

Date:

**CROHN'S & COLITIS UK
Grant Terms and Conditions**

Between:

- (1) **Crohn's & Colitis UK**, a registered charity in England & Wales (1117148) and in Scotland (SC038632) and a registered company limited by guarantee in England & Wales (5973370), whose registered office is at Helios Court, 1 Bishops Square, Hatfield Business Park, Herts AL10 9NE (the "Charity");
- (2) **The Host Institution**; and
- (3) **The Principal Investigator**.

(each a "Party", together the "Parties")

Host Institution (name & address)	
Principal Investigator (name & address)	
Project Title	
Duration	
Award value	
Grant Reference	

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DEFINITIONS

Grant Holder	The person (the Principal Investigator) who applied for the grant and who is responsible for the Project at the Host Institution
Host Institution	The institution receiving the Award and at which some or all of the Project will be carried out and which employs the Grant Holder
Researcher(s)	The individual(s) undertaking the Project
Project	The activity(ies) approved by the Charity and funded by the Award under the Project Title
Application	The Grant Holder's application to the Charity requesting funding for the Project and any representations made by or on behalf of the Grant Holder in connection with the application
Agreement	This agreement and any Scheduled annexed hereto
Award	The monies described in the Offer Letter corresponding to the budget approved for funding by the Charity and payable to the Host Institution subject to the terms of this Agreement
Commencement Date	The date of this Agreement, executed by the final party to sign
Completion Date	The end date of the Grant Period as agreed between the Charity and the Grant Holder
Term	The period starting on the Commencement Date and ending six (6) months after the end of the Grant Period unless extended in accordance with Clause 5
Offer Letter	The letter summarising the Award offered by the Charity
Researchfish	The research impact platform (researchfish.net) used to collate data on outcomes and impacts of funded research
Grant Period	The period commencing with the Start Date and finishing with the Completion Date of the Project
Interim Report	A written assessment of the Project's progress to date
Final Report	A detailed summary and assessment of the results of the Project following its completion

Start Date	The date for the Project to start, as agreed between the Grant Holder and the Charity under clause 2.3
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1. THE AWARD

- 1.1 The Charity makes the Award to the Host Institution for the Grant Holder to undertake the Project.
- 1.2 The Grant Holder must use the Award only for the delivery of the Project and must not, without the prior written consent of the Charity:
 - 1.2.1 make any material changes to the Project;
 - 1.2.2 make any material changes to the approved budget; or
 - 1.2.3 use any portion of the Award for any purpose or activities outside the Project; or spend any of the Award on liabilities incurred before the Grant Period (unless expressly covered in the Offer Letter).
- 1.3 The Grant Holder and the Host Institution understand and acknowledge that:
 - 1.3.1 the Charity is not responsible for any overspend (e.g. increased costs arising from price or salary increases part-way through the Grant Period) by the Grant Holder on the Project and the Charity has no obligation to increase the Award in those circumstances;
 - 1.3.2 the Charity is under no obligation to fund any subsequent activities or projects related to the Project that the Grant Holder may wish to carry out; and
 - 1.3.3 the Charity will not provide funding or bear any responsibility for any exit costs (including but not limited to employment costs) that may be incurred by the Grant Holder at the end of the Project unless they were included and approved within the Application and are part of the Award.
- 1.4 The Grant Holder must inform the Charity if, at any time before the end of the Grant Period, the Grant Holder and/or the Host Institution receive any funding from any other source or person towards the Project, including the amount of that funding and purposes to which it is to be applied.
- 1.5 If, before or during the Grant Period, the Grant Holder and/or Host Institution receive any funding from any other source or person towards the Project that was undisclosed prior to the date of this Agreement, the Charity may, where that funding duplicates funding contained in the Award, require repayment of that part of the Award that has been duplicated.
- 1.6 Should the Grant Holder move to another institution during the Grant Period, the Award may not move with them unless the Charity agrees to such a move. The Charity will not pay any additional costs as a result of such a move.
- 1.7 The Host Institution and Grant Holder shall inform the Charity of any pre-existing arrangements of which they are aware, and which could lead to a breach of these Grant Terms and Conditions. The Host Institution shall use all reasonable endeavours to ensure that no consultancies, third party restrictions or arrangements which might impact on the Award are entered into in relation to any Charity-funded person or activity without prior agreement of the Charity. The Charity-funded investigators or individuals involved in the Project shall not use materials or compounds (other than those obtained commercially), on terms which would place restrictions on the publication of the results. The Host Institution shall use all reasonable endeavours to ensure that "reach through rights" have not been granted on any Charity-funded Intellectual Property in favour of commercial organisations providing materials or compounds to Charity-funded individuals for research purposes. However, the Charity recognises that companies providing materials may often require exclusive rights to any Intellectual Property arising from use of that material, and that this requirement is often

non-negotiable. Where Arising Intellectual Property (as defined in Appendix 1) arises from research linked indirectly to the use of material provided under such agreement, the provider shall be offered a time-limited opportunity to take out a revenue generating licence.

2. THE TERM

- 2.1 This Agreement shall endure for the Term, unless terminated earlier in accordance with clauses 3.2 and/or 16.
- 2.2 This Agreement must be signed by the Grant Holder and Host Institution and returned to the Charity no later than [DATE]. Should this Agreement not be signed and returned by the specified date, the Charity shall be entitled to terminate this Agreement and withdraw the Award.
- 2.3 The start date of the Project must be agreed by the Grant Holder with the Charity in writing ("Start Date"). The Project should start within one year of the Commencement Date. If there are exceptional reasons why this is not possible, an explanation must be submitted to the Charity for consideration by the Charity's Research Awards Panel. The Panel's decision whether or not to revoke the Award will be final.

3. OBLIGATIONS OF THE HOST INSTITUTION AND THE GRANT HOLDER

- 3.1 The Host Institution agrees to take full responsibility for:
 - 3.1.1 administering the Award in accordance with the terms of this Agreement
 - 3.1.2 management, monitoring and control of the Project
 - 3.1.3 the employment of staff working on the Project and any unexpected associated costs arising (e.g. maternity leave payments, sickness benefit, unfair dismissal costs etc.). meeting and maintaining all required ethical and licensing requirements for human and animal work in line with current regulation
 - 3.1.4 ensuring all Awards and Grant Holders comply with current data protection regulations and any subsequent changes
- 3.2 The Host Institution must promptly inform the Charity if the Grant Holder becomes unable or unwilling to continue with the Project. If the Charity and the Host Institution, acting reasonably, cannot agree on a substitute within 30 days after receiving notice that the Principal Investigator is unable or unwilling to continue with the Project, each of the Parties shall be entitled to terminate this Agreement by giving 90 days' notice in writing to the other.
- 3.3 The Grant Holder should contact The Charity as soon as possible if they identify or anticipate any difficulties which could affect delivery of the Project.

4. PAYMENT OF THE AWARD

- 4.1 Payment of the Award will be made quarterly in arrears on receipt of an invoice from the Host Institution and providing that the terms of this Agreement are being met.
- 4.2 Invoices should be addressed to the Director of Finance, Crohn's & Colitis UK, 1 Bishops Square, Hatfield Business Park, Hertfordshire, AL10 9NE (finance@crohnsandcolitis.org.uk) and must:
 - a. describe the cost(s) invoiced by reference to the approved budget, including names of staff whose salary is being claimed;
 - b. quote the Grant Reference (stated on page 1); and
 - c. specify the time period to which they apply.

Invoices that do not quote these details cannot be paid.

- 4.3 Any items of equipment purchased using the Award shall be owned by the Host Institution. Additional costs including but not limited to insurance, maintenance and repair costs will be the responsibility of the Host Institution. Equipment purchased using the Award must be used primarily for the Project, during the Grant Period.
- 4.4 For any individual consumables items costing £1,000 and over, and all items of equipment, a copy of the original purchase invoice must be provided by the Host Institution to the Charity with the expenditure breakdown.
- 4.5 The first payment of the Award shall not be made until the Charity has agreed in writing the Start Date with the Grant Holder under clause 2.3.
- 4.6 The final claim must be submitted within six months of the termination of the Award. No reimbursement against claims received outside this period will be considered.
- 4.7 The Award is made on condition that it is used for the Project during the Grant Period. Any unspent monies (e.g. arising from a lower price or salary being paid than was estimated in the application) will revert to the Charity at the end of the Grant Period.
- 4.8 Nationally awarded salary increases will only be allowed if they have been provided for in the Grant Application and subsequent Award. Reasonable allowance for such increases whether known, pending or anticipated must be included in the Grant Application.
- 4.9 Requests for virements of the awarded budget between headings or years must be made in advance and in writing (by email) to the Charity and may require the permission of the Chair of the Awards Panel.
- 4.10 The Charity reserves the right to audit the finance of the Award at any time, either itself or using a third party, and the Host Institution shall provide such breakdowns, receipts, supplementary evidence and reasonable assistance as the Charity may require for this to be effected.
 - 4.10.1 The Host Institution is required to have in place formal purchasing procedures that ensure only valid grant expenditure is charged.
 - 4.10.2 The Award may be cancelled if such procedures are found not to be in place.

5. EXTENSIONS TO THE GRANT PERIOD

- 5.1 The Charity will consider extensions of the Grant Period but is not obligated to grant any requested extensions.
- 5.2 Requests for extensions will only be considered on a no-cost basis. All requests must be submitted to the Charity in writing (by email) a minimum of 30 days in advance of the start of the extension.

6. SUSPENSION

- 6.1 The Charity may agree to the Grant Holder suspending the Project and suspend payments of the Award in the following circumstances:
 - 6.1.1 if the Grant Holder or a Researcher working on the Project is absent for a prolonged period of time due to illness;

- 6.1.2 if the Grant Holder or a Researcher leaves the team working on the Project;
- 6.1.3 if the Grant Holder or a Researcher is away from the Host Institution on the grounds of parental leave or adoption leave.

- 6.2 The Charity will confirm any suspension of the Project and payments of the Award in writing. The suspension will have a designated end date which may, with the agreement in writing of the Charity, be further extended at the request of the Grant Holder or the Host Institution if the Grant Holder is unable to make such a request.
- 6.3 If the Project and the payment of the Award is suspended the Grant Period will stop running. Following the suspension of the Project and the payment of the Award, the Grant Period shall resume and shall continue until the full Grant Period has been reached.

7. TRANSFER OF AWARD TO A NEW INSTITUTION

- 7.1 Should the Grant Holder wish to transfer the Project from the Host Institution to another institution, the Grant Holder shall obtain the prior written consent of the Charity. Such consent shall be at the sole discretion of the Charity and shall only be given as a result of a written application from the Grant Holder to the Charity.
- 7.2 If the Charity consents to the transfer of the Project to another institution, it will issue to the Grant Holder, the Host Institution and the new institution a letter with an agreed transfer date for the Award.
- 7.3 If the Charity consents to the transfer of the Project to another institution, it will issue to the Grant Holder and the new institution an agreement which the new institution must agree to prior to the Award being transferred.

8. REPORTING REQUIRED BY CROHN'S & COLITIS UK

- 8.1 If the Grant Period is longer than one year, an Interim Report must be prepared by the Grant Holder and submitted to the Charity each year, usually on the anniversary of the Start Date during the Grant Period (except in the year of completion), for review (within one month of receipt) and approval by the Research Awards Panel.
- 8.2 The Charity may suspend further payments of the Award until the relevant Interim Report has been approved.
- 8.3 The Grant Holder is required to submit a Final Report following completion of the Project which should be received by the Charity no later than three (3) months after the Completion Date.
- 8.4 The Final Report must be submitted in the form prescribed by the Charity for review (within one month of receipt) and approval by the Research Awards Panel.
- 8.5 The Charity may withhold up to 10% of the Award until the Final Report has been approved.
- 8.6 As set out in Clause 13.14 below, it is the responsibility of the Host Institution to notify the Charity if any Intellectual Property (as defined in Appendix 1) has been created in the course of the research. When such notification has been received, the Charity will not publish or disclose the reports provided without prior consent from the Host Institution.
- 8.7 In addition to the Interim and Final Reports the Grant Holder must complete an annual submission on Researchfish in February of each year. All sections of the database including any additional fields added by the Charity must be completed.

- 8.8 The Grant Holder will respond promptly to any other requests by the Charity for additional reports during the Grant Period, for example to satisfy the requirements of charitable trusts who may be providing financial support to the project.
- 8.9 Unless otherwise agreed by the Charity in writing, the Host Institution shall ensure that the Grant Holder will complete an annual submission on Researchfish once each year for up to five years following the end of the Grant Period. For the avoidance of doubt this clause shall remain in force until the end of the fifth year following the end of the Grant Period.
- 8.10 Site visits may be made at any time upon reasonable notice by the Charity. These may be attended by a range of individuals including, but not limited to, Charity staff and Trustees, fundraisers and donors.

9. PUBLICATIONS AND OPEN ACCESS

- 9.1 As a charity, the Charity is under an obligation to ensure that the useful results of research that it funds (whether in whole or in part) are applied for the public good. In some circumstances, this obligation may be best achieved through the protection of Intellectual Property and commercial exploitation. The Charity expects the Grant Holder to disseminate the results of the Project promptly, subject to any delays to ensure the protection of any Intellectual Property, the protection of which is subject to confidentiality prior to protection being granted.
- 9.2 In line with the Charity's charitable objects to disseminate the results of research, the Charity may use the information from research it has funded to promote public or professional awareness of the research undertaken.
- 9.2.1 If the results of research must be kept confidential to ensure the protection of any Intellectual Property, the Grant Holder is required to notify the Charity in writing (by email).
- 9.3 The Grant Holder shall provide the Charity with any manuscript approved for publication relating to the Project or its results as soon as possible after the manuscript is accepted and before it is published.
- 9.4 The Charity requires electronic copies of any research articles that have been accepted for publication in a peer-reviewed journal, and acknowledge Crohn's & Colitis UK funding, to be made available through an open access publication as soon as possible and no later than 6 months after publication.
- 9.4.1 The Charity encourages the Grant Holder to select publishing routes that ensure the work is available immediately on publication in its final published form, wherever such options exist for their journal of choice.

10. ACKNOWLEDGEMENT OF CROHN'S & COLITIS UK AND BRANDING

- 10.1 The Grant Holder will give appropriate acknowledgement of the Charity in any publication or presentation of research findings in connection with the Project.
- 10.2 The Grant Holder and Researchers must ensure that the full name of Crohn's & Colitis UK (not CCUK or any other abbreviation) is used in publications, presentations or other materials produced in connection with the Project.
- 10.3 For the purposes of this clause 10, the Grant Holder and Researchers will use the official Crohn's & Colitis UK branding which can be found at:

<https://www.crohnsandcolitis.org.uk/get-involved/volunteering/vr/network-volunteers/creating-communications>

(or such other location as the Charity shall advise) but must obtain the Charity's prior written consent to use the branding for any other purpose.

11. PRESS AND MEDIA REPORTING

- 11.1 The Grant Holder will notify the Charity's Research and Quality Improvement Manager at the earliest opportunity if it believes that the research relating to the Project may be mentioned by the press, in broadcast media or on social media. Any public statement issued by the Grant Holder and/or the Host Institution concerning the research must be approved in advance by the Charity.
- 11.2 The Charity itself may wish to prepare a public statement about the Award and/or the results arising from it. In such cases the Host Institution shall ensure that the Grant Holder shall provide the Charity with full co-operation in the preparation of the same..

12. RESEARCH INTEGRITY AND GOOD PRACTICE

- 12.1 The Grant Holder and the Host Institution agree to manage the Project in line with the Universities UK's Concordat to Support Research Integrity (www.universitiesuk.ac.uk/topics/research-and-innovation/concordat-support-research-integrity) to ensure that it is conducted to the highest standards of rigour and integrity, with the core elements of research integrity; Honesty, Rigour, Transparency & Open Communication and Duty of Care to participants, to be upheld at all times.
- 12.2 The Host Institution must have formal written procedures for the investigation of allegations of scientific misconduct and fraud.
- 12.3 If a case of fraud is suspected in the course of the research, then the Charity must be notified and kept informed of further developments by the Grant Holder and/or the Host Institution.
- 12.4 At the initial stages of any fraud enquiry, the Charity would not normally suspend the Award. However, if in the Charity's reasonable opinion adequate steps are not taken to proceed with the investigation, the Award will be suspended.
- 12.5 If fraud is proven, the Charity will terminate the Award immediately and will consider a claim against the Grant Holder and/or Host Institution for funds so lost.

13. INTELLECTUAL PROPERTY

- 13.1 Certain capitalised terms used in this section are defined as part of the **Charity's IP Management & Revenue Sharing Policy in Appendix 1** (the "IP Policy").
- 13.2 The Host Institution is required, if not already in place, to develop and implement strategies and procedures for the proper and efficient identification, protection, management and exploitation of Intellectual Property.
- 13.3 All Arising Intellectual Property shall vest in and be owned by the Host Institution; the Host Institution shall ensure that all workers (including employees, students and visiting staff), contractors and agents who work on the Project have either signed agreements providing for automatic and immediate vesting in the Host Institution of Arising Intellectual Property, or are employed or retained on terms that vest in the Host Institution all the Charity-funded IP.
- 13.4 If the Project is to be a collaboration involving the Host Institution and Collaborating Institution(s), then the Host Institution is required to execute promptly a collaboration

agreement, which shall bind the Collaborating Institution(s) to the provisions of this Agreement. The Host Institution shall indemnify the Charity for any failure by the Host Institution to ensure that the obligations of this Agreement are passed on to any Collaborating Institution(s). In the event that some of the Arising Intellectual Property is generated or developed at a Collaborating Institution, the Host Institution shall require that the Collaborating Institution assigns their part of the Arising Intellectual property to the Host Institution.

- 13.5 The Host Institution and Collaborating Institution shall provide all background Intellectual Property that is necessary for undertaking the Project. Further, the Host Institution and Collaborating Institution shall provide their background Intellectual Property if necessary to exploit the Arising Intellectual Property. The Host Institution and Collaborating Institution(s) will also use reasonable endeavours to provide any third party Intellectual Property that is necessary for undertaking the Project and the exploitation of the Arising Intellectual Property.
- 13.6 The Host Institution hereby grants to the Charity, a perpetual, sub-licensable, irrevocable, world-wide, non-exclusive royalty-free licence to the Arising Intellectual Property for the purposes of academic/not-for-profit research (including in collaborations), clinical, teaching, and publicity purposes.
- 13.7 If the Host Institution fails to adequately manage or exploit the Arising Intellectual Property which the Charity reasonably considers should/can be exploited, then the Charity may exploit the Arising Intellectual Property, including by way of granting licences in respect of such Arising Intellectual Property to third parties. If the Charity decides to exercise its right to protect and exploit Arising Intellectual Property, the Host Institution shall procure that its employees, students and any third parties acting on its behalf carry out all acts reasonably required by the Charity to assist the Charity in such protection and exploitation.
- 13.8 If there is a dispute between the Charity and the Host Institution in relation to whether Arising Intellectual Property is being exploited adequately, this shall be resolved by means of binding expert determination in accordance with the procedures of the Chartered Institute of Arbitrators. The Host Institution will provide all assistance reasonably requested by the Charity. Such assistance may include but is not limited to licensing, assigning or otherwise transferring all rights in the Arising Intellectual Property to the Charity.
- 13.9 Arising Intellectual Property may not be exploited in any way (e.g. by licence, assignment, option or otherwise) without the prior written consent of the Charity. Consent will not be unreasonably withheld, and the Charity will only refuse the Host Institution's request where it considers that the proposed commercial exploitation would run counter to the Charity's interests and charitable objectives. If the Charity does not provide a response to the Host Institution's written request within thirty days of receiving such request, the Host Institution or its technology transfer subsidiary will automatically have the right to proceed with such commercial exploitation. The Host Institution is not required to seek the Charity's consent in assigning intellectual property to its technology transfer company. In the case of exploitation of the Arising Intellectual Property (e.g. through a licence or assignment via a commercial party of patent rights under the Arising Intellectual Property), consent shall require the execution of a revenue sharing agreement, consistent with the IP Policy (Appendix 3).
- 13.10 The requirement to share revenues with the Charity in accordance with the IP Policy shall survive expiry or termination of this Agreement.
- 13.11 If the Host Institution decides to discontinue exploitation of the Arising Intellectual Property, it shall (within a reasonable time) offer it to the Charity and, if such offer is accepted, will grant the Charity the rights necessary for the Charity to take on exploitation (without unreasonable delay).
- 13.12 If Materials are generated, developed or validated using the Award, the Materials must be

made available to non-commercial third parties for academic or not-profit research in line with Host Institution's standard terms and conditions. The Host Institution is encouraged to make use of public/not for profit repositories for the purposes of such dissemination, under an appropriate agreement with said repository. The Host Institution is also encouraged to make such Materials available to commercial third parties for appropriate consideration. Such consideration is also subject to the IP Policy.

- 13.13 Employees and students may be rewarded under the Host Institution policies in respect of the Arising Intellectual Property, subject to the provisions of this Agreement; however such sums shall come out of the Host Institution share of Net Revenue. Students shall be treated as employees for the purposes of receiving any rewards in consideration of assigning their share of the Arising Intellectual Property to the Host Institution.
- 13.14 The Host Institution shall notify the Charity promptly in writing on the creation or generation of Arising Intellectual Property. In particular, the Charity shall be notified prior to the registration or filing of any application relating to Arising Intellectual Property. The Host Institution shall take all reasonable steps to ensure that such Arising Intellectual Property is protected and not published or otherwise disclosed publicly prior to protection (whilst at the same time ensuring that potential delays in publication are minimised)
- 13.15 The Charity shall be provided with opportunities in good time, to comment on any draft agreement in relation to the Arising Intellectual Property. Further, the Charity shall be provided with a copy of any and all agreements in relation to or concerning the Arising Intellectual Property. The Charity shall be provided with copies of and associated details of any registered Arising Intellectual Property.
- 13.16 The Host Institution must use diligent endeavours to ensure that no publication or presentation compromises its ability to seek appropriate protection of the Arising Intellectual Property. Any publication, presentation or other dissemination of the results from the Project may be reasonably delayed in order to seek appropriate protection.
- 13.17 If the Project is part-funded by a third party, the Host Institution must inform the Charity promptly of the identity of such third party and the nature of their contribution.
- 13.18 The Charity may use a Technology Transfer Agent (TTA). The Host Institution is required to co-operate with the TTA as though it were the Charity itself. Any confidential information provided to the TTA shall be treated in confidence. The Charity and TTA may visit the Host Institution and Collaborating Institution(s) at mutually agreeable reasonable times in order to speak with scientists or TTO staff in relation to technology transfer and connected matters.
- 13.19 The Host Institution must provide written notification at the time of making, or as soon as reasonably possible after making, any application to NICE or other such entity which might bring the Charity into a conflict of interest should it be invited to comment as a patient organisation on such application as a result of e.g. any revenue sharing agreement between the Host Institution and the Charity.

14. RESEARCH INVOLVING ANIMALS AND PATIENTS

14.1 The Host Institution shall ensure that the Grant Holder will:

- 14.1.1 where possible, adopt procedures and techniques which avoid the use of animals, and where this is not possible to use the minimum number of animals considered necessary to achieving a valid result in any experiment by adhering to the 3R's by using the minimum number of animals possible and causing the least suffering (this may involve the use of animals of a higher quality or species);

- 14.1.2 comply with all applicable laws, regulations and guidelines, related to the use of animals in research and not commence any activities under the Project that require the use of animals until all the necessary licences and certificates have been obtained.
- 14.1.3 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.
- 14.2 In relation to clinical trials and all other involvement of human subjects as participants within the Project, the Host shall ensure that the Grant Holder shall treat all such persons in accordance with all applicable laws, regulations and guidelines including where applicable the World Medical Association Declaration of Helsinki and the Guidelines for Good Clinical Practice.
- 14.3 It is a requirement that all research carried out involving humans or human tissue must have a sponsor which accepts the sponsor responsibilities as defined by the NHS Research Governance Framework for Health and Social Care. The Charity is not able to sponsor the work it funds. The appropriate NHS Trust or Host Institution must accept responsibility as sponsor of the research.
- 14.4 Where human subjects are involved in research the Grant Holder is required within the bounds of the relevant ethical framework to provide feedback to participants or their carers at appropriate intervals during and after the Project.
- 14.5 The Host Institution shall make available on request, confirmation of its policies and procedures in respect of the issues set out in Clauses 14.1 and 14.2 above within ten (10) Business Days of a request from the Charity.

15. LIMITATION OF LIABILITY

- 15.1 The Host Institution accepts full responsibility for the management, monitoring and control of the Project and all those staff employed or involved in the Project, including compliance with the requirements of all applicable laws and regulations.
- 15.2 The Charity accepts no responsibility, financially or otherwise, for the expenditure or liabilities arising out of the Project other than as expressly stated in this Agreement.
- 15.3 Under no circumstances will the Charity be liable to the Grant Holder, to the Host Institution or to any third party in excess of the amount of the Award or for any expenses incurred following the date of termination of this Agreement.
- 15.4 The Charity shall not be responsible for any injury to or for the death of any person, or for any loss of or any damage to property of any kind, occasioned by or arising out of the Grant Holder's own negligence or the negligence of any other person employed by the Grant Holder.
- 15.5 The Charity will not indemnify the Grant Holder against any claim for compensation or against any other claim for which the Grant Holder may be liable.

16. TERMINATION AND REPAYMENT OF THE AWARD

- 16.1 The Charity or the Grant Holder may terminate this Agreement upon 28 days' prior written notice where it considers that the other has committed a fundamental breach of this Agreement. Such notice will only be given after full discussion between the Parties of the reasons for the proposed early termination.

- 16.2 The Charity may terminate this Agreement in writing with immediate effect if in its reasonable opinion it considers that the Grant Holder and/or the Host Institution has committed an act or omission which damages the reputation of the Charity.
- 16.3 The Charity may at its absolute discretion withhold, suspend, or require the Grant Holder to repay, all or part of the Award if:
- 16.3.1 The information disclosed in the Application was materially inaccurate or misleading;
 - 16.3.2 The Charity reasonably considers that delivery of the Project falls short of the standards required under this Agreement;
 - 16.3.3 The Grant Holder or any of staff under their direct or indirect management acts dishonestly or negligently in connection with the Project or breaches any of its or their legal obligations in a way that could lead to reputational damage for the Charity;
 - 16.3.4 The circumstances described in clause 4.7 apply (in which case, the Charity's rights under this clause relate to the unspent amount only);
 - 16.3.5 Where the Grant Holder and/or the Host Institution receives duplicate funding for the Project as referred to in Clause 1.5 (in which case, the Charity's recovery will be limited to a part of the Award equivalent to the amount of duplicate funding);
 - 16.3.6 The Grant Holder and/or the Host Institution applies any of the Award in a manner not permitted under this Agreement;
 - 16.3.7 The circumstances described in clause 3.2 apply;
 - 16.3.8 The Grant Holder fails to commence, progress or complete the Project substantially in accordance with any timescales or milestones contained in the Application;
 - 16.3.9 The Grant Holder ceases to carry out the Project, or ceases to hold any regulatory consent necessary for the Project; or
 - 16.3.10 The Grant Holder and/or the Host Institution fails to comply with any of the terms of this Agreement and (where that failure is capable of being remedied) fails to remedy that failure within 20 days of the receipt of a notice from the Charity to remedy the failure.
- 16.4 If the Charity requires repayment of any part of the Award under this clause 16, the Grant Holder must repay that amount in full within 30 calendar days of receipt of the Charity's notice requiring repayment. The Charity may alternatively, at its discretion, set off any amounts due to it under this clause 16 against any further payments of the Award due to be paid, or against any other payments due from the Charity to the Grant Holder under this Agreement or otherwise.
- 16.5 The Charity's rights of withholding or recovery under this clause 16 are in addition to any other rights or remedies it may have.
- 17. GENERAL**
- 17.1 The Grant Holder shall not assign or otherwise transfer any rights or obligations under this Agreement without the prior written agreement of the Charity.
- 17.2 This Agreement may only be amended in writing signed by duly authorised representatives of the Charity, the Host Institution and the Grant Holder.

- 17.3 This Agreement including any Appendices sets out the entire agreement between the Charity, the Host Institution and the Grant Holder relating to the Project and supersedes all prior oral or written agreements, arrangements or undertakings between the Parties relating to the Project. The Charity, the Host Institution and the Grant Holder acknowledge that they are not relying upon any representation, agreement, term or condition which is not set out in this Agreement.
- 17.4 Nothing in this Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between either of the Parties, constitute any Party the agent of the other Party, nor authorise either Party to make or enter into any commitments for or on behalf of the other Party.
- 17.5 The Grant Holder and the Host Institution undertakes not to, unless it has obtained the prior written consent of the Charity: (a) act as an agent of the Charity, (b) contract with any person or entity on behalf of or in the name of the Charity, (c) commit the Charity and (d) in any other way make the Charity liable.
- 17.6 The Grant Holder and the Host Institution shall keep and make available to the Charity on request all invoices, receipts, accounting records and accounts and other documentation relating to the expenditure of the Award for a period of 12 months following receipt of any Award monies to which they relate, and cooperate with any audit of the Agreement carried out by or on behalf of the Charity.
- 17.7 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.
- 17.8 The Parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).
- 17.9 This Agreement does not create any right enforceable by any person not a Party to it.

APPENDIX 1

IP Management & Revenue Sharing Policy¹

1. Definitions

- 1.1 The following words and phrases shall have the following meanings unless the context requires otherwise:

“Charity” means Crohn’s & Colitis UK, whose registered office is at 1 Bishops Square, Hatfield Business Park, Herts AL10 9NE.

“Host Institution” means the university, institution, research council or other entity receiving the Award and at which some or all of the Project will be carried out or which employs the Principal Investigator.

“Principal Investigator” means the individual responsible for supervising and delivering the Project.

“Project” means the research and activity(ies) which are the subject of the Award.

“Award” means the funding awarded by the Charity to the Host Institution to undertake research.

“Intellectual Property (IP)” means all Materials, Patent Rights, Know-How, copyright, patents, database rights, trademarks, service marks, designs, confidential information and any similar rights recognised from time to time anywhere in the world whether registered or not, including applications and the right to apply for any such rights, together with all rights of action in relation to the infringement of any such rights.

“Arising Intellectual Property” means IP generated from the Project.

“Collaborating Institution” means a university, institution, research council or other entity working with the Host Institution in connection with the Project.

“Combination Package” means a package containing Arising Intellectual Property bundled together with any other IP which the Host Institution owns or is the beneficial owner (or otherwise has access to); *OR*, Arising Intellectual Property containing intellectual/inventive contribution and intellectual/inventive contribution arising from a project with a different source of project funding.

“Combination Package Gross Revenue” means all consideration received by the Host Institution from the commercial exploitation of the Arising Intellectual Property in a Combination Package including licence fees, option fees, up-front fees, royalties, minimum royalties or milestone payments, sub-licence initiation fees, or any other fixed sum payments received by the Host Institution from the licensing or other disposition of the Arising Intellectual Property in a Combination Package.

“Combination Package Net Revenue” means Combination Package Gross Revenue multiplied by the WR, less Direct Costs and any taxes including, but not limited to, value added tax, sales, excise and withholding tax, imposed on the Host Institution in connection with Gross Revenue which the Host Institution is unable to offset or

¹ A revenue sharing agreement would only be executed where there is Arising Intellectual Property and should be based on the provisions of the Research Award Agreement, and this Policy fully taking into account the proportionate contribution made to the Arising Intellectual Property by all relevant parties.

recover.

“Direct Costs” means all external expenses incurred and paid by the Host Institution in connection with the filing, prosecution and maintenance of the Arising Intellectual Property including, but not limited to, official filing fees, agent costs, and reasonable legal, litigation and other advisory and consultancy fees. To avoid doubt, Direct Costs shall not include the Host Institution’s internal costs relating to these activities, regardless of the legal constitution of the Host Institution’s TTO. The Organisation may not make deductions for salary or taxes in respect of the Organisation or the inventors or generators on the Arising Intellectual Property.

“Gross Revenue” means all consideration received by Organisation from the commercial exploitation of the Arising Intellectual Property pursuant to this Policy, including licence fees, option fees, up-front fees, royalties, minimum royalties or milestone payments, sub-licence initiation fees or any other fixed sum payments received by the Host Institution from the licensing or other disposition of the Arising Intellectual Property in forms including but not limited to monies, shares or options.

“Know-How” means unpatented technical information (including, without limitation, information relating to inventions, discoveries, concepts, methodologies, models, research, development and testing procedures, the results of experiments, tests and trials, manufacturing processes, techniques and specifications, quality control data, analyses, reports and submissions) that is not in the public domain.

“Materials” means the biological or biochemical matter generated or validated in the course of research (whether living or not), for example (without limiting the foregoing), viruses, cell lines, plasmids, new varieties or genetically modified organisms, such as mice or bacteria.

“Net Revenue” means Gross Revenue less Direct Costs and any taxes including but not limited to value added tax, sales, excise and withholding tax, imposed on Host Institution in connection with Gross Revenue which the Host Institution is unable to offset or recover.

“Organisation” means the Host Institution together with the TTO.

“Parties” mean the Charity and the Host Institution and **Party** means either of them.

“Patent Rights” means (a) any national , regional or international patent application or patent , including any provisional patent application, (b) any patent application filed either from such a patent, patent application or provisional application or from an application claiming priority from any of these, including any divisional, continuation, continuation-in-part, provisional, converted provisional, and continued prosecution application, (c) any patent that grants from any of the foregoing patent applications ((a) and (b)), including any utility model, petty patent, design patent and certificate of invention, (d) any extension or restoration by existing or future extension or restoration mechanisms, including any revalidation, reissue, re-examination and extension (including any supplementary protection certificate and the like) of any of the foregoing patents or patent applications ((a), (b) and (c)), and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent application or patent.

“Research Award Agreement” means the agreement between the Charity, Host

Institution and Principal Investigator setting out the terms of the Award.

“TTO” means technology transfer office (or equivalent body).

“TTO translation costs” are set at 5-10% after deducting direct costs. Where a higher percentage fee is sought by the Host Institution, the onus will be on the Host Institution to demonstrate why a higher fee is warranted (for example because relevant service cost has been absorbed by the TTO other than those already deducted as Direct Costs).

“Weighting Ratio” or “WR” means the reasonable inventive relative weighting given by the Host Institution in good faith to each technology/intellectual property included in the Combination Package as a contribution to the whole.

2. Arising Intellectual Property ownership

- 2.1 The Host Institution is responsible for ensuring that the inventors or generators or authors of the Arising Intellectual Property assign their rights in the Arising Intellectual Property to the Host Institution, in order to enable the Host Institution to properly exploit the Arising Intellectual Property.
- 2.2 The Host Institution is responsible for ensuring that the Host Institution has all the necessary rights to comply with this revenue sharing policy and, subject to third party rights, is able to distribute any Materials arising from the Project for commercial and non-commercial purposes.
- 2.3 The Host Institution hereby grants to the Charity, a perpetual, sub-licensable, irrevocable, world-wide, non-exclusive royalty-free licence to the Arising Intellectual Property, for the purposes of academic/not-for-profit research (including in collaborations), clinical, teaching, and publicity purposes.
- 2.4 The Host Institution may transfer or assign or license the Arising Intellectual Property to a technology transfer company for the purpose of distributing or commercialising it. However, such transfer of rights must not be to the detriment of the Charity’s rights or the terms and conditions of the Award.
- 2.5 This revenue sharing policy also applies to revenue received by any Collaborating institution(s) who received, directly or indirectly, the Award or any part of it.

3. Arising Intellectual Property and expenses

- 3.1 The Parties agree that the Host Institution shall have sole responsibility and authority to manage and execute the duties required for the filing, prosecution and maintenance of the Arising Intellectual Property, including the Patent Rights. The Host Institution shall keep or shall procure that their agents keep all notices, applications and correspondence filed in connection with the Arising Intellectual Property, and shall provide copies of such documents to the Charity or their agent on reasonable request.
- 3.2 Direct Costs shall be paid by the Host Institution and will then be deducted from Gross Revenue and/or Combination Package Gross Revenue.
- 3.3 If, at any time, the Host Institution decides to abandon in any territory any or all patent applications or patents included in the Patent Rights (“Patent Rights for Abandonment”), the Host Institution shall notify the Charity in writing of its intention at least sixty (60) days prior to the date any Patent Office action concerning the Patent Rights for Abandonment is due and shall offer to assign the

Patent Rights for Abandonment to Charity. If the Charity wishes to receive assignment of the Patent Rights for Abandonment, the Charity will be responsible for all further costs arising from the Patent Rights for Abandonment and the Parties will negotiate a separate assignment and revenue sharing agreement that specifies the rights each Party shall have in relation to the Patent Rights for Abandonment and any related data or information.

3.4 If the Arising Intellectual Property rights are infringed by a third party, the Host Institution shall have the sole right to defend the Arising Intellectual Property rights and shall do so at its own cost but shall not be obliged to do so. However, the Host Institution shall not issue a claim or threaten to issue a claim against a charitable or not-for-profit organisation without the express approval of Charity.

4. Exploitation

4.1 Subject to paragraph 2.4, prior to granting any rights under the Intellectual Property to any third party, the Host Institution shall provide to the Charity or its agent on a confidential basis in such reasonable detail as may be requested, details of the proposals for the exploitation of the Arising Intellectual Property including where applicable the identity of any proposed licensee or assignee of the Arising Intellectual Property and the intended terms under which such rights will be granted.

4.2 The Host Institution shall take into account in its negotiations with any such third party, any representations made by the Charity or its agent bearing in mind the legitimate interest of the Charity in such negotiations as a potential recipient of a share of Net Revenue or of Combination Package Net Revenue.

4.3 Subject to the paragraphs 4.1, 4.2 and 4.5, the Host Institution will have the sole responsibility to exploit the Arising Intellectual Property commercially in any manner it decides including, but not limited to, licensing, selling and assigning in exchange for consideration. The decision whether or not to conclude any agreement in relation to such commercial exploitation shall be matters for the sole discretion of Host Institution.

4.4 The Host Institution shall provide the Charity or its agent on a confidential basis with copies of all agreements related to the Arising Intellectual Property. Without limiting the foregoing, this shall include administration agreements, assignments, licences, and sublicences granted under the Arising Intellectual Property.

4.5 If the Host Institution elects not to exploit the Arising Intellectual Property commercially it will notify the Charity (within a reasonable period of time) and the Charity will inform the Host Institution of whether it, or a third party acting as the Charity agent, wishes to be granted the right of exploitation, and if so, the Parties will meet to agree upon the best way to proceed, and in accordance with the terms and conditions of the Award.

4.6 Subject to third party rights, the Host Institution agrees to make freely available the Materials and associated Know-How arising from the Project for academic or not-for-profit research, to the maximum extent possible. To that end, the Host Institution may deposit the Materials arising from the Project in an appropriate repository, for subsequent onward distribution.

4.7 The Host Institution agrees to use the Arising Intellectual Property in a lawful manner according to applicable law and any associated guidelines and guidance. In relation to Materials, the Host Institution agrees to act (and shall require that any assignee or licensee acts) with the utmost care in terms of human and animal

health, wellbeing and ethics.

- 4.8 Where the Arising Intellectual Property is to be licensed or assigned as part of a Combination Package, the Host Institution shall determine an appropriate and reasonable WR, in accordance with the custom and practice of reasonable technology transfer offices. The Host Institution shall consult with the Charity or its agent in making a determination of an appropriate WR.

5. Revenue sharing²

- 5.1 The Parties shall share all Net Revenue received from the exploitation of the Arising Intellectual Property as follows:

Cumulative Net Revenue	TTO translation costs	Remaining split
£0-100,000	10%	50% Charity, 50% Host Institution
£100,001+	5%	50% Charity, 50% Host Institution

- 5.2 In the event that the Arising Intellectual Property is exploited through a Combination Package, the Parties agree to share all Combination Package Net Revenue as follows:

Cumulative Combination Package Net Revenue	TTO translation costs	Remaining split
£0-100,000	10%	50% Charity, 50% Host Institution
£100,001+	5%	50% Charity, 50% Host Institution

- 5.3 The Host Institution will be solely responsible for distributing its share of the Net Revenue or Combination Package Net Revenue to researchers who contributed to the Arising Intellectual Property in accordance with any policy of the Host Institution, subject to the terms of the Research Award Agreement.

6. Records and payments

- 6.1 The Host Institution shall keep complete and accurate accounts of all Direct Costs plus Gross Revenue and/or Combination Package Gross Revenue. The Host Institution shall make these accounts available on reasonable notice for inspection and verification during business hours by an independent professionally qualified accountant nominated by the Charity and reasonably acceptable to the Host Institution. The Charity shall be responsible for the accountant's charges unless the accountant finds an underpayment of at least five percent (5%) between sums due and sums paid to the Charity since the last most recent inspection.

² As described in this Policy, the revenue due to the Charity is to be reduced to take into account other project funding the Host Institution received, and any other IP the Host Institution has, which is being exploited together with the Arising Intellectual Property.

- 6.2 The Host Institution, within thirty (30) days after 31 March each year, shall provide the Charity with a statement setting out Gross Revenue or Combination Package Gross Revenue received and Direct Costs incurred during the previous twelve (12) month period, together with the value of the Net Revenue or Combination Package Net Revenue arising therefrom. If no revenue is due to Charity, the Host Institution shall so report. On receipt of such statement from the Host Institution the Charity shall issue the Host Institution with an invoice for any payment due to the Charity, which will be paid by the Host Institution in accordance with the instructions set out in the Charity invoice.
- 6.3 In the event that the Host Institution is obliged by law to deduct tax from any payment to the Charity under this Policy, it shall provide the Charity with documentary evidence of such deduction and shall assist the Charity to seek relief under a double taxation agreement or other applicable agreements.

7. Confidentiality

- 7.1 The Charity will use all reasonable endeavours to keep confidential all information relevant to the Arising Intellectual Property and all information provided under paragraph 4 which is in Charity possession, and which is not disclosed by the Host Institution.
- 7.2 the Charity may disclose the information referred to in paragraph 7.1 to a third party which is acting as its agent provided that such third party is bound by obligations of confidentiality no less protective of the Host Institution's rights than this Policy.
- 7.3 Unless otherwise provided under the terms of the Research Award Agreement, each Party agrees not to use the names or marks of the other Party without the prior written consent of the other Party.