and take appropriate corrective action, including disciplinary action, against the Key Staff and others employed or retained by them to perform the Research, and will keep Keele and relevant authorities informed of the progress of the investigations as appropriate.
- 13.5 In the event that any Party fails to comply with any of this Clause 13, Keele reserves the right to:
  - 13.5.1 deem this to be a material breach and terminate this Agreement in accordance with Clause 8 or Clause 20.3 of the Main Contract; and/or
  - 13.5.2 suspend or reduce its payment of amounts due under the payment schedule in Schedule 3 of this Agreement; and/or
  - 13.5.3 require repayment of all or part of the funding provided under this Agreement.
- 13.6 For the avoidance of doubt, each Party, and any subcontractor, confirms by signing this Agreement that they accept the standards set out in this Clause, and will ensure that all subcontracts reflect the terms and requirements of this Clause in each case, prior to the Party or other subcontractor performing any activity under this Agreement.
- 13.7 For the purposes of this Clause 13:

13.7.1. Sexual Exploitation means any actual or attempted abuse of a position of vulnerability, differential power, or trust, for sexual purposes and includes but is not limited to profiting monetarily, socially, or politically from sexual exploitation of another.

13.7.2. Sexual Abuse means the actual or threatened physical intrusion of a sexual nature, whether by force or under unequal or coercive conditions and includes but is not limited to all sexual activity with someone under the age of 18, regardless of local age of majority or consent.

13.7.3. Sexual Harassment means any unwelcome sexual advances (including but not limited to sexual advances made without touching) and includes but is not limited to requests for sexual favours, or other verbal or physical behaviour of a sexual nature, which may create a hostile or offensive environment.

#### 14 GENERAL

14.1Clause headings are inserted in this Agreement for convenience only, and they shall not be taken into account in the interpretation of this Agreement.

- 14.2 Nothing in this Agreement shall create, imply or evidence any partnership or joint venture between the Parties or the relationship between them of principal and agent.
  - 14.3 Each Party shall use best endeavours to ensure that the Research Project is conducted in accordance to the principles of the UK Concordat to support Research Integrity which can be found at <a href="https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf">https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf</a>
- 14.4 Collaborator(s) shall either:
  - 14.4.1 have an institutional-level risk register that considers the Research Project risks and mitigation strategies; or
  - 14.4.2 create a risk register specifically for the Research Project that will be managed and maintained for the duration of the Research Project.
  - 14.5 Each Party shall have a Whistle-blowing policy and if not, must follow standards equivalent to those of Keele's Whistle-blowing policy (which can be found at <a href="https://www.keele.ac.uk/media/keeleuniversity/policyzone20/studentandacademicservic">https://www.keele.ac.uk/media/keeleuniversity/policyzone20/studentandacademicservic</a> es/Whistleblowing%20Policy%202019.pdf ).
  - 14.6 If a Collaborator does not have a Travel and Subsistence policy that can be shared with Keele, the Collaborator must adopt Keele's Travel and Subsistence policy for the Research (The duration of the Project. policy can be found at https://www.keele.ac.uk/media/keeleuniversity/fait/finance/accountspayable/travel%20p rocedures%20%20201718.pdf).
- 14.7 Each Collaborator must declare any appropriate conflicts of interest concerning the Research Project to the Lead Applicant.
- 14.8 Each Party shall ensure that it has well defined arrangements for investigating and resolving allegations of research misconduct. Where an allegation of research misconduct arises in respect of an individual Party's participation in the Research Project and leads to a subsequent formal investigation, the relevant Party shall inform Keele and the Funder of the investigation and its outcome. Where an allegation of research misconduct arises in respect of several Parties' participation in the Research Project, the relevant Parties will work together to determine how the allegation will be investigated and reported.
- 14.9 No Party shall use the name or any trade mark or logo of any other Party or the name of any of its staff or students in any press release or product advertising, or for any other commercial purpose, without the prior written consent of the Party(s).
- 14.10 Except as otherwise expressly provided for herein, the Parties confirm that nothing in this Agreement shall confer or purport to confer on any third party any benefit or any right to enforce any term of this Agreement for the purposes of the Contracts (Rights of Parties) Act 1999.
- 14.11 The Parties shall procure that in carrying out the Research Project they comply with the Data Protection Legislation.

- 14.12 This Agreement and its Schedules (which are incorporated into and made a part of this Agreement) constitute the entire agreement between the Parties for the Research Project and no statements or representations made by any Party have been relied upon by the other in entering into this Agreement. Any variation shall be in writing and signed by authorised signatories for each Party.
- 14.13 This Agreement shall be governed by the laws of England and Wales and the courts of England and Wales shall have exclusive jurisdiction to deal with any dispute which may arise out of or in connection with this Agreement.
- 14.14 If any dispute arises out of this Agreement the Parties will first attempt to resolve the matter informally through designated senior representatives of each Party to the dispute, who are not otherwise involved with the Research Project. If the Parties are not able to resolve the dispute informally within a reasonable time not exceeding two (2) months from the date the informal process is requested by notice in writing, they will attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure.
- 14.15 If any one or more clauses or sub-clauses of this Agreement would result in this Agreement being prohibited pursuant to any applicable competition law, then it or they shall be deemed to be omitted. The Parties shall uphold the remainder of this Agreement, and shall negotiate an amendment which, as far as legally feasible, maintains the economic balance between the Parties.
- 14.16 This Agreement may be signed, including by exchange of document; or in portable document format (pdf) sent by email, in any number of counterparts, each of which will constitute an original of this Agreement, and all counterparts will together constitute the same agreement. No counterpart will be effective until each Party has executed at least one counterpart.

Agreed by the Parties through their authorised signatories:

#### **SIGNED** for and on behalf of **UNIVERSITY OF KEELE**:

Name:	Dr Mark Bacon
Position:	Chief Operating Officer / Director of Research, Innovation & Engagement
Signature:	Dr Mark Bacon
Date:	01 June 2020   7:37 AM BST

### SIGNED for and on behalf of FEDERAL UNIVERSITY OF BAHIA, BRAZIL

Name: João Carlos Salles Pires da Silva

Position: Dean of the Federal University of Bahia

Signature: MMS

SIGNED for and on behalf of MEKELLE UNIVERSITY, ETHIOPIA Name: Dr Amanuel Haile Position: Chief Executive Director, College of Health Sciences, Mekelle University Signature: no ti mme d ollege of V ę

# SIGNED for and on behalf of RAJARATA UNIVERSITY OF SRI LANKA

Name: Dr Batagalle Ananda Karunarathne

Position: Vice Chancellor Rajarata University of Sri Lanka

Signature:

Dr. B.A. Karunaratne Vice Chancellor Rajarata University of Sri Lanka Mihintale

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#### Schedules:

- Schedule 1: Research Project Summary
- Schedule 2: The Main Contract (incorporating the Application)
- Schedule 3: Breakdown of costs to Collaborators
- Schedule 4: Roles and Responsibilities of Management Committees and Groups
- Schedule 5: Allocated Tasks

#### Schedule 1: Research Project Summary

Funder Name	National Institute for Health Research (NIHR)			
Total Funding Awarded	£4,576,819.00			
Commencement Date	1 November 2019			
End Date	31 October 2023			
Funder Reference	NIHR200135			
Project	Empowering people with Cutaneous Leishmaniasis: Intervention Programme to improve patient journey and reduce Stigma via community Education (ECLIPSE)			
Lead Applicant	Professor Lisa Dikomitis and Dr Helen Price			
Co-Investigator(s)	<ul> <li>Professor Christian Mallen, Keele University</li> <li>Professor Athula Sumathipala, Keele University</li> <li>Dr Toby Helliwell, Keele University</li> <li>Dr Thomas Shepherd, Keele University</li> <li>Mrs Linda Parton (lay applicant), Keele University</li> <li>Dr Paulo Machado, Federal University of Bahia, Brazil</li> <li>Dr Leny Trad, Federal University of Bahia, Brazil</li> <li>Dr Marie Aliaga, Federal University of Bahia, Brazil</li> <li>Dr Afework Mulugeta, Mekelle University, Ethiopia</li> <li>Dr Zenawi Zerihun, Mekelle University, Ethiopia</li> <li>Dr Nega Berhe, honorary contract with Mekelle University, Ethiopia</li> <li>Professor Suneth Agampodi, Rajarata University of Sri Lanka</li> <li>Professor Nadira Karunaweera, honorary contract with Rajarata University of Sri Lanka</li> </ul>			

#### Schedule 2: The Main Contract (incorporating the Application)





#### Schedule 3: Breakdown of Costs to Collaborators

#### Funder Grant Ref: NIHR200135

<u>Research Project Title</u>: Empowering people with Cutaneous Leishmaniasis: Intervention Programme to improve patient journey and reduce Stigma via community Education (ECLIPSE)

#### Two Co-Lead Applicants: Professor Lisa Dikomitis and Dr Helen Price

#### Payment Schedule

Keele will pay to each Collaborator, in consideration of each Collaborator's involvement in the Research Project, the sums set out below, subject to receipt of a valid invoice. Payment will be made in accordance with clause 3.2 of this Agreement. The annual figures in the table will be paid into equally quarterly amounts.

Payment schedule						
	Host and Collaborators	Brazil	Ethiopia	Sri Lanka		
			Amount	Amount		
		Amount	receivable	receivable		
	Date due	receivable £	£	£		
Project	On signing collaboration agreement	67,789.39	66,625.00	61,165.25		
Year 1	01/04/2020	67,789.39	66,625.00	61,165.25		
	01/07/2020	67,789.39	66,625.00	61,165.25		
	01/10/2020	67,789.39	66,625.00	61,165.25		
	01/01/2021	61,999.37	56,442.50	47,744.45		
Project	01/04/2021	61,999.37	56,442.50	47,744.45		
Year 2	01/07/2021	61,999.37	56,442.50	47,744.45		
	01/10/2021	61,999.37	56,442.50	47,744.45		
	01/01/2022	66,992.28	58,747.95	54,470.11		
Project Year 3	01/04/2022	66,992.28	58,747.95	54,470.11		
	01/07/2022	66,992.28	58,747.95	54,470.11		
	01/10/2022	66,992.28	58,747.95	54,470.11		
	01/01/2023	69,111.15	61,730.95	55,145.80		
Project	01/04/2023	69,111.15	61,730.95	55,145.80		
Year 4	01/07/2023	69,111.15	61,730.95	55,145.80		
	01/10/2023	69,111.15	61,730.95	55,145.80		
	Total (excluding any liability for VAT) which shall be paid from time to time, according to law	1,063,568.7 5	974,185.60	874,102.45		

All invoices should be marked for the attention of: Research Management Accountant, Finance and IT Directorate, Innovation Centre 2, Keele University Science & Innovation Park, Keele University, Staffordshire, ST5 5NH (email: j.r.allman@keele.ac.uk) and should include the purchase order reference, which can be obtained from the Research Management Accountant. Keele shall pay the Collaborators within 30 days of said invoices,

#### Schedule 4: Roles and Responsibilities of Management Committees

#### STUDY STEERING COMMITTEE (SSC)

**Details of membership:** This group comprises four disciplinary experts. The SSC will have full independence from the ECLIPSE project and research team. Independent scrutiny of the project is critical, therefore, the four SSC members will be external to ECLIPSE funded institutions and potential conflicts/interests must be declared. NIHR will be notified of the confirmed membership and of any changes to this committee during the lifetime of the project.

#### The SSC will:

- meet annually face-to-face
- provide expert advice and oversight of the ECLIPSE programme, ensuring that the work follows standards set by the Department of Health in terms of management, progress, finance and governance
- monitor progress against pre-agreed milestones (detailed in the MD-1 form) and adherence to the agreed programme. They will review more detailed protocols, and any new evidence from the Research Project or externally
- receive, scrutinise and discuss reports from the ECLIPSE Management Group (EMG) and the Financial Monitoring Committee (FMG)
- advise on proposed changes to the ECLIPSE plans in light of new evidence or other unanticipated developments
- encourage appropriate efforts to disseminate the ECLIPSE findings

#### **ECLIPSE MANAGEMENT GROUP (EMG)**

Details of membership: The EMG comprises of 11 members, as follows:

- The two co-leads (Professor Lisa Dikomitis and Dr Helen Price)
- Three country leads (Dr Paulo Machado, Dr Afework Mulugeta, Professor Suneth Agampodi) or a representative
- The UK ECLIPSE Programme Manager and the three ECLIPSE country coordinators
- The ECLIPSE Research Associate in Global Health and the ECLIPSE Research Associate in Public Engagement in Global Health

#### The EMG will:

- meet monthly via teleconference
- review progress against pre-agreed timelines and milestones as listed in the MD-1 form
- discuss any issues related to staffing and delivery of research
- ensure clear communication between country leads and members in each country team
- ensure timely preparation of progress reports
- discuss and monitor spending plans
- discuss and action plans for disseminating outputs

#### FINANCIAL MONITORING COMMITTEE (FMC)

Details of membership: The FMC comprises of 4 members, as follows:

- An Independent External Chair
- Three representatives from Finance and Research and Innovation Support Enhancement (RaISE) at Keele

The FMC will:

• meet quarterly to scrutinise spending and financial reporting for all ECLIPSE partners

• discuss and advise on financial forecasts prior to submission of quarterly financial reports to the funder

#### Schedule 5 – Allocated Tasks

The three designated Country Leads for the ECLIPSE teams in Brazil, Ethiopia and Sri Lanka will have responsibility for the daily management of the research activities planned and carried out by the team members, working towards the milestones and objectives detailed in the NIHR-approved MD1 form (attached to this Collaboration Agreement, see Appendix 4). This MD1 form will be reviewed when needed, or at least on an annual basis, by the NIHR and modified as appropriate.

All financial interactions need to be documented and reported on a monthly basis to Keele.

All Country Leads are expected to contribute to the annual ECLIPSE report to be submitted to the NIHR.

All research by the three ECLIPSE country teams must follow the standards set by the UK Department of Health and Social Care in terms of project and data management, progress, finance, intellectual property rights and governance.

#### WP1: ESTABLISH ECLIPSE RESEARCH HUBS

# OBJECTIVE: To formalise the ECLIPSE partnership, prepare study protocols and materials, gain ethical and regulatory approvals, establish community and public involvement groups and ECLIPSE committees

- Recruit ECLIPSE team members
- Establish a Community of Practice (COP) in each ECLIPSE country
- Set up Community Advisory Groups (CAGs) in each of the three fieldsites in each ECLIPSE country
  - Contribute to producing study protocols and study materials
  - Recruit key policymakers for the ECLIPSE policy network and study trip
  - Contribute to the evidence synthesis of CL
  - Prepare and submit multiple ethics applications
  - Recruit 3 PhD students in each ECLIPSE country, develop ECLIPSE PhD

projects and assign supervisory teams

#### WP2: UNDERSTANDING LOCAL CL SYNDEMICS (M9-M24)

OBJECTIVE 1: To explore local perspectives, experiences and priorities of rural communities around the biopsychosocial dimensions of CL, CL-associated stigma, health-seeking behaviour, healthcare access, treatment options and compliance

- Long-term multi-sited participant-observation in each of the three fieldsites in each country
- Conduct semi-structured interviews with CL patients and healthcare professionals as approved by the Keele and Collaborator's institutional ethics boards
- Conduct four creative community workshops
- Conduct focus groups with each CAG to discuss ECLIPSE interventions
- Conduct an ongoing iterative data analysis throughout WP2

#### OBJECTIVE 2: To adapt stigma and QoL scale to CL and measure individual and community CLassociated stigma

• Adapt stigma and Quality of Life (QoL) scales

- Collect stigma and QoL scales (total of ~400 per ECLIPSE country)
- Conduct an ongoing iterative data analysis throughout WP2

#### WP3: DEVELOPING AND PILOTING ECLIPSE INTERVENTIONS

#### **OBJECTIVE 1:** To co-design and develop ECLIPSE interventions with COPs and CAGs

- Co-developing two ECLIPSE interventions with COPs and CAGs:
  - 1) Develop an ECLIPSE community education campaign
  - 2) Design a training package for healthcare professionals

Each country's community education campaign will have two distinct components:

- (1) aimed to increase awareness about a range of aspects of CL
- (2) a *psychosocial support* toolkit aimed to empower CL patients and reduce stigma and stigmatizing practices in local communities

#### **OBJECTIVE 2:** To investigate feasibility and acceptability of ECLIPSE interventions

• Test feasibility and accessibility of interventions

For each intervention, one local community will be used as the test bed site. We will use a contextappropriate form of think-aloud interviews with CL patients, relatives and community members to assess feasibility and intervention acceptability.

• Adapt the interventions and incorporating feedback as appropriate

#### WP4: IMPLEMENTATION OF ECLIPSE INTERVENTIONS

OBJECTIVES: To implement and roll out interventions in ECLIPSE field sites and determine which interventions improve CL patient journey, are effective in reducing stigma and empower CL patients and their communities

The country-specific ECLIPSE interventions should be implemented as soon as these have been tested and refined, and ethical approvals have been obtained, in order to maximise exposure time during the lifetime of the project.

#### WP5: EVALUATION OF PROCESSES AND IMPACT

OBJECTIVES: To undertake mixed methods process evaluation to identify contextual and implementation factors that impact on delivery and routine implementation of ECLIPSE interventions

- Conduct a longitudinal qualitative evaluation
- Conduct a longitudinal quantitative evaluation
- Analysis through triangulation of qualitative and quantitative evaluation data
- Development of ECLIPSE implementation recommendations

#### WP6: COMMUNITY AND PUBLIC INVOLVEMENT

## OBJECTIVES: To robustly involve local communities and engage the wider public throughout the ECLIPSE project

- Establish a Community of Practice (COP) in each ECLIPSE country
- Set up Community Advisory Groups (CAGs) in each of the three fieldsites in each ECLIPSE country
  - Recruit key policymakers for the ECLIPSE policy network and study trip

#### **DISSEMINATION**

#### Two-step review for any outputs from the ECLIPSE project:

All outputs, regardless of the language in which it is written, need to be reviewed and approved by the ECLIPSE Co-leads (Dr Helen Price and Professor Lisa Dikomitis). Each collaborator will provide any outputs for dissemination to Keele giving 28 days notice before the submission deadline of the output. This applies to all outputs, regardless of the language of the output. Keele will review any output within 14 days and after that review, Keele then has a contractual obligation with the NIHR which requires 14 days notice to review outputs from the ECLIPSE project. Outputs include: abstracts, posters, presentations, manuscripts for journals, book chapters, dissertations, newsletters and any other public-facing materials.

#### 1. ACADEMIC DISSEMINATION

- Write high-quality journal articles
- Contribute to the open-access learning resource (ECLIPSE book)
- Contribute to conference presentations
- Co-organise and contribute to the four annual scientific meetings
- Produce three doctoral dissertations for each ECLIPSE country

#### 2. POLICY-ORIENTED DISSEMINATION

- Contribute to policy briefs and policy recommendations
- Contribute to the ECLIPSE Policy Network

#### 3. PUBLIC-FACING OUTPUTS

- Contribute to producing material for the ECLIPSE online platform
- Contribute to the ECLIPSE exhibitions with photographic, artistic and video material from each ECLIPSE country
- Contribute to public engagement throughout the lifetime of the project

Appendix 1 – List of transactions (LOTs). This file may be updated and subject to change.



Appendix 2 – Timesheet template and guidance. This file may be updated and subject to change.





Appendix 3 – Financial Guidance for NIHR Global Health Research Programme Contract Holders: Exchange Rates



Appendix 4 - MD1 Form This is a dynamic document and subject to change.

