

Framework Heads of Terms (HoT) for Substantive Sites

This Framework HoT dated XXX 2017, between:

- (1) XXX of XXX (“the Applicant”)
- (2) Health Data Research UK (company number 10887014) of c/o Medical Research Council, Polaris House, North Star Avenue, Swindon, SN2 1FL (“HDR UK Ltd”)

Background:

Health Data Research UK (“the Institute”) has been created through a joint investment of circa £50m over the next five years through the MRC, health research departments of England, Scotland and Wales, EPSRC, ESRC, Wellcome and British Heart Foundation (together the “Funders”). Harnessing the power of the NHS and associated health and biomedical data in the UK, the Institute will develop and apply the cutting edge informatics approaches needed to address the most pressing health research challenges facing patients and the public. The Institute will bring together, under a single Institute Director’s vision, the breadth of interdisciplinary skills, expertise and national and international partnerships needed to accelerate progress, analysing complex and diverse health related data at an unprecedented depth and scale.

Purpose:

This Framework HoT sets out the key principles of the Institute’s legal and operational structure, and the principles of engagement between HDR UK Ltd and those research organisations who’s bid to host one of the Institute’s Substantive Sites is successful. These principles will form the basis of the final Site Agreements setting out the formal and legally binding relationship between HDR UK Ltd and the successful Coordinating RO.

Each research organisation seeking to host an Institute Substantive Site, either as Coordinating RO or Associate RO is required to enter into this Framework HoT prior to the submission of bids. Each of HDR UK Ltd and the Applicant acknowledges that in operationalizing this framework, minor amendments of the HoT may be exceptionally required in the final Site Agreement to fit individual circumstances however no deviation from the common principles will be permitted. Accordingly, HDR UK Ltd expects successful Coordinating ROs to sign a final Site Agreement no more than 2 months after Sites are announced. Site Agreement negotiations will only take place between HDR UK and the Coordinating RO, who will negotiate on behalf of all participating ROs within a substantive site and be responsible for managing the legal relationship with HDR UK Ltd. The relationship between Coordinating RO and each Associate RO comprising the Substantive Site must adhere to the principles set-out within this Framework Heads of Terms, to ensure a consistency of approach across the Institute.

Clauses:

1. Definitions and interpretation

In this Framework HoT the following definitions apply:

- Associate Director - a senior research leader providing leadership within the Institute’s Associate Site and responsible to the Site Director, Institute Director and Board in this capacity for delivering the Institute’s scientific strategy.
- Associate RO – those research organisations (other than the Coordinating RO), involved in Institute research activity at a Substantive Site
- BHF - British Heart Foundation

- Board - The board of trustees of HDR UK Ltd, being the highest governing board of HDR UK Ltd
- Company Members – the company Members of HDR UK Ltd from time to time
- Coordinating RO – The coordinating research organisation, with responsibility for coordinating a Substantive Site, designated as such by HDR UK Ltd
- EPSRC – Engineering and Physical Sciences Research Council
- ESRC – Economic and Social Research Council
- Funders – The founding funders of HDR UK Ltd being: MRC, the health research departments of England, Scotland and Wales, EPSRC, ESRC, BHF and Wellcome
- Health research departments of England, Scotland and Wales – collectively: National Institute for Health Research/The Department of Health; Chief Scientist Office of the Scottish Government Health and Social Care Directorates; Health and Care Research Wales (HCRW), Welsh Government
- HDR UK Ltd – a company limited by guarantee with company number [INSERT] with charitable objectives, which will seek registration with the Charity Commission
- The Institute – Health Data Research UK as carried on through HDR UK Ltd and each of the Sites
- Institute Director - the Institute's research Director, in the first instance Professor Andrew Morris
- MRC – Medical Research Council
- RO – research organisations (including the Applicant) involved in undertaking Institute research activity
- Site – a Substantive Site of the Institute
- Site Agreement – The legally binding agreement between HDR UK Ltd and each RO regarding the funding and operational arrangements for a Substantive Site.
- Site Director – a senior research leader providing leadership within the Institute's Substantive Site and responsible to the Institute Director and Board in this capacity for delivering the Institute's scientific strategy.
- Substantive Site – a site(s) of major HDR UK Ltd funded research activity, designated as such by HDR UK Ltd and led by the Coordinating RO.
- Wellcome – the Wellcome Trust

2 Key principles for the establishment of the Institute and the relationship between HDR UK Ltd and the ROs hosting the Sites

The RO agrees the Institute's purpose, aims and operational structure are intended as follows:

2.1 The operational vision for Institute Sites

Substantive Sites may comprise one or more research locations hosted by a number of ROs. Substantive Site activities will be led by and be the responsibility of the Coordinating RO. The Coordinating RO will enter into a Site Agreement with HDR UK Ltd in relation to the Substantive Site activities and operations and the Coordinating RO will be responsible and accountable for the fulfilment of the relevant terms of the Site Agreement by both the Coordinating RO and each of the Associate ROs involved in the Substantive Site. HDR UK Ltd and each of the Institute Sites will operate as if a single entity and are expected to:

- 2.1.1 constitute a tightly woven critical mass of researchers, support staff and infrastructure with a cohesive range of broadly based research programmes fully aligned with the Institute's mission and scientific strategy;
- 2.1.2 operate under the scientific direction of the Institute Director, with changes in the RO's management model if necessary to allow the Site Director latitude and authority to, in

consultation with the Institute Director, direct the activities of the Substantive Site in line with the overall objectives of the Institute, as if a single entity;

- 2.1.3 report to the Board at least annually, and be subject to periodic review of scientific quality and performance through the Funders' established peer review mechanisms.

2.2 The need for investment

- 2.2.1 The Funders have recognised the need to build capacity in informatics to enable a dramatic change in the use of large patient and research data sets, leading to better treatments, the identification of health risks and a greater understanding of the causes of disease. The Institute is founded on the mission to provide the capacity and tools to accelerate the pace and scale of health and biomedical data science to improve health and care for patients and the public, and grow capability and economic opportunity in the UK. It will provide national co-ordination of relevant informatics infrastructures and develop the skills, capacity, methods and analytical tools to address research challenges that require integration across biological, clinical, environmental and social data. Through harnessing the power of the NHS and associated health and biomedical data in the UK, the Institute will develop and apply the cutting edge informatics approaches needed to address the most pressing health research challenges facing patients and the public.
- 2.2.2 The Institute Director, in consultation with the Board, will be empowered by HDR UK Ltd to direct the Institute's research programmes across all Sites, in consultation with the Site Directors as appropriate, to set the research strategy for the Institute, and to control the Institute budget.
- 2.2.3 The Institute will serve UK scientific and public health needs as its first priority: contribution to the development of the RO's own research strategy will not take precedence.

2.3 The relationship between HDR UK Ltd and the Coordinating ROs

- 2.3.1 The Coordinating RO must support an agreed long-term vision for the Institute, negotiate in good faith, and share risks in relation to operation of the Institute. HDR UK Ltd and the Coordinating RO will co-operate in an open and flexible approach towards the delivery of the Institute's objectives.
- 2.3.2 HDR UK Ltd and the Coordinating RO will work together to create added-value and new opportunities for science and deliver value for money. This includes (but is not limited to) promoting synergies between respective investments, aligning strategies, access to infrastructure and facilities, and building research capacity particularly with regard to new recruitment and career development opportunities.
- 2.3.3 HDR UK Ltd and the Coordinating RO will work together to ensure long-term planning, effective change management and sustainability for the Institute, including any changes in senior leadership in the Substantive Site.
- 2.3.4 The Institute's research programme overall is expected to be of an internationally competitive standard. It is the responsibility of the Institute Director to maintain standards, which will be monitored by the HDR UK Ltd Board and be subject to the periodic review by the Funders' established peer-review mechanisms, typically on a 5-year basis.
- 2.3.5 All staff associated with the Institute will operate to the highest standards of conduct, consistent with public service standards, demonstrating selflessness, integrity, objectivity, accountability, openness, honesty and leadership.

- 2.3.6 The Coordinating RO will procure adherence to these principles and requirements by each of the RO's involved in the relevant Substantive Site and their respective Associate Director.

2.4 Potential benefits for ROs in hosting a Site

- 2.4.1 Building on and enhancing excellent science.
- 2.4.2 Opening up new scientific opportunities, funding streams and access to infrastructure investments.
- 2.4.3 Strengthening integration with RO and broader UK research activities.
- 2.4.4 Prestige and high visibility.
- 2.4.5 Funding award allocations, both directly from HDR UK Ltd and from participating in the delivery of other Institute associated awards. This additional research income will increase metrics associated with REF.
- 2.4.6 Where appropriate, ownership of IPR arising from Institute research and income streams therefrom.
- 2.4.7 Where appropriate, an allocation of HDR UK Ltd capacity building funds.

3. Science

3.1 The Substantive Sites

- 3.1.1 Sites will undertake HDR UK Ltd funded research in pursuit of the Institute's mission.
- 3.1.2 Research in Substantive Sites will be founded on long term programmes (usually 5-year, with options to renew) each led by a Site Director who will operate under the direction of the Institute Director.
- 3.1.4 On establishment of the Institute, the Funders together with the Board and Institute Director will determine which Sites and research initiatives will initially comprise the Institute. Thereafter, the Board will (in consultation with the Institute Director and the Institute's independent scientific advisers) determine which funded programmes should be within the Institute, as advised by a review model agreed with the Funders.
- 3.1.5 The Institute Director and Site Directors will spend sufficient time on Institute research such that the Institute Director and Board are fully satisfied that the relevant Institute objectives are being delivered. This will be judged through annual reporting and periodic reviews of the quality and outputs of the research programmes.
- 3.1.6 The activities of the Institute will play a critical part in developing capacity in UK health and biomedical informatics research. Each RO accepts a role as a leading UK advocate in developing/establishing new career pathways, founded on Institute principles to encourage and support best practice in the management, training, mentoring and career development of RO staff and students associated with the Institute. RO's will also agree, in good faith and where appropriate, to hosting and supporting staff directly employed by HDR UK Ltd who will work alongside the RO's own staff.
- 3.1.7 ROs comprising the Sites will work cohesively with the primary goal of delivering the Institute mission in support of impactful health and biomedical informatics research. This will be underpinned by cooperative working within and between ROs, commercial, international and charitable organisations, that will provide mutual benefit to all parties, for example through supporting the integration of external grant funding aligned with the Institute's objectives.

3.2 RO relationship to the Institute Director

- 3.2.1 The Institute Directorship will be institutionally agnostic, underpinned by a published open and transparent framework to address conflicts of interest, working closely with and accountable to the Board.
- 3.2.2 The Institute Director is responsible for delivery of the Institute's agreed strategy (research, training, knowledge transfer, public engagement and commercialisation), ensuring the scientific excellence of the Institute's research and its value for money.
- 3.2.3 The RO's structures, will collectively provide (where applicable and under the direction of the Institute Director) the Site Director with the latitude and authority to act to: i) direct programmes; ii) move resource, according to scientific need; and iii) make appointments within the relevant Site at appropriate levels, in each case as required to deliver the Institute's scientific initiatives and associated scientific objectives.
- 3.2.4 When research initiatives cease or move out of a Site, the Institute Director will have scope to recycle funds (less any transitional costs) to invest in new programmes.

3.3 The Site Director and Associate Director(s)

- 3.3.1 The relationship between HDR UK Ltd, the Institute Director and the Site Director will be clearly defined in the Site Agreement. HDR UK Ltd will expect to jointly agree with the Coordinating RO, the appointment and, where necessary, the removal and replacement of the Site Director. The Institute Director will be consulted during the appointment of Site Directors and will retain the option to require the removal of a Site Director from the HDR UK leadership team, in consultation with the Coordinating RO.
- 3.3.2 The Site Director will have sufficient status within their host Coordinating RO commensurate with their role, enabling them to enact the Site's scientific strategy as agreed with the Institute Director. Associate ROs will agree to act on the direction of the Site Director and to appoint Associate Directors to support the Site Director and Institute Director in the delivery of their functions.
- 3.3.3 The Site Director and each Associate Director will play a significant role in the respective RO's health data science research strategy development and planning, interacting closely with the Institute Director to ensure the Institute's strategic mission and wider UK needs within the field of health and biomedical informatics are taken into consideration.
- 3.3.4 The RO will enable the Site Director (and Associate Director(s) as applicable) to manage the deployment of leveraged RO resources committed to HDR UK Ltd during competitive allocation of Sites (including but not limited to accommodation, capital, other infrastructure, staff and studentships).
- 3.3.5 The RO will support the Site Director (and Associate Director) as applicable to manage the recruitment of associated RO staff and students, ensuring that the recruitment and selection process gives due consideration to existing RO processes and policies.

3.4 Research Data

- 3.4.1 An important national research asset is the data and meta-data hosted and controlled by ROs and associated partners. HDR UK Ltd and the RO's will endeavor to work with this distributed data asset network as expert data users and in accordance with the requirements of the Data Controllers. Each RO will support Institute's activities by endeavoring to enhance data asset availability, quality, comparability and new data asset creation, for example asset and metadata cataloguing, documentation of data

standards, data dictionaries, ontologies, and meta-data convergence. RO's who are Data Controllers will be expected to share data assets and facilitate access between Sites and across Institute researchers in as seamless a way as possible.

3.4.2 HDR UK Ltd will develop a single, consistent and transparent framework for the ethical and legal research use of data assets within the Institute. Each RO will be expected to subscribe to this framework, incorporating the governance, data sharing and public engagement approaches of the Institute.

3.4.3 In particular (but not limited to) the RO will be responsible for:

3.4.3.1 the operation of a secure infrastructure for data management and data sharing, in compliance with all relevant regulations / legislation;

3.4.3.2 the provision of robust data stewardship, evidenced by organizational arrangements proactively governing data management and data sharing.

3.4.3.3 the professional and effective management of relationships and coordinating activity with partner data custodians e.g. local NHS Trusts and other healthcare data providers.

4. Governance of the Institute

4.1 HDR UK Ltd will be established as a company limited by guarantee which will seek registration with the Charity Commission.

4.2 HDR UK Ltd will be governed by a Board of Directors, with responsibility for delivery of the Institute mission and use of company funds, as provided for by the Funders and other additional external funding from time to time. The Board will be chaired by an independent chair; the first Chair of the Board is Dr Graham Spittle.

4.3 The Board and the Institute Director will be advised by independent international scientific advisers and will consult with the Funders on significant issues and policy, in accordance with Funder's terms and conditions of award.

4.4 The Board will be made up of Non-Executive Directors appointed by the Company Members, the Chair and independent representatives from academia, industry etc. The RO will not be a member of, and shall have no appointment rights to, the Board.

4.5 An Institute Senior Scientific Leadership Committee will be established, comprising senior Institute leaders and which would include, amongst others, the Site Directors as representatives of their respective Site's ROs.

4.6 There will be clear requirements on ROs for management, finance, accountability, branding and intellectual property and its commercialisation, and for regular communication with HDR UK Ltd, which will be set out in the Site Agreement. Coordinating RO's will be required to procure the compliance with these requirements by Associate ROs.

5. Ethics/ Good practice

5.1 The Institute will be a beacon of best practice and each RO will embrace all requirements, as per usual Funders' requirements, with respect to all aspects of research conduct and practice, including ethics, misconduct, research involving human participants or animals, data handling/sharing, open access, confidentiality, clinical research governance, propriety in relationships with NHS staff, anti-corruption, among other matters.

5.2 The Institute Director will be required to submit an annual 'assurance' return to the Board, who in turn will report to the Funders. The RO's and Site Directors will cooperate with the Institute Director in the preparation of that assurance statement.

- 5.3 Where there is an allegation of scientific or other misconduct, fraud or bribery, either the Board (in the case of HDR UK Ltd employees) or the Coordinating or Associate RO (as the employer for seconded staff or other Institute RO staff) will take the lead in the investigation. However, in both cases, the coordinating party will inform the other parties as soon as possible and who should be consulted about the process at the earliest stages with the offer of direct involvement.

6. Funding Model

- 6.1 HDR UK Ltd will receive core funding from the Funders. HDR UK Ltd will only use its funding for purposes which are charitable in law and consistent with its constitution. Any additional funding received from third parties will be applied by HDR UK Ltd in accordance with either the conditions of the third party awards, or as determined by the Board.
- 6.2 HDR UK Ltd will fund the Coordinating RO through a non-FEC (non-full economic cost) award(s) that will cover the research costs of Institute research programmes within the Site (providing direct and directly incurred overhead costs) . The Coordinating RO will be responsible for overall management of the Site award. To aid transparency and attribution of leveraged and other costs, ROs will establish separately identifiable cost centres for Institute activity.
- 6.3 For the purposes of determining the proportion of charity quality related funding (or future equivalent), should this be recoverable, the award will be made up in proportion to the Funders' contributions to HDR UK Ltd, unless otherwise stated.
- 6.4 All central RO services provided to support Institute funded research activity should be clearly linked to the Institute and will be provided transparently.
- 6.5 Requests for HDR UK Ltd capital investment (where allowed) are required to be co-invested by the RO (unless otherwise specified at the time by the funders). For a period of five years in the first instance, and subject to review after this time, the RO will be expected to provide a significant in-kind and leveraged financial support aligned to the capital request, or otherwise a RO financial contribution at a minimum of 50% of the HDR UK Ltd contribution.
- 6.6 The RO will contribute to the delivery of the Institute mission through provision of additional funding 'leveraged resources' made available to the Site Director. These resources will be used as required to support delivery of the Institute funded research, training and innovation.
- 6.7 The RO will contribute to the delivery of the Institute mission through provision of wider and equitable access to relevant RO facilities and services, e.g. IT systems, technology platforms and library, as required to support delivery of the Institute funded research, training and innovation.
- 6.8 The RO will sponsor and provide appropriate insurance and/or ethical approvals for any Institute funded studies involving their employees.

7. Employment Model

- 7.1 HDR UK Ltd may directly employ a small number of staff including on its future leader researcher programme. As employer, any redundancy, employment, pensions or liabilities related to such staff will lie with HDR UK Ltd, unless otherwise agreed.
- 7.2 HDR UK Ltd will also seek to second RO staff into the Institute, particularly to support the core executive team based in HDR UK Ltd's head office. Any secondment or other hosting arrangements for HDR UK Ltd staff will be discussed and agreed with RO's as appropriate.
- 7.3 The RO will employ academic, scientific and operational staff engaged in or supporting Institute funded activities. This will include senior research and technical leadership positions who are needed to deliver each Site's research.

- 7.4 Any redundancy, employment, pensions or liabilities related to RO staff will lie with the employing RO.
- 7.5 The RO should view the Substantive Site award as a long-term commitment and not just a grant with an end-date. There will be cases where the RO will be expected to make open-ended appointments and they will be expected to manage the associated risk. HDR UK Ltd will not underwrite such appointments.
- 7.6 The RO will have or be actively working towards Athena Swan Silver as a minimum.
- 7.7 Each Coordinating RO will procure that Associate ROs accept and comply with these requirements.

8. Reporting/audit

- 8.1 The RO must maintain a separate cost centre and be able to provide an auditable account relating to all Institute funded expenditure, including an analysis of research and training by activity and cost type. The RO will be responsible for implementing measures to ensure the proper application of Institute funds (which include public money) in accordance with HM Treasury guidelines and for implementing reasonable protections against fraud, cyber and financial crime.
- 8.2 HDR UK Ltd, the Company Members or their appointed agents reserve the right to inspect the RO's accounts relating to the Site at any time, giving reasonable notice and to be given such information, explanation, and assistance as they reasonably require.
- 8.3 HDR UK Ltd will require research to be well defined and to be costed at an individual programme level with a unique identifier provided by HDR UK Ltd and represented this way in the Site portfolios, which will be used in submissions to MRC's Researchfish® portfolio, and for relevant Funders' submission to Gateway to Research etc.
- 8.4 The RO will have adequate systems in place to enable reporting on science (delivery and outputs) and spend. Reporting points will be the Board annual meetings and periodic scientific review points. Additional reports on a regular basis as required by the Institute Director will be requested as agreed. All RO employees working in the Institute will have ORCID IDs as appropriate.

9. Communications

9.1 Branding

- 9.1.1 It will be a condition of funding that each Site will use "Health Data Research UK" as its main title; with wider branding showing the relevant RO relationship. Brand management (including any branding of Associate ROs) will be agreed with HDR UK Ltd (and, through the Board, the Funders) from time to time.

9.2 Visibility

- 9.2.1 The Institute is expected to be recognised widely as a significant MRC, health research departments of England, Scotland and Wales, EPSRC, ESRC, BHF and Wellcome investment, with the Institute Director representing the Funders' Institute science/informatics portfolio to external audiences (e.g. stakeholders, partners, in the media, etc.) as and when needed.
- 9.2.2 The Funders' brand identities may be utilised alongside the Institute (e.g. name, logo, etc.) where appropriate and as agreed with HDR UK Ltd.

9.3 Dissemination

- 9.3.1 All institutions and scientists conducting Institute research will acknowledge the support of HDR UK Ltd and its Funders in all communications (including manuscripts submitted for publication, posters at conferences and other presentations). Other funders/partners will be recognised commensurate to their investment in HDR UK Ltd as agreed in each supplementary award.
- 9.3.2 The RO will recognise the need to publish research outputs in a timely manner and operate in line with the open-access policies of HDR UK Ltd and/or the Funders. HDR UK will develop a joint publication and attribution policy which ROs must adopt.
- 9.3.3 All promotional work relating to the work of the Institute (e.g. press releases, exhibitions, events, etc.) will be drafted in consultation with, and approved by HDR UK Ltd, as agreed.

9.4 Patient and Public Involvement and Engagement

- 9.4.1 Institute activities will involve active engagement with the patients and public and HDR UK Ltd will develop a Patient and Public Involvement (PPI) policy, which the RO will support and all Institute RO staff will be expected to comply with the policy.

10 Intellectual Property

- 10.1 HDR UK Ltd will develop a single IPR policy that provides a consistent and transparent framework for engagement with ROs in relation to the Institute.
- 10.2 ROs will own IP generated by them from HDR UK-funded research (Foreground IP). If two or more partner ROs jointly generate Foreground IP and it is not possible to separate their different contributions then the Foreground IP will be owned jointly.
- 10.3 Ownership of background and sideground IPR by ROs should be unaffected by creation of new foreground IPR where that foreground IPR arose from Institute research.
- 10.4 ROs will use reasonable endeavours to allow their background or sideground IP to be used in HDR UK-funded research where they are free to do so and such IP will be accessible to other partner ROs and/or HDR UK Ltd itself (a) free of charge to assist other HDR UK-funded research and (b) on reasonable terms if it is required to enable exploitation of Foreground IP by other partner ROs and/or HDR UK Ltd itself ("accessible IP terms").
- 10.5 Foreground IP (as well as all results, material and data arising from HDR UK-funded research) will be made freely available for (UK-wide academic) research purposes.
- 10.6 For arising foreground IP wholly or partially funded by HDR UK Ltd, the relevant RO will solely determine the protection and exploitation pathway, working cooperatively with other ROs in the case of joint ownership of IP, but HDR UK Ltd's prior consent is required before commencing any and all IP protection and/or exploitation.
- 10.7 Internal reward policies will apply in relation to arising foreground IPR. Awards to inventors will be handled by individual ROs employing relevant staff, or their collaborators, consultants and visiting workers from its share of any revenue, in line with existing policies within that RO.

11. Estates and Assets

11.1 Assets

- 11.1.1 Any land, building and equipment funded by HDR UK Ltd will be owned, maintained and insured by the RO, ensuring any HDR UK Ltd-funded equipment can be used across all Sites to provide appropriate flexibility to Institute programmes and Institute

science delivery. A process for maintaining confidentiality and publication procedures will be established.

11.2 Accommodation

11.2.1 The RO will make available appropriate accommodation to enable Institute funded research to be undertaken effectively and in fulfilment of the Institute's scientific aims. Any proposed significant changes regarding space allocation, or potential relocation from what is agreed in the Site Agreement must be discussed with the Board and Institute Director before any decisions are taken.

11.2.2 Subject to Clause 6 and commitments made by the RO, HDR UK Ltd will make appropriate financial provision for sustainability/provision of major equipment by the RO essential for delivery of the Institute's mission.

12. Exiting/Sun-setting

12.1 HDR UK Ltd will fund longer term programmes of research (for periods of up to 5 years' duration, with the option to renew) through Substantive Sites. The terms governing the relationship between HDR UK Ltd and the RO will be set out in the Site Agreement.

12.2 If circumstances are such that HDR UK Ltd wishes to withdraw its investment from only some of the programmes comprising a Site, the closing programmes will normally be wound up within one year. Funds remaining after any transitional arrangements may be recycled under the direction of the Institute Director either in the same Site, or in other Sites.

12.3 HDR UK Ltd and its Sites will be subject to periodic (usually 5 yearly) scientific reviews by its Funders. In the event that the Funders are not satisfied with any aspects of any Site's activities then HDR UK Ltd may terminate the funding provided to Sites for the funded activities in question by giving not less than one year's written notice of termination.

12.4 In the event that HDR UK Ltd and the RO agree that the funded activities are, for whatever reason, unlikely to contribute to the achievement of the Institute's mission they may agree to terminate the Site Agreement. In addition, either party may terminate the Site Agreement at any time on not less than 12 months written notice to the other and the Site Agreement will include usual termination rights in respect of a party's material or persistent default.

12.5 On termination of the Site Agreement HDR UK Ltd and the RO will arrange for an orderly wind down of the funded activities and arrangements for the on-going use and licensing to or by either party of the data and intellectual property rights used or created in the course of the funded research all with the aim of achieving the mission of the Institute will be determined.

13. Implementing the Site Agreement and establishing the relationship

13.1 HDR UK Ltd expects that the RO will engage fully in a structured process for negotiation and implementation to the timeframe outlined at the outset of this Framework HoT. The appropriate individuals with experience and expertise to engage will be identified early on, and the decision-making process within each RO will be made clear.

13.2 The Site Agreement and such other agreements as will be necessary to confirm the parties' relationship regarding the Institute shall be legally binding, on arms-length terms and contain the usual legal provisions for agreements of that nature, including without limitation confidentiality provisions, disputes process, warranties and termination provisions.

13.3 The Funders may continue to pursue opportunities to provide additional support for the Institute throughout its life. The Funders and the RO will work together as needed to co-ordinate such activities.

13.4 Any RO communications about the Institute will require HDR UK Ltd's consent until a Site Agreement setting out detailed communications requirements is in place.

14 General

14.1 No party shall make any public announcement or communication about this Framework HoT that causes any other party, HDR UK Ltd or the Funders to be brought into disrepute or which names any of them without their consent (such consent not to be unreasonably refused).

14.2 Each party shall:-

14.2.1 treat as secret and confidential and not (without consent of the other party) disclose or permit to be disclosed any confidential information that it obtains about the other party or related parties in the course of discussions or activities carried out in furtherance of this Framework HoT, unless disclosure is require by law or to auditors or professional advisers;

14.2.2 bear its own costs and expenses incurred in connection with the preparation and agreement of this Framework HoT, the Site Agreement and all other legal documents to be entered into by a party necessary for the establishment of the Institute.

14.3 With the exception of this clause 14, this Framework HoT is not intended to be legally binding or confer legal rights or obligations or to impose financial or commercial responsibilities on the parties or Funders.

14.4 A person who is not a party to this agreement shall have no rights under this agreement under the Contracts (Rights of the Third Parties) Act 1999, with the exception of the Funders.

14.5 This agreement and any non-contractual obligations arising out of or in connection with it shall be governed by and construed in accordance with the laws of England and Wales. The parties submit to the non-exclusive jurisdiction of the courts of England and Wales in respect of any claim, dispute or difference arising in respect of this Agreement (including (without limitation) in relation to any non-contractual obligations).

Signed for and on behalf of:

Signed for and on behalf of:

Health Data Research UK

XXX

Name:

Name:

Role:

Role:

Date:

Date: