

Terms and Conditions for Grant Awards

Health Data Research UK

OVERVIEW

The terms and conditions set out below are the standard terms and conditions for Health Data Research UK (HDR UK). [HDR UK](#) is an independent, non-profit organisation supported by ten funders in the UK. It brings together leading experts and leads programmes in health data research and innovation, and provides training and education, with the aim of making health data available to researchers to develop a better understanding of diseases and discover ways to prevent, treat and cure them.

In this context, HDR UK has convened the [International COVID-19 Data Alliance](#) (ICODA), which is partnering with the Bill & Melinda Gates Foundation's Grand Challenges programme to pilot the Grand Challenges ICODEA COVID-19 Data Science initiative, supported by the COVID-19 Therapeutics Accelerator.

The organisation that hosts the successful applicants for this grant award scheme, the **Lead Organisation**, will receive their awards directly from HDR UK and therefore HDR UK's standard grant award terms and conditions will apply.

GLOSSARY

The table below sets out the acronyms/abbreviations used in this document.

Abbreviation	Organisation/ Framework
EIR	Environmental Information Regulations (UK)
FOIA	Freedom of Information Act (UK)
GBER	General Block Exemption Regulation: sets out categories of aid exempt from European Commission's formal notification procedures
HDR UK and its funders:	Health Data Research UK
- MRC	Medical Research Council
- EPSRC	Engineering & Physical Sciences Research Council
- ESRC	Economic & Social Research Council
- NIHR	National Institute for Health Research
- CSO, Scotland	Chief Scientist Office of the Scottish Government Health & Social Care Directorate
- HCRW	Health & Social Care Research & Development Division, Welsh Government
- PHA	Public Health Agency, Northern Ireland

- BHF - Wellcome Trust	British Heart Foundation Wellcome Trust Ltd
ICODA	International COVID-19 Data Alliance
ISA 260	International Standard on Auditing
VAT	Value Added Tax (UK)

TERMS AND CONDITIONS FOR AWARD HOLDERS

These terms and conditions relate specifically to funding from Health Data Research UK (UK company registration number 10887014; “HDR UK”). HDR UK is funded by the Medical Research Council (MRC), Engineering and Physical Sciences Research Council (EPSRC), Economic and Social Research Council (ESRC), National Institute for Health Research (NIHR); Chief Scientist Office of the Scottish Government Health and Social Care Directorates, Health and Social Care Research and Development Division (Welsh Government; HCRW), Public Health Agency (Northern Ireland; PHA), British Heart Foundation (BHF) and the Wellcome Trust Limited as trustee of the Wellcome Trust (together the “Funders”). These terms and conditions reflect the Funders’ requirements.

Acceptance of a grant constitutes acceptance of both these standard conditions and any additional conditions in the award letter. These conditions also apply to activities subcontracted to third parties. These conditions cannot be waived or varied without the consent of HDR UK.

Data Protection Regulations

Provided in accordance with applicable data protection laws (including the Data Protection Act 2018, the EU General Data Protection Regulation 2016/679 and the Privacy and Electronic Communications (EC Directive) Regulations 2003 (in each case as amended or replaced from time to time and together the “Data Protection Legislation”)):

- HDR UK will use information provided by the **Lead Organisation** for processing funding proposals, the award of any consequential funding, and for the payment, maintenance and review of the funding and may share the information with Funders. This may include, but is not limited to:
 - Registration of proposals
 - Operation of processing, funding, and management information systems
 - Preparation of material for use by peer reviewers and peer review panels
 - Administration, investigation, and review of funding proposals
 - Sharing proposal information on a strictly confidential basis with other funding organisations to seek contributions to the funding of proposals
 - Statistical analysis in relation to the evaluation of research and the study of trends
 - Policy and strategy studies

- To meet HDR UK's accountability obligations to the Funders and to disseminate information on Institute research and training programmes, details of Institute budget/awards, and research and training will be made publicly available, such as through: International COVID-19 Data Alliance (ICODA), Grand Challenges or HDR UK's websites, and/or other publicly available databases; in reports and documents, including annual reports, Council/Board papers; and through responses by the relevant Funders to UK parliamentary business (e.g. parliamentary questions, inquiries, debates etc). Disclosable information would include:
 - general overview information on budget and research/training programmes
 - the names of investigators
 - the dates associated with the Award(s)
 - a description of research/training programmes (e.g. project summary/abstract, and impact summary information)

During and after completion of the Award, HDR UK or its Funders, may contact named Principal Investigators concerning funding opportunities or events, or for the purposes of evaluation.

Freedom of Information Act and Environmental Information Regulations

Attention is drawn to the provisions of the Freedom of Information Act 2000 ("FOIA") and the Environmental Information Regulations 2004 ("EIRs"), and their equivalents in Scotland where applicable, which apply to a number of HDR UK's Funders including the MRC, EPSRC, ESRC, NIHR, HCRW, CSO (Scotland), and PHA (but not BHF and Wellcome Trust). The relevant Funders have an obligation to respond to valid requests for information relating to these terms and conditions and may be required to disclose information in relation to HDR UK funding. In some cases, such Funders may consult with the Lead Organisation before disclosure, but they are under no obligation to do so. Where such Funders do consult, they will do so as soon as is reasonably practicable and shall take account of any representations made in respect of that information by the Lead Organisation as part of reaching their own, unfettered, independent decision on disclosure of the requested information.

In some cases, a Lead Organisation may be directly responsible for complying with requests made under the FOIA and the EIRs; in such cases HDR UK accepts no responsibility for any failure by the Lead Organisation to comply with its own obligations in this regard. To the extent that any request for information under the FOIA or the EIRs is received by a Lead Organisation which includes information relating to HDR UK, any of the Funders or these terms and conditions, the Lead Organisation receiving the request shall promptly notify HDR UK as soon as reasonably practicable and in any event within 5 business days and shall take account of any representations made in respect of that information by HDR UK or any of the Funders as part of reaching its own, unfettered, independent decision on disclosure of the requested information

AWARDS CONDITIONS

1. Accountability & Responsibilities of the Lead Organisation

- The Lead Organisation is accountable for the conduct of the research/training/activities, the use of funds and for ensuring the proper financial

management of grants. These obligations apply wherever the research/training/activity is carried out; either at the Lead Organisation or a collaborating organisation or other third party.

- The Lead Organisation must ensure that funds are spent in a way that is consistent with the purpose and conditions of the award.
- The Lead Organisation is responsible for the timely and accurate submission of all grant claims, invoices, expenditure statements and reports required by the award.
- The Lead Organisation shall ensure that it carries out appropriate due diligence on any third parties used to deliver any part of the work funded by the grant and shall ensure, that activities carried out by such third parties comply with these terms and conditions. The Lead Organisation shall provide HDR UK on request with details of expenditure of the grant by any third party.
- The Lead Organisation must ensure that the grant holder and co-investigators are made aware of their responsibilities and that they observe the terms and conditions of grants, as set out in these terms and conditions and in the associated award letter.
- The Lead Organisation must ensure that the research/training/activities supported by the grant complies with all relevant legislation and government regulation, including that introduced while work is in progress. This requirement includes approval or licence from any regulatory body that may be required before the research/training can commence.
- The Lead Organisation must ensure compliance with all relevant legislation and government regulation relating to staff, including any subsequent amendments introduced while work is in progress.
- Where relevant, the Lead Organisation is responsible for compliance with the terms of the UK Equality Act 2010 including any subsequent amendments introduced while work is in progress; and for ensuring that the expectations set out in the Research Councils UK statement of expectations for equality and diversity are met.
- Where relevant, the Lead Organisation shall comply with European Union state aid law in their own uses of HDR UK funding. In the case of any breach of state aid law, HDR UK may be required to recover all or some funding, together with interest. HDR UK may also be required to withhold funding or aspects of funding where the Lead Organisation is subject to a state aid inquiry or which has an outstanding recovery notice against it. By accepting this award, the Lead Organisation agrees not to act in any way to undermine HDR UK's ability to comply with the operations terms under Commission Regulation (EU) No 651/2014 ("the General Block Exemption Regulation (GBER)"). No subcontract may be made which would constitute a breach of State aid obligations.
- The Lead Organisation must create an environment in which public engagement is valued, recognised and supported. It must ensure that reliable systems and processes are in place so that the principles of the Concordat are embedded into practice within the Lead Organisation.
- The Lead Organisation must notify HDR UK of any change in its status, or that of the grant holder, that might affect the eligibility to hold a grant.
- The Lead Organisation must ensure that the requirements of the Employing Organisation under the Department of Health's Research Governance Framework for

Health and Social Care (or equivalent) are met for research involving NHS patients, their organs, tissues or data, and that the necessary arrangements are in place with partner organisations. Where it also accepts the responsibilities of a Sponsor (as defined in the Governance Framework), it must also ensure that the requirements for sponsors are met.

- The Lead Organisation must ensure that adequate business continuity plans are in place to ensure that operational interruptions to the research are minimised.
- The Lead Organisation must retain all accounting information relating to the grant for the current financial year plus the subsequent six years after the submission date of the final expenditure statement.

2.1 Health and Safety

The Lead Organisation is responsible for ensuring that a safe working environment is provided for all individuals associated with the funded work. Its approach and policy on health and safety matters must meet all regulatory and legislative requirements and be consistent with best practice recommended by the Health & Safety Executive.

Appropriate care must be taken where researchers are working off-site. The Lead Organisation must satisfy itself that all reasonable health and safety factors are addressed.

HDR UK reserves the right to require the Lead Organisation to undertake a safety risk assessment in individual cases where health and safety is an issue, and to monitor and audit the actual arrangements made.

2.2 Misconduct and Conflicts of Interest

The Lead Organisation must ensure that potential conflicts of interest in research are declared and subsequently managed. Guidance on providing declarations of interest can be found at <https://www.ukri.org/wp-content/uploads/2020/11/UKRI-261120-Declaration-of-Interests-for-applicants-v2.pdf>

3. Use of Funds

Subject to the conditions set out in the awards letter and these terms and conditions, funds may be used, without reference to HDR UK, in such a manner as to best carry out the funded work. Funds should be deployed with due consideration to value for money across all activities. Any travel claims should evidence value for money as the primary consideration. Consequently, these should only include travel by standard class by train and economy class by air for flights.

The value of the grant may be varied by HDR UK during the lifetime of the grant to take into account any decision of the Funders affecting the funding available to HDR UK. Funds are provided for the specific piece of work, under no circumstances may funds be used to meet costs on any other project or activity.

4. Starting Procedures

The Lead Organisation must formally accept the grant by completing and returning the Offer

Acceptance within ten days of the offer letter being issued.

Payment of the award will be made on production of a grant claim quoting the award reference.

Each of HDR UK and the Lead Organisation acknowledge and agree that any grant award monies made by HDR UK hereunder pursuant to the terms and conditions laid out under the award letter and Annex 1 and 2 shall not constitute consideration for VAT purposes in return for any supplies from the Lead Organisation and, for the avoidance of doubt, any award from HDR UK shall be VAT-inclusive, such that any amount in respect of VAT shall not be payable in addition to any award.

Payment will be made by HDR UK in accordance with the terms and conditions laid out in the award letter and this Annex 2.

5. Changes to Programme

HDR UK must be consulted in the event of any major change in the proposed work, including failure to gain access to facilities and services, to gain ethical committee approval for the research, or substantive changes to the proposed training programme, particularly those which make it unlikely that the objectives of the work can be achieved. The ICODA team may be able to provide tools and resources to support efficient ethical committee review.

If appropriate, revised proposals may be required. HDR UK reserves the right to make a new grant in place of the existing grant, or to revise, retain or terminate the existing grant.

6. Extensions and Supplements

No extensions or supplements will be made to the awards. Costs of Parental Leave and Sickness Absence during the original period of the grant can be claimed from the award, in proportion to the percentage of that person's time allocated to the funded work. The Lead Organisation is responsible for any liability for costs of Parental Leave and Sick Leave pay for staff supported by the grant outside the original period of the grant.

7. Staff

The Lead Organisation must assume full responsibility for staff funded from the grant and, in consequence, accept all duties owed to and responsibilities for these staff, including, without limitation, their terms and conditions of employment and their training and supervision, arising from the employer/employee relationship.

If the terms of the award specify funding of new roles only, the Lead Organisation may not claim grant funds for internal secondments where the secondees' current post is not back-filled by another individual. Evidence of such back-fill may be requested by HDR UK as part of assurance of expenditure.

8. Equipment

The procurement of equipment, consumables and services, including maintenance, must comply with all relevant national and EU legislation and the Lead Organisation's own

financial policy and procedures. For all equipment and services where the contract value is more than £25,000, excluding VAT, professionally qualified procurement staff must be consulted before the procurement process begins, and, where appropriate, at the market research stage, and must approve the order/contract before it is placed with a supplier.

Equipment purchased from grant funds is primarily for use on the work for which the grant was awarded and belongs to the Lead Organisation.

9. Transfer of a Grant

It is not possible for the grant to be transferred to another Lead Organisation. The Lead Organisation must consult with HDR UK if it is proposed to change the grant holder, for example, following retirement or resignation. In such cases HDR UK may consider termination of the award.

10. End of Grant Reconciliation

The Lead Organisation is accountable for funds dispersed and must provide information documenting spend on the project on request by HDR UK.

11. Disclosure and Inspection

HDR UK reserves the right to have reasonable access to inspect the records and financial procedures associated with the grant or to appoint any other body or individual for the purpose of such inspection. This includes expenditure by third parties. HDR UK shall be entitled to request and/or have access to any financial records and reports that are deemed appropriate to demonstrate the regularity and propriety of expenditure, including but not limited to:

- Annual report & accounts
- External audit management letter
- Where relevant, meet ISA 260 audit regulations
- Related internal audit reports
- That required licenses, approvals, permissions, and consent are in place, or were in place when the activity occurred.

The Lead Organisation must report to HDR UK:

- Any investigations (and their outcomes) into research misconduct associated with the grant at the stage that it is decided to undertake an informal inquiry; and on request provide information on:
 - Its management of [research integrity and ethics](#) as described by the UK Research & Innovation (UKRI)
 - Details of any retractions or withdrawal of submissions/publications
 - Any allegations, proven or not, of any cases of fraud.

The Lead Organisation must, if required by HDR UK, provide a statement of account for the

grant, independently examined by an auditor who is a member of a recognised professional body, certifying that the expenditure has been incurred in accordance with the research grant terms and conditions.

12. Reporting on the conduct and results of research

HDR UK may require a final report on the conduct and outcome of the project. If so, it must be submitted by the Lead Organisation within one month of the end of the grant, on the form provided.

If the Lead Organisation is also a Coordinating Research Organisation or Associate Research Organisation within the Substantive Site structure of HDR UK, the principal investigator will contribute to any reporting required of the site as part of the Funders reporting processes at the request of the site director and/or HDR UK.

13. Sanctions

HDR UK reserves the right to impose financial and other sanctions where they identify areas of non-compliance with these terms and conditions.

14. Communications, Branding and Public Engagement

The public announcement of this award will be managed by Grand Challenges and HDR UK and is under embargo until notified by HDR UK. The Lead Organisation is expected to coordinate local announcements in line with Grand Challenges, COVID-19 Therapeutics Accelerator, HDR UK and ICODA's requirements, and will contribute content (in the form of quotes and material for a case study) to support this.

In any online or printed materials (including procurement, press releases, poster, exhibition materials, PowerPoint presentations, digital and social media) related to activities funded by this grant, the Organisations must make reference to the Grand Challenges, COVID-19 Therapeutics Accelerator and HDR UK/ICODA funding. Logos and other materials will be provided to the Lead Organisation to ensure appropriate representation of the Grand Challenges, HDR UK and ICODA brands. Agreement on appropriate attribution should be agreed in advance by contacting enquiries@hdruk.ac.uk.

All outcomes and achievements should be communicated to HDR UK's Communications Team (media@hdruk.ac.uk) before publication

All publications resulting from this award are subject to the HDR UK Attribution Policy. <https://www.hdruk.ac.uk/about/governance/policies/hdr-uk-attribution-policy/>

Award holders must inform HDR UK as soon as a paper presenting outcomes funded by this grant is accepted for publication. HDR UK must be notified at least five working days in advance of any publicity arising from work funded by this grant, and any press releases referencing HDR UK must be approved by HDR UK before it is released to the media.

Funded organisations may be required by HDR UK to participate in communications activities e.g. blog posts and case studies.

It is the responsibility of the Lead Organisation and the grant holder and co-investigators to involve and communicate the research to patients and the wider public at both local,

national and international level, and to raise awareness of the role of science and research in any related issues of public interest.

15. Exploitation and Impact

It is the responsibility of the Lead Organisation, and all engaged in the work, to make every reasonable effort to ensure that the intellectual assets obtained in the course of the work, whether protected by intellectual property rights or not, are used to the benefit of society and the economy. Unless stated otherwise, the ownership of all intellectual assets, including intellectual property, and responsibility for their application, rests with the organisation that generates them. Where the grant is associated with more than one research organisation and/or other project partners, the basis of collaboration between the organisations, including ownership of intellectual property and rights to exploitation, is expected to be set out in a formal collaboration agreement. It is the responsibility of the Lead Organisation to put such an agreement in place before the research begins. The terms of collaboration agreements must not conflict with the HDR UK terms and conditions.

Arrangements for collaboration and/or exploitation must not prevent the future progression of research and the dissemination of research results in accordance with academic custom and practice. A temporary delay in publication is acceptable in order to allow commercial and collaborative arrangements to be established.

Project outcomes should be disseminated to both research and more widespread audiences, for example to inform potential users and beneficiaries of the work.

16. Monitoring and Evaluation

While it is the responsibility of the Lead Organisation to manage the research and/or training and/or activity, HDR UK reserves the right to call for periodic information on progress or to visit the project team. The grant holder may also be asked to attend meetings to exchange information and ideas with others undertaking work in the same or similar fields.

The grant holder must make all reasonable efforts, if so invited, to respond to requests for information or to attend events or activities organised by HDR UK concerning the work undertaken. Such events may be held after a grant has finished.

17. Open Access and Data Sharing

The grant holder should, subject to the procedures laid down by the Lead Organisation, publish the results of the research in accordance with normal academic practice and the UKRI policy on open research: [Open research – UKRI](#)

HDR UK requires all publications to be deposited at the earliest opportunity, and certainly within six months of publication, in Europe PubMed Central (europepmc.org/). This applies both during and after the period of funding. The condition is subject to compliance with publishers' copyright and licensing policies. Whenever possible, the article deposited should be the published version.

The Lead Organisation is expected to adopt the principles of the Concordat on open research data (or equivalent). Award holders must comply with the MRC policy on research

data sharing (www.mrc.ac.uk/documents/pdf/mrc-data-sharing-policy/) along with the MRC policy on sharing of research data from population and patient studies (www.mrc.ac.uk/publications/browse/mrc-policy-and-guidance-on-sharing-of-research-data-from-population-and-patient-studies/).

If the product of research/training/activity is code then it should be published in accordance with [HDR UK's Attribution Policy](#) on Github.

18. Disclaimer

HDR UK accepts no liability, financial or otherwise, for expenditure or liability arising from the funded work, except as set out in these terms and conditions, or otherwise agreed in writing.

Where studies are carried out in an NHS Trust, the Trust has a duty of care to its patients. HDR UK does not accept liability for any failure in the Trust's duty of care, or any negligence on the part of its employees.

HDR UK reserves the right to terminate the grant at any time, subject to reasonable notice and to any payment that may be necessary to cover outstanding and unavoidable commitments. HDR UK reserve the right to amend the payment profile at their discretion. The Lead Organisation will be advised, in advance, of any such a change. Changes to payment profiles may affect the overall value of the grant.

If a grant is terminated or reduced in value, no liability for payment or redundancy or any other compensatory payment for the dismissal of staff funded by the grant will be accepted.

Notwithstanding any other term of the award letter or these terms and conditions, nothing set out herein shall operate so as to exclude or limit the liability of either party to the other for fraud, death or personal injury arising out of negligence or any other liability which cannot be excluded or limited by law.

19. Status

These terms and conditions will be governed by the laws of England and Wales; all matters relating to the terms and conditions will be subject to the exclusive jurisdiction of the courts of England and Wales.

If any provision of these terms and conditions is found by a court or other legitimate body to be illegal, invalid or unreasonable, it will not affect the remaining terms and conditions which will continue in force.

These terms and conditions, together with any additional conditions set out in the grant; contain the whole agreement between HDR UK and the Lead Organisation in relation to the stated research grant. HDR UK and the Lead Organisation do not intend that any of these terms and conditions should be enforceable by any third party.

Version Control

HDR UK reserves the right to amend these Terms and Conditions. The most recent version of the terms and conditions will apply.

Version	Date of Document	Approved by	Changes
1.0	31 January 2019	HDR UK	
2.0	28 August 2019	HDR UK	To include reference to funded training programmes
3.0	06 February 2020	HDR UK	To streamline for non-research funding
4.0	17 Dec 2020	HDR UK	To update for global Grand Challenges ICODA initiative