Histiocytosis UK – Terms & Conditions – February 2020

Notes: Should any award be offered, the host body/organisation MUST accept, process and complete the Histio UK documentation within six months of the date of any award offer letter.

TERMS AND CONDITIONS OF HISTIOCYTOSIS UK GRANTS EFFECTIVE FROM February 2020

Issued to:

Date:

Project:

Project Title:

1. Introduction

1.1. These Terms and Conditions, along with the Grant, and Grant Award Letter, constitute the whole agreement between the Grant-holder, the Host Institution and Histiocytosis UK relating to the Research/Project and supercedes all previous agreements between them.

1.2. Histiocytosis UK reserves the right to amend these terms and conditions at any time. Any change to these terms and conditions will be notified on Histiocytosis UK's website

2. Opening of trials

2.1 No material change shall be made to the Grant, the Research/Project or the Research/Project Personnel without the prior written approval of Histiocytosis UK.

2.2 The Host Institution must ensure that the Grant is used for the purposes for which it was awarded. Any plan to diverge from the aims outlined in the original grant application requires prior written agreement from Histiocytosis UK. In the event the Research/Project is terminated early, Histiocytosis UK must be notified in writing.

2.3 It is the responsibility of the Host Institution and Grant-holder to ensure that all parties, including collaborators, supervisors, and staff employed on Histiocytosis UK grants comply with the terms and conditions.

2.4 The Host Institution shall notify Histiocytosis UK immediately if there is any change in its status, or that of the Research/Project Personnel, that might affect its eligibility to hold the Grant.

2.5 The Host Institution will allow Histiocytosis UK access to its facilities, at reasonable times, to inspect the conduct of the Research/Project and to ensure compliance with the terms of the Grant.

3. Grant Award

3.1 The Host Institution and Grant-holder must formally accept, in writing, the Award as detailed in the Grant Award Letter and agree to this the Terms and Conditions of the award. This will be deemed to have been executed and accepted by the Host Institution and Grant Holder by completing section 26 of this document.

3.2 The Grant must be activated by the Grant-holder within three months from the start date indicated on the Grant Award Letter. Any delay to the start date must be agreed by Histiocytosis UK in writing.

3.3 Any Grant in excess of 12 months will be funded in two phases, Confirmed and Contingent. Confirmed funding will cover 24 months of the grant. Contingent funding will only be released if Histiocytosis UK deems satisfactory progress has been made, to an appropriate standard of Research/Project, and in compliance with the terms and conditions of the Grant.

3.4 The Grant termination date is defined by the duration of the award from the activation date.

3.5 The Host Institution will inform Histiocytosis UK promptly of any pre-existing arrangements which may lead to a breach of the Grant conditions. The Host Institution shall not enter into, or permit any person involved with the project to enter into, consultancies, third party restrictions or arrangements which may affect the Research/Project without the prior written agreement of Histiocytosis UK.

3.6 The Host Institution and the Grant-holder must notify any commercial collaborators of the application and obtain their agreement for the disclosure of confidential information.

3.7 Histiocytosis UK acknowledges that the Host Institution is subject to the Freedom of Information Act 2000. If the Host Institution receives a “Request for Information” in respect to any part of the Grant, the Host Institution must notify and consult with Histiocytosis UK on any response to the request.

4. Ethical responsibilities

4.1 The Host Institution must ensure that before the Research/Project funded by the Grant commences and during the full Grant Period, all necessary legal and regulatory requirements, including any necessary or appropriate ethical approval, in order to conduct the Research/Project are met. This includes obtaining all licences and approvals. The Host Institution accepts full responsibility for ensuring that any such approvals are in place at all

relevant periods of the Grant. The Grant must not be used for any Research/Project on animals which has not been approved and set out in the grant application

4.2 All Grant-holders using animals must adhere to the Guidelines for the Welfare and Use of Animals in Cancer Research/Project as set out by Workman, et al. (2010: Br. J. Cancer 102, 1555–1577) and implement the principles in the cross-funder guidance Responsibility in the Use of Animals in Bioscience Research/Project. Experiments using animals funded by the Histiocytosis UK must:

4.2.1 use animals only where there are no alternatives;
4.2.2 use the simplest possible, or least sentient, species of animal;
4.2.3 ensure that distress and suffering are avoided wherever possible; and,
4.2.4 employ an appropriate design and use the minimum number of animals consistent with ensuring that the scientific objectives will be met.
4.2.5 See the NC3Rs website for further information and guidance.

4.3 Grant-holders should make use of the ARRIVE guidelines when designing their experiments and ensure that they report animal-based studies in accordance with the ARRIVE guidelines as far as possible, taking into account the specific editorial policies of the journal concerned.

4.4 All Research/Projects using cell culture must incorporate a specific cell line authentication protocol into their experimental framework, following the best practice for cell culture procedures (UKCCCR Guidelines for the Use of Cell Lines in Cancer Research/Project, 2000: Br. J. Cancer 82, 1495–1509

4.5 All Researchers /Project Managers are expected to follow the principles and guidelines set out by MRC's Good Research/Project Practice (2012: http://www.mrc.ac.uk/Research/Project/Research/Project-policyethics/good-Research/Project-practice/).

5. Support from Host Institution

5.1 The Host Institution shall ensure that the Premises are:
5.1.1 appropriate to house the Research/Project Personnel and all equipment used in the Research/Project;
5.1.2 at all times fully maintained.
5.1.3 kept in an appropriate and safe state of repair; and,
5.1.4 properly serviced.

5.2 The Host Institution shall comply with and perform all obligations and duties at law (including all applicable health and safety legislation) in respect of the Premises

5.3 The Host Institution must ensure that adequate resources are provided to support the activities and timeframe described in the Grant Award Letter.

5.4 The Host Institution shall provide the Research/Project Personnel with support services and facilities on the same terms and at the same level as that provided for similar Research/Project groups within the Host Institution.

5.5 The Host Institution shall comply with all relevant laws and regulations and shall obtain and maintain all necessary licences and approvals in respect of the Research/Project.

6. Equipment

6.1. Except as specifically agreed in writing by the Parties, the Host Institution shall provide and maintain all equipment in good and safe working order and in a state and sufficiency appropriate for the purposes of the Research/Project.

6.2. Any equipment purchased using funds from the Grant shall belong to the Host Institution but may only be used for the purposes of the Research/Project until the Research/Project is complete.

7. Staff

7.1. The Host Institution shall:
7.1.1. employ or engage as the case may be the Research/Project Personnel in accordance with its normal procedures and under its normal terms and conditions appropriate to the grade and status of the individual;
7.1.2. ensure it has and follows its standard formal equal opportunities policy with respect to hiring staff on the Grant;
7.1.3. be fully responsible in all respects for the Research/Project Personnel; and,
7.1.4. comply with and perform all obligations and duties at law in respect of the Research/Project Personnel.

7.2 The Host Institution shall notify Histiocytosis UK as soon as reasonably practicable the names, dates of appointment and starting salaries of the Research/Project Personnel and keep Histiocytosis UK fully and promptly advised of any alterations thereto; and seek the advance approval of Histiocytosis UK prior to awarding any Research/Project Personnel a salary increase (giving full details of the additional cost over the remaining period of the Grant and supplying copies of any relevant salary scales).

7.3 In the event that the Host Institution deems it necessary to take any disciplinary or other action resulting in (or potentially resulting in) the dismissal or suspension of a member of the Research/Project Personnel, the Host Institution shall notify Histiocytosis UK of such action as soon as practicable (and preferably in advance) and will similarly notify Histiocytosis UK of the progress and outcome of such action. For the avoidance of doubt, the Host Institution shall seek the prior written approval of Histiocytosis UK, before replacing the Grant-holder for any reason.

7.4 Research/Project Personnel in receipt of salary support from Histiocytosis UK must ensure that their time commitments to commercial organisations and other non-Research/Project activities are compatible with the policies of the Host Institution and any conditions in the Grant Award Letter.

7.5 Histiocytosis UK-funded Research/Project Personnel must disclose to their institutions (a) benefits in cash (or equivalent value) in excess of £10,000 per annum or (b) benefits in equity of any level, received either as compensation for work undertaken for a commercial organisation, or in consideration of the transfer of intellectual property.

7.6 In managing a perceived or actual conflict of interest, the Host Institution must use all reasonable endeavours to ensure that Histiocytosis UK is not put at risk of being in breach of charity law or regulation because of the relationship of a Histiocytosis UK-funded Research/Project with a commercial organisation. In particular, the Host Institution should act to ensure that the useful results of Histiocytosis UK-funded Research/Project are applied for the public benefit, with only incidental private benefit.

7.7 Histiocytosis UK does not act as an employer with respect to the Grant. Histiocytosis UK will not be responsible for, nor will it indemnify the Host Institution against, any claim for redundancy, compensation, dismissal or discrimination or any other claims for which the Host Institution or any permitted sub-contractor may be liable as an employer or otherwise.

8. Financial

8.1. The Host Institution must ensure proper financial management of grants and accountability for the use of public funds. The Host Institution will allow Histiocytosis UK, on reasonable prior notice, to inspect all such records and accounts.

8.2. The Grant may only be used in respect of the Research/Project and the Host Institution shall ensure that it is not utilised for any other project or activity. Furthermore, the Host Institution will ensure that funds are not transferred between fund headings within the Grant without the prior written approval of Histiocytosis UK.

8.3. Histiocytosis UK does not pay Directly Allocated Costs unless specifically and clearly identified in the Grant Award Letter. Histiocytosis UK does not pay any indirect costs. In no circumstances will Histiocytosis UK reimburse any costs relating to professional indemnity insurance or any similar costs or expenses.

8.4. All amounts specified in the Grant Award Letter are inclusive of Value Added Tax (VAT).

8.5. Funds for equipment are awarded on the condition that only those items specified on the Grant Award Letter may be purchased.

8.6. The Host Institution must ensure that it has in place clearly defined procedures for the procurement of equipment and that equipment funded by the Grant is acquired in accordance with these procedures. Histiocytosis UK will not accept any liability to pay VAT due to any failure of the Host Institution to claim relief on qualifying equipment.
8.7. Equipment purchased through a Histiocytosis UK grant is awarded to the Host Institution specifically for the purpose of the Grant-holder's Research/Project. The equipment must be used primarily for the approved Research/Project during the lifetime of the Grant.

8.8. Histiocytosis UK will not pay any access charges for use of equipment funded by Histiocytosis UK.

8.9. The Host Institution must ensure that the equipment funded by the Grant is appropriately insured and maintained throughout its useful life. Histiocytosis UK will meet any agreed maintenance costs for awarded equipment for the period of the Grant. If any equipment funded under the Grant is lost, damaged or destroyed during the life of the Grant, the Host Institution will be required to repair or replace it at its cost.

8.10. The Host Institution will be responsible for any expenditure on the Grant in excess of the funding stipulated in the Grant Award Letter.

8.11. The Host Institution must reclaim expenditure under the Grant within 12 months of it being incurred and Histiocytosis UK will not reimburse any claims falling outside this period. In order to secure reimbursement for approved equipment costs, the Grant-holder must submit copies of the corresponding invoices to Histiocytosis UK with the relevant claim form.

8.12. Histiocytosis UK will reimburse the Host Institution expenditure properly incurred in respect of the Grant quarterly in arrears upon receipt of a properly and promptly completed official Histiocytosis UK claim form bearing the Histiocytosis UK Grant reference and duly signed on behalf of the Host Institution subject to any further reasonable explanations Histiocytosis UK may require.

8.13. If Histiocytosis UK has reason to believe that the Host Institution and/or the Grant-holder are in breach of any of these terms and conditions, then it may suspend all payments pending further enquiry. If, as a result of such enquiry, Histiocytosis UK reasonably concludes that the breach is material, then it shall be entitled, without prejudice to any other rights it may have, to terminate the Grant forthwith and make no further payments.

9. Salary allocation

9.1. Salary allocation may be used to fund salary, the employer's national insurance contribution, and an employer's pension contribution which will not be higher than the rate used by the USS or NHS scheme. It must not be used to offset any prior underfunding of the pension scheme.

9.2. Salary allocation may not be used for any bonus or merit awards.

9.3. All advertisements for staff that will be funded by a grant must indicate that the Research/Project is funded by Histiocytosis UK. The Host Institution is responsible for advertising posts and must meet recruitment-associated costs.

9.4. The Grant-holder must notify Histiocytosis UK when the situation for long-term leave arises. Any unspent salary allocation for the post after long-term leave has been paid may be used to employ temporary cover.

10. Virement

10.1 Histiocytosis UK may allow allocations for salary and running expenses to be vired to other salary and running expense allocations subject to prior written approval.

11. Reconciliations

11.1. Histiocytosis UK reserves the right to reduce the Grant by any amounts unclaimed in relation to each Grant Funding Phase.

11.2. Where any amounts paid by Histiocytosis UK exceed the amounts justified or the Grant has not been used in accordance with the terms and conditions of award, Histiocytosis UK will recover the sum in question on whatever terms it may specify. Histiocytosis UK may recover sums owed to it by offsetting them against any other sums (including grant payments) owed to the Host Institution.

11.3. At the request of Histiocytosis UK, the Host Institution and/or its external auditors shall provide written confirmation that the Grant has been used for the purpose for which it was

awarded and that the costs incurred meet the conditions of the Grant. On request, the Host Institution shall also make the necessary arrangements to enable Histiocytosis UK and its agents to visit the Host Institution to discuss the administration and accounting of its awards, and if necessary, to conduct its own audit of any Histiocytosis UK grant account at the host Institution or the activities funded. For this purpose, Histiocytosis UK and its agents and advisors may inspect and take copies of all relevant books of accounts and records. Where elements of expenditure under the Grant have been subcontracted, the Host Institution should ensure that the right of access extends to the accounts, records, equipment and facilities of any such subcontractor relevant to the management of the Grant.

12. Transfer of Grant

12.1. If a Grant-holder would like to transfer the Grant to another Institution and the Institution agrees, or the current Grant-holder/Host Institution would like to transfer the award to a new Grant-holder, any such transfer will be subject to prior written approval from Histiocytosis UK. Transfers are only permitted to institutions within the UK that are eligible to receive funding from Histiocytosis UK and are able to demonstrate to Histiocytosis UK's satisfaction the ability to support the Research/Project during the tenure of the grant. The new Host Institution/Grant-holder must agree to abide by the Terms and Conditions of award.

12.2. If the Grant-holder transfers to another institution during the Grant Period, Histiocytosis UK reserves the right to require that the equipment funded by the Grant is transferred with him/her.

13. Progress reporting and publications

13.1. The Grant-holder shall submit a written report on the progress of the Research/Project in a form agreed by Histiocytosis UK at an agreed date each year. Furthermore, the Host Institution shall provide copies of any information relating to the Research/Project as Histiocytosis UK may, from time
to time, request. The Grant-holder will submit a final written report to Histiocytosis UK in respect of the conduct and outcome of the Research/Project within three months of its completion.

13.2. The Host Institution and the Grant-holder shall take all necessary steps to disseminate the results of the Research/Project in accordance with normal academic practice, preferably as immediate open access (see 13.3), making appropriate reference to Histiocytosis UK in any published material and other relevant documents about or arising from the Research/Project. This includes confirmatory, replication and negative result studies. Notwithstanding the foregoing, the publication of the results of the Research/Project may be delayed where

reasonably necessary to protect any intellectual property rights that have arisen during the course of the Research/Project in accordance with clause 17.

13.3. All original Research/Project published as an article in a peer-reviewed journal and that is supported in whole or in part by the Grant is subject to Histiocytosis UK's policy on open access.

13.4. Before publication, the Host Institution must ensure the Research/Project undergoes the Host Institution's standard procedures for ensuring the validity of the results and the suitability of the Research/Project for general publication. Histiocytosis UK takes no responsibility for the validity of the Results or for any statements made by the authors in the publication.

13.5. Histiocytosis UK expects valuable data, reagents and software arising from Histiocytosis UK-funded Research/Project to be made available to the scientific community with as few restrictions as possible so as to maximize the value of the Research/Project and for eventual patient and public benefit. Such data must be shared in a timely and responsible manner, making use of online open repositories, public databases and community-led reagent stores.

13.6. Grant-holders must provide Histiocytosis UK with details of all publications arising from the Histiocytosis UK Research/Project, whether wholly or partly funded. Details should be provided at the time of submission for publication to ensure that Histiocytosis UK is kept fully informed of all Results entering the public domain and has sufficient notice to arrange any publicity (see 15.2). A copy of any published material shall be sent to Histiocytosis UK as soon as possible after publication.

13.7. Studies involving human subjects represent a special case, especially if the publication, either in print or electronic format, of the results enables individuals the subjects or others to gain knowledge about their personal condition which they otherwise not have had. In any clinical study where this is possible the matter must be addressed in the protocol and discussed with the Chair of the Scientific Research Board.

13.8. Investigators must consider whether a mechanism is needed for human subjects to be made aware of the results and the implications for them personally before publication (communication with their GP or the consultant entering them into the trial, with a clear indication of their responsibility for communicating to the patient, would be deemed to be Histiocytosis UK – Terms & Conditions – June 2016
sufficient). If such a mechanism is put in place, there must also be procedures for dealing with any consequences arising from its use.

13.9. Researchers/Project Managers are reminded that electronically published descriptions of work that involve the use of animals will more easily be seen by those who may seek to misuse the information. Whilst Histiocytosis UK supports appropriate animal Research/Project,

Researchers/Project Managers are requested to be mindful of this in what they write and specially to avoid publication of photographs. If in doubt, Researchers /Project Managers should refer to the guidelines published by their Host Institution.

13.10. Histiocytosis UK shall be permitted to disclose information regarding the award to relevant regulatory authorities, Higher Education Funding Councils and other agencies administering governmental funding.

14. Recognition of support

14.1. In any oral or written report or poster presentation of Results or otherwise relating to the Research/Project, the author must acknowledge the support of Histiocytosis UK. All references to Histiocytosis UK-funded work placed on websites, electronic bulletin board or similar must state clearly that the work is funded by Histiocytosis UK and, where practical should include a link to Histiocytosis UK's website.

14.2. It is essential that investigators acknowledge that their Research/Project has been supported wholly or in part by Histiocytosis UK.

15. Publicity

15.1. In order to sustain our reputation for patient benefit and funding it is essential that Histiocytosis UK is well known and respected amongst a wide range of different communities, including scientific, media, political, health and general public. The Grant-holder and/or Host Institution may be required to co-operate with Histiocytosis UK over any publicity or fundraising activity arising from Histiocytosis UK-funded Research/Project. Where Histiocytosis UK is the main funder of the Research/Project, Histiocytosis UK reserves the right to lead on publicity in cooperation with the Host Institution and any other funders. Grant-holders and Host Institutions are required to contact the Histiocytosis Administration prior to any publicity releases about Histiocytosis UK-funded Research/Projects.

15.2. For academic journal publications, Grant-holders are encouraged to contact Histiocytosis UK's office (histio@histiouk.org) at the time of manuscript submission, and certainly with a pre-print version of the article prior to a manuscript being published, to allow Histiocytosis UK to arrange any publicity in time for publication of the final article. When speaking publicly about their Research/Project and particularly when speaking to representatives of the media, Research/Project Managers should ensure that their Research/Project is recognised as Histiocytosis UK-funded work. However, Research/Project Managers should not speak to the media as a "Histiocytosis UK scientist" without prior consultation with Histiocytosis UK's Administration team.

15.3. Research/Project Managers are not authorised to act as a representative of the charity without prior approval from Histiocytosis UK. Research/Project Managers who speak to the media must ensure that their personal views are not misrepresented as being attributable to Histiocytosis UK.

15.4. Histiocytosis UK reserves the right to use data and other material from Research/Project that it funds as part of its fundraising or publicity activities, upon gaining prior written approval from the Host Institution to ensure that no proprietary information is disclosed.

16. Studentships

16.1. Studentships funded by Histiocytosis UK provide the following:
16.1.1. A stipend set by Histiocytosis UK;
16.1.2. Running expenses;
16.1.3. Standard university consolidation fees; and,
16.1.4. College fees for Oxford and Cambridge.

16.2 Histiocytosis UK will pay fees only at the UK/EU level. However, there are no restrictions on the nationality of the Histiocytosis UK-funded PhD student.

16.3 Histiocytosis UK will not pay expenses for interviewing candidates.

16.4 The Host Institution is expected to provide the student the stipend at the level set by Histiocytosis UK, for four years. Histiocytosis UK will not pay more than the stipend specified.

16.5 The Grant-holder must notify Histiocytosis UK of the student's start date within thirty (30) days of that date.

16.6 Histiocytosis UK does not encourage registration for PhD or MPhil by Research/Project assistants or technicians unless they transfer to a studentship. Running expenses on awards cannot be used to allow Research/Project Personnel to register for PhD, MD or MPhil awards.

16.7 If the student has to take time out of their studies due to illness or maternity leave, the guidelines of your Host Institution must be followed. The leave and requests for extensions should then be discussed with Histiocytosis UK.

16.8 Depending on local arrangements and agreement from the supervisor, students may spend up to 10 percent of their time undertaking teaching duties. However, if they are paid for this activity students may become liable for tax and this should be checked carefully before undertaking such work.

16.9 If a student fails to complete their PhD, Histiocytosis UK must be informed of the reason. When possible, Histiocytosis UK requires details of a student's first career post after completion of their PhD. If the first post is a one-year fill-in position then, when possible, details of the second post should also be provided to Histiocytosis UK's Research/Project team.

17. Ownership and exploitation of intellectual property and materials arising from the Research/Project

17.1. The Parties' aim is to exploit the results of the Research/Project so that the understanding, diagnosis and treatment of haematological malignancies and related diseases are maximised.

17.2. All rights to intellectual property (including the copyright in any drawings, plans or software), data and materials arising from the Research/Project (Resulting IP) shall, in the first instance, vest in the Host Institution. The Host Institution shall ensure that the contracts of employment
or other terms of engagement of the Research/Project Personnel provide for automatic and immediate vesting in the Host Institution of the Resulting IP.

17.3. The Host Institution shall allow Histiocytosis UK to visit the Premises at reasonable times and to liaise freely and at will with the Research/Project Personnel for the purpose of identifying Resulting IP.

17.4. Promptly following the identification of any Resulting IP (whether such identification is as a result of the Host Institution's own initiative or through information supplied to the Host Institution by Histiocytosis UK or another party), the Host Institution shall notify Histiocytosis UK as soon as it becomes aware in writing giving full details of the nature of the relevant Resulting IP and an initial view on the commercial potential of such Resulting IP.

17.5. Provided that the Host Institution has notified Histiocytosis UK in accordance with clause 17.4 above, the Host Institution shall take all necessary steps, including the filing of patent applications, to protect the Resulting IP fully. Notwithstanding the foregoing, the Host Institution shall not be under an obligation to protect the Resulting IP where, in its reasonable opinion, there is insufficient commercial justification to do so. The Host Institution shall promptly provide Histiocytosis UK with details of all patent applications filed and other protection sought for Resulting IP.

17.6. The Host Institution shall seek the prior written consent of Histiocytosis UK (not to be unreasonably withheld) before it makes any commercial use of, or grants to any third party any exploitation rights over the Resulting IP. Consent will not be unreasonably withheld, and Histiocytosis UK shall only refuse consent where it considers that the proposed commercial

exploitation would run counter to its interest and charitable objectives. In the event that Histiocytosis UK does not provide a response to the Host Institution's request within ninety (90) days, the Host Institution or technology transfer office acting on its behalf will automatically have the right to proceed with such commercial exploitation. For the avoidance of doubt, apart from transfers to other academic institutions, the Host Institution may not assign, licence, charge or encumber any rights in or to the Resulting IP without first obtaining Histiocytosis UK's written consent.

17.7. If so, requested by Histiocytosis UK, the Host Institution shall meet with Histiocytosis UK, the Grant-holder and such other persons as may be nominated by Histiocytosis UK, to discuss matters relating to the commercial exploitation of the Resulting IP. Should the Host Institution decide to withdraw or abandon patent or similar protection in respect of the Resulting IP, Histiocytosis UK shall be entitled to take an assignment of the property concerned and the Host Institution shall give Histiocytosis UK no less than thirty (30) days' notice to allow it to do so effectively.

17.8. If the Host Institution fails or decides not to protect or exploit the Resulting IP to the reasonable satisfaction of Histiocytosis UK, then Histiocytosis UK shall have the right, but not the obligation, to protect and/or exploit such Resulting IP itself. The Host Institution agrees to do and will procure that the Research/Project Personnel shall do, all reasonable acts required to assist Histiocytosis UK in such protection or exploitation.

17.9. All Net Revenue received from the commercial exploitation of Resulting IP generated without Third Party Funding, whether such commercial exploitation is effected by the Host Institution or by Histiocytosis UK, shall be divided equally between the Parties. The Party responsible for exploitation (the Commercialising Party) will account to the other Party for its share of Net Revenue on a quarterly basis, in pounds sterling, to the bank account nominated by such other Party from time to time. The Commercialising Party will provide the other Party with a quarterly written statement detailing the Gross Revenue received during that period and a breakdown of all the Direct Costs deducted, unless no Gross Revenue is received during that quarter. Where the Commercialising Party grants rights in the Resulting IP to a company in return for an equity stake or other interest in such company, then the Commercialising Party shall provide the other Party with a corresponding share of such stake or interest.

17.10. In the event that Resulting IP is generated with Third Party Funding, the Parties and the third-party funder shall meet to agree a revenue share which reflects Histiocytosis UK's and the third-party funder's financial contribution to the costs of the Research/Project. For clarity, where the Research/Project receives Third Party Funding, Histiocytosis UK shall continue to be entitled to half of any Net Revenue which is attributable to the Research/Project funded by Histiocytosis UK. By way of example only, where the Grant accounts for 40% of the total grant

funding used to support the Research/Project, Histiocytosis UK will be entitled to 20% of Net Revenue.

17.11. The Commercialising Party shall provide the other Party with a written report on its efforts to exploit the Resulting IP at least once per calendar year.

17.12. The Commercialising Party will keep full and complete financial records documenting all Net Revenue and shall make such records available to the other Party for inspection on receipt of reasonable notice.

17.13. The Commercialising Party will keep copies of all agreements entered into in relation to the commercialisation of Resulting IP and shall provide a copy of any such agreement to the other Party upon request (and the Commercialising Party shall ensure that it is entitled to do so when it negotiates the terms of the relevant agreement). The Party receiving any such agreements shall hold them in confidence and shall only use them for the purposes of assessing the commercialisation of the Resulting IP and ensuring compliance with these terms and conditions.

17.14. The Host Institution shall be solely responsible for rewarding the inventors and department in which the Research/Project Personnel are situated out of its share of Net Revenue. The Host Institution and the Grant-holder shall keep Histiocytosis UK fully and promptly informed in writing of:

I. any directorships, consultancies or other appointments (whether or not remunerated) that the Grant-holder and others connected with the Research/Project hold with commercial or other organisations that might have an interest in the Resulting IP; and,
II. any gifts of whatever nature in connection with the Research/Project received by or proposed to be made to the Grant-holder and others connected with the Research/Project (and furthermore shall, to Histiocytosis UK's reasonable satisfaction, ensure that such appointments or gifts do not in any way impinge upon Histiocytosis UK's rights in connection with the Research/Project).

18. Clinical Trials

18.1. Upon receipt of the Grant Award Letter, all Grant-holders must register their trial on the ISRCTN register. Grant-holders should submit details of the unique ISRCTN trial ID code to Histiocytosis UK.

18.2. Histiocytosis UK expects that the Host Institution shall own all Clinical Trial Results.

18.3. Histiocytosis UK expects publication of all Clinical Trial Results, whether reporting significant or non-significant results, in accordance with normal academic practice and Histiocytosis UK's open access policy (see 13.3).

18.4. Where a Clinical Trial is supported in any way by a commercial entity, the Host Institution shall be responsible for negotiating any agreements with such commercial entity, provided that where the Host Institution intends to grant such entity any rights in respect of Clinical Trial Results:

18.4.1. The Host Institution notifies Histiocytosis UK of such commercial interest as soon as practicable; and,
18.4.2. The Host Institution leads the negotiations with the commercial entity, but regularly consults with Histiocytosis UK and incorporates all reasonable amendments relating to such grant of rights that it may suggest.

18.5. Such agreement when in relation to commercialisation of intellectual property should normally be put in place after the relevant Clinical Trial has been completed.

18.6. The Host Institution will promptly notify Histiocytosis UK following receipt by the Host Institution of any monetary consideration from a commercial entity in respect of rights granted to Clinical Trial Results. Following such notification, the Host Institution will negotiate and enter into and appropriate revenue sharing agreement with Histiocytosis UK under which it will share with Histiocytosis UK a fair proportion of such monetary consideration (which shall at least reimburse Histiocytosis UK for the corresponding amount of funding it has provided in support of the relevant Clinical Trial, whether in respect of the set-up/management of the trial or any other costs).

19. Liability, Insurance and Indemnity

19.1. Histiocytosis UK accepts no responsibility for costs or liabilities incurred in connection with the Research/Project or other work funded by a Histiocytosis UK award other than those costs specifically set out in the Grant Award Letter and in these Terms and Conditions.

19.2. Histiocytosis UK takes no responsibility for expenditure incurred before the award is activated or after the Grant has been closed. Histiocytosis UK shall not be held responsible for any loss or liabilities if it transpires that an award is ineligible for government support through one of the Higher Education Funding Councils or other schemes.

19.3. Histiocytosis UK is not liable for loss or injury caused or deemed to be caused by the use or misuse of any equipment funded under the Grant.

19.4. Histiocytosis UK requires the Host Institution to provide a no-fault compensation scheme for participants in a Histiocytosis UK-funded clinical trial as per the relevant local ethics committee approval. Histiocytosis UK does not provide indemnity cover for or accept any liability for harm to participants in Histiocytosis UK funded trials where Histiocytosis UK is not the trial sponsor.

19.5. The Host Institution shall indemnify and hold harmless Histiocytosis UK, its trustee/ directors, officers, employees and agents (each an Indemnified Party) from and against any and all costs, claims, damages, losses and expenses that arise in relation to the Research/Project, the Research/Project Personnel, the Premises and the Host Institution's equipment, except to the extent that such costs, claims, damages, losses and expenses arise as a result of the negligence of an Indemnified Party.

19.6. The Host Institution must hold appropriate policies of insurance covering personal indemnity, public liability, and employer's liability and shall maintain such insurance policies throughout the Project. On request, the Host Institution shall provide Histiocytosis UK with a copy of such insurance policies.

20. Professional Misconduct and Conflicts of Interest

20.1. It is acknowledged and agreed that the Host Institution and the Grant-holder will:
20.1.1. operate approved and effective procedures to prevent professional misconduct and to manage conflicts of interest; and,
20.1.2. promptly and vigorously investigate any allegations of professional misconduct that may arise before during or as a result of the Research/Project and keep Histiocytosis UK fully informed of progress and the outcome.

20.2. The Host Institution shall provide Histiocytosis UK with reasonable assistance and information for consideration in circumstances where Histiocytosis UK, using its reasonable discretion, decides to carry out its own investigation into any aspect of fraud or misconduct once the Host Institution has completed its own processes, made its final decision under clause 20.1 and shared any findings with Histiocytosis UK.

20.3. Where allegations of scientific misconduct are investigated and upheld, Histiocytosis UK reserves the right to impose appropriate sanctions on the Grant-holder which may include (but are not restricted to):
20.3.1. Removal from a particular project;
20.3.2. Retraction of published material;
20.3.3. Monitoring of future work; iv. Withdrawal of funding; v. Termination of Grant.

21. Gifts

21.1. Histiocytosis UK shall have absolute right to any bequest, donation or other gift to or made in the name of Histiocytosis UK and such right shall extend beyond the term of the Research/Project without time limitation.

22. Miscellaneous

22.1. All grants awarded by Histiocytosis UK are subject to the terms and conditions that apply at the time the grant is awarded and any subsequent amendments. Histiocytosis UK reserves the right to amend these Terms and Conditions, any terms and conditions of the Grant Award Letter and general funding policies from time to time. Histiocytosis UK will notify Grant-holders of any change to the Terms and Conditions.
22.2. In the event of a conflict between the provisions of these Terms and Conditions as amended from time to time and of the Grant Award Letter, the provisions of the Grant Award Letter will take precedence.
22.3. If any provision of these terms and conditions (or part thereof) is found by any court or other authority of competent jurisdiction to be invalid, unenforceable or illegal, the other provisions shall remain in force.
22.4. The Host Institution may not assign any of its rights in respect of the Grant to any other party without Histiocytosis UK's prior written consent.
22.5. Save for the Indemnified Parties who may enforce the terms of clause 19.5, a person who is not a party to these terms and conditions shall not have any rights under or in connection with them by virtue of the Contracts (Rights of Third Parties) Act 1999 or otherwise. Notwithstanding the provisions of this clause, Histiocytosis UK shall be entitled to amend, suspend, cancel or terminate the Grant (or any part of it), without the consent of any third party including those referred to in this clause.

23. Termination

23.1. Histiocytosis UK reserves the right to terminate the Grant at any time without notice. Save where Histiocytosis UK terminates the Grant due to any default of the Host Institution, Histiocytosis UK shall reimburse, in accordance with clause 8, any expenditure properly incurred by the Host Institution in relation to the Research/Project prior to the date of termination.

24. Governing Law

24.1. The validity, construction and performance of these terms and conditions shall be governed by English Law. All disputes, claims or proceedings between the parties relating to the

validity, construction or performance of these terms and conditions shall be subject to the exclusive jurisdiction of the English Courts.

25. General Data Protection Regulation GDPR/UK Data Protection Act 2018 and Section 251 of the NHS Act 2006 - Consent

The combined effect of the Data Protection Legislation (including General Data Protection Regulation GDPR/UK Data Protection Act 2018 and Section 251 of the NHS Act 2006) is that much information sharing between NHS organisations does not need explicit consent from patients/carers. Information sharing between NHS and non-NHS organisations is likely to require more explicit consent from patients/families.

Data must be collected and shared in compliance with the GDPR/Data Protection Act 2018. That is, NHS Trusts must state on their data protection notification to the Information Commissioner (ICO) the reasons why they collect information, and how they make patients, families or staff aware of these reasons.

The Trust will inform individuals of the likelihood of sharing their information with other organisations, where appropriate. In circumstances where sharing personal information between organisations is routine, mechanisms must be in place to ensure that the individual is aware of such information sharing. In the case of patient's information awareness may be with the family or the carer.

The NHS Trusts must promote the right for an individual to withhold information about them from a third party who might otherwise have received it. All organisations party to the agreement must respect this right where applicable, unless there are exceptional circumstances. Every effort should be made to explain the consequences of withholding information and any possible impact that will have on the level and quality of care that can be provided. However, it is important to note that the final decision does lie with the individual/family concerned.

NHS organisations may need to submit details of their proposed information sharing to the Confidentiality Advisory Group to ensure that it is covered by the terms of Section 251 of the NHS Act 2006, which provides NHS organisations with the interim facility to share patient information without explicit patient consent.

If data is to be used for a purpose different to that for which it was originally provided, it should only be disclosed if the individual/family has given their specific consent, the disclosure is a statutory requirement, or if there is an overriding public interest.

A decision to disclose information without or against the consent of an individual can only happen when the information is required by a court order/statute, where there is an overriding public interest to do so, or where it is in the best interests of the individual. This judgement must be made on a case-by-case basis, after seeking additional legal or specialist advice. A record must be kept as to the reason why a disclosure of personal information was made in line with the individual organisation's policies and procedures.

Notes: Should any award be offered, the host body/organisation MUST accept, process and complete the Histio UK documentation within six months of the date of any award offer letter.

26. Special Conditions to your award

27. Agreed and Approved by Host Institution and Applicant(s) as per section 3 of this document.

Signature:
Designation:
Name:
Date:
Official Stamp of Institution

Applicant(s)
Signature of Applicant:
Designation:
Name:
Date:

Signature of Co Applicant (s)
Signature:
Designation:
Name:
Date:

Agreed and Approved by Histiocytosis UK
Signature
Name
Date

Definitions

Directly Allocated Costs – The cost of resources used by a project that are shared by other activities. They are charges to projects on the basis of estimates rather than actual costs and do not represent actual costs on a project by project basis, e.g. electricity, water.

Clinical Trial Results – All results arising from a clinical trial, other than Human Biological Samples.
Commercialising Party – The Party responsible for commercial exploitation
Direct Costs – The external costs and expenses directly incurred in carrying out commercial exploitation of Resulting IP (including legal, patent and travel costs, but excluding the Host Institution's staff costs).
Equipment – The equipment required to conduct the Research/Project.
Funded Materials – Biological and chemical materials comprised in Resulting IP
Grant – The funding made pursuant to and described in the Grant Award Letter
Grant Award Letter – The letter from Histiocytosis UK to the principal Grant Holder specifying the amount of the Grant and confirming the award of the Grant.
Grant-holder(s) – The lead applicant, any joint applicant as specified in the Grant Award Letter or any persons to whom the Host Institution allocated the Grant or any part thereof.
Grant Funding Phase – The funding period of the grant as described by Clause 3.3.
Grant Period – The Duration of the grant as set out in the Grant Award Letter.
Gross Revenue – Any and all income of any nature received by the Host Institution, any of its Affiliates or technology transfer office acting on its behalf from time to time in respect of or as a result of the commercial exploitation of the Resulting IP
Host Institution – The university, institution or other body at which some or all of the Research/Project funded by the Grant will be carried out.
Human Biological Samples – Tissue, blood and other biological samples taken from humans.
Indemnified Parties – Histiocytosis UK, its Directors, Officers, Employees and Agents
Indirect Costs – Non-specific costs charged across all projects based on estimates that are not otherwise included as Directly Allocated Costs. They include the costs of the Host Institution's administration such as human resources, finance, library and departmental services.
Net Revenue – Gross Revenue minus Direct Costs.
NIHR CRN Portfolio – A database of clinical Research/Project studies that are supported by the National Institute of Health Research/Project Clinical Research/Project Network in England.
Party and the Parties – Histiocytosis UK and/or the Host Institution as appropriate
Premises – All Research/Project facilities where the Research/Project is conducted.
Research/Project – The Research/Project and investigation which is the subject of the Grant.
Research/Project Personnel – The Grant-holder and the person or persons salaried using Grant funds to carry out the Research/Project
Resulting Intellectual Property (Resulting IP) – All Results other than Clinical Trial Results.
Results – All inventions, discoveries, materials (including biological and chemical materials), technologies, products, data, algorithms, software, patents, databases, copyright, other intellectual property and know-how arising from Research/Project
Studentship – A grant to provide the stipend and other costs associated with a non-clinical PhD student.
Terms and Conditions – The conditions set out in this document.
Third Party Funding - Any funding provided to support the Research/Project other than:

(i) the Grant funding provided by Histiocytosis UK;

(ii) the internal funding provided by the Host Institution (which includes all government funding provided to the Host Institution by the Higher Education Funding Council for England, the Scottish Funding Council, the Higher Education Funding Council for Wales and other equivalent government funding bodies and their successors); and,

(iii) any funding provided by an NHS Trust or similar entity to support clinical Research/Project costs, where the applicable rules and/or guidelines of such entity (or its governing body) state that such costs are to be absorbed by the entity.

Histiocytosis UK - A charity registered in England and Wales (no. 1158789).
Correspondence address: Histiocytosis UK. PO Box 159, LISKEARD, PL14 9DQ.

Clinical Trials
CONDITIONS OF FUNDING
Introduction

The Histiocytosis UK Scientific Review Board reserves the right to recommend withdrawal of funding from a clinical trial when it is considered to be no longer innovative or of clinical merit. The most likely reasons to consider closure of a trial are an unacceptable delay in set up or a poor rate of accrual.
The Scientific Review Board will consider all opinions before making a recommendation on whether funding should be continued or discontinued.

Opening of trials

1. Trials approved for funding (or 'badging') by Histiocytosis UK SRB should be opened to accrual no longer than two years after receipt of the award letter. Any trial not open within that time will be subject to further peer review to ensure that the Research/Project question remains relevant. In such circumstances Histiocytosis UK will inform the SRB and chair of the appropriate sub-group that unless there are compelling reasons to maintain funding it will be withdrawn from the trial portfolio. The SRB and sub-group chair will be asked to justify why a trial should be continued.

2. Where possible Histiocytosis UK will also ask one or more of the original referees whether, in their opinion, the trial remains innovative and likely to contribute to clinical progress.

3. If the reviewers re-approve the trial, the applications will have a maximum of six months from the date of approval to open the trial to accrual.

4. If the study is not re-approved, or has not opened within the additional six months, Histiocytosis UK funding (and badging) will be withdrawn.

Accrual

1. SRB will monitor accrual to all Histiocytosis UK-funded clinical trials at each meeting.

2. Initial accrual targets for all applications will be reviewed by the Histiocytosis UK Management Team for feasibility. Statistical review will remain a function of SRB.

3. The review will be made available to applicants and to the SRB members before each meeting. Applicants will have the opportunity to respond to the review at the SRB meeting.
4. If funding is approved, SRB will set accrual targets in discussion with applicants.

5. For phase I and II studies, the aim should be to reach up to 25% of the required number one year after opening to recruitment; thereafter accrual should be maintained at the same rate as the first year. If the accrual rate is poor, the SRB will re-evaluate funding.

Funding

1. When initial funding is required for the manufacture of reagents or cellular products, Histiocytosis UK will agree a schedule for milestone payments, according to progress. Milestone payments linked to the accrual goals outlined above will be determined for all Histiocytosis UK-funded clinical trials and will be reviewed by SRB at each meeting.

2. Investigators will be required to incorporate a financial statement into their progress reports to allow SRB to monitor the release of funds according to the agreed milestones.