



## HEALTH RESEARCH BOARD

TERMS AND CONDITIONS (October 2021 Edition) FOR RESEARCH INFRASTRUCTURE AWARDS

«Grant Reference»

«Grant Title»

«Host Institution»

Health Research Board  
Grattan House  
67-72 Lower Mount Street  
Dublin 2  
[www.hrb.ie](http://www.hrb.ie)

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This Agreement is made the \_\_\_\_\_

## Between

1. The **Health Research Board** having its principal offices at Grattan House, 67-72 Lower Mount Street, Dublin 2 (the “**HRB**”); and
2. The Host Institution being the Party Named in Schedule 1 («**Host Institution**» )  
  
(each a “**Party**” and, together, the “**Parties**”).

## WHEREAS

1. The HRB is a state agency whose aim is to foster, fund and support health research in Ireland.
2. The Host Institution wishes to carry out the Grant Funded Activities (defined below).
3. The Parties have therefore agreed to enter into this Agreement with effect from the date it is executed by the Parties and this Agreement will govern the provision and use of the Grant and conduct of the Grant Funded Activities for the duration of the Term (as such terms are defined below).

## 1. Definitions

In this Agreement,

- 1.1. “**Acceptance Documentation**” means any written acceptance on behalf of the Host Institution of any HRB letter of outcome (or similar) including any Host Institution letter of acceptance (or similar), together with any other documentation included or referred to in any such acceptance documents.
- 1.2. “**Agreement**” means this agreement and its schedules together with any binding variation and including the Application and the Acceptance Documentation.
- 1.3. “**Applicable Law**” means any law applicable in Ireland (without further enactment) or any other relevant jurisdiction and shall include common law, statute, statutory instrument, proclamation, bye-law, directive, decision, regulation, rule, order, notice, code of practice, code of conduct, rule of court, instrument, or delegated or subordinate legislation having force of law.
- 1.4. “**Application**” means the application submitted by or on behalf of the Host Institution, all documents attached to it, and all other documentation furnished to the HRB prior to the issuing of the Grant.
- 1.5. “**Approvals**” means, from time to time, all (a) research ethics committee approvals (or similar) and (b) all other regulatory approvals, consents, authorisations, licences and permissions (or similar) required under Applicable Law, in each case for conduct of the Grant Funded Activities, to include any required for any Underlying Research Activities.
- 1.6. “**Approvals Declaration**” means a written declaration signed by, or on behalf of, the Host Institution, in the form required by the HRB from time to time, confirming that all Approvals are in place as at the date of each such declaration.

- 1.7. **“Asset”** means any asset, including buildings or equipment, acquired, generated or established directly or indirectly in connection with the Grant Funded Activities or any part of them.
- 1.8. **“Bi-annual Report”** means the report to be submitted by the Host Institution to the HRB in accordance with Clause 5.2 of Schedule 2.
- 1.9. **“Budget”** means the budget or funding arrangement (if any) identified in Schedule 4 hereof and any binding variation thereof.
- 1.10. **“Bullying”** is repeated inappropriate behaviour that undermines your right to dignity at work including any persistent, offensive, abusive, intimidating, insulting or malicious behaviour, language, action of conduct. It involves the misuse of power and can make the person(s) being bullied feel vulnerable, upset, undermined, humiliated or threatened.
- 1.11. **“Business Day”** means a day which is not a Saturday or a Sunday or public holiday in Ireland on which banks in Dublin are generally open for business.
- 1.12. **“Co-Investment”** means any and all investments or contributions in or to, or in respect of, the Grant Funded Activities in whatever form (including in kind) by the Host Institution or any third party source (other than the HRB) as set out or referred to in this Agreement, and **“Co-Investor”** shall have a corresponding meaning.
- 1.13. **“Commencement Date”** means the **«Grant Start Date»**.
- 1.14. **“Core Team”** means the Infrastructure Director, co-applicants, funding collaborators (including Co-Investors), any other persons named in the Application and any other senior employee or contractor employed, involved or otherwise engaged by the Host Institution (or by any such named third parties) for the purposes of the Grant Funded Activities.
- 1.15. **“Data Protection Law”** means all Applicable Law relating to the protection of personal data, including the GDPR and the Data Protection Act 2018 (including SECTION 36(2) (HEALTH RESEARCH) REGULATIONS (S.I No. 314 of 2018) and amendments thereof)
- 1.16. **“Final Report”** means the report to be furnished by the Host Institution to the HRB in accordance with Clause 5.3 of Schedule 2.
- 1.17. **“Final Financial Statement”** means the report to be furnished by the Host Institution to the HRB in accordance with Clause 5.4 of Schedule 2.
- 1.18. **“Financial Records”** means such ledgers, bank statements, accounts, invoices, vouching documentation, authorities, directions and also instructions to auditors, accountants, banks and other servants or agents of the Host Institution and any other materials in both paper and electronic form which may be reasonably necessary to enable the HRB exercise its rights of audit and to satisfy the HRB that the Host Institution has complied with this Agreement.
- 1.19. **“GEMS”** means the HRB online Grant E-Management System, or its relevant replacement from time to time.
- 1.20. **“GDPR”** means the General Data Protection Regulation (Regulation (EU) 2016/679).
- 1.21. **“General Terms and Conditions”** means the terms and conditions set out in Schedule 2 and referred to in Clause 3.

- 1.22. **“Grant”** means the grant awarded by the HRB to the Host Institution in accordance with the terms of this Agreement.
- 1.23. **“Grant Funded Activities”** means the activities, items, resources or infrastructure in respect of which the Grant is awarded being named **“«Grant Title»” («Grant Reference»)**, excluding any Underlying Research Activities.
- 1.24. **“Grant Intellectual Property”** or **“Grant IP”** means Intellectual Property generated by, or resulting from, the Grant Funded Activities.
- 1.25. **“Harassment”** is any unwanted physical, verbal or non-verbal conduct that has the purpose or effect of violating a person’s dignity or creating an intimidating, hostile, degrading, humiliating or offensive environment for them. It may be persistent or a single incident.
- 1.26. **“Host Institution”** means the body or entity set out in Schedule 1.
- 1.27. **“Host Institution Variation Request”** means a request from the Host Institution to the HRB to vary the terms of this Agreement.
- 1.28. **“HRB”** means the Health Research Board established under S.I. No. 279 of 1986 as amended.
- 1.29. **“HRB Approval”** means any approval, consent or similar right capable of being exercised by the HRB under the terms of this Agreement.
- 1.30. **“HRB Engagement Forum”** means the group established and maintained to periodically review and discuss mutually beneficial actions related to the Grant and the Grant Funded Activities as set out in Schedule 5.
- 1.31. **“HRB Policy”** means any HRB policy or similar document relating to grants made by the HRB which is published on the HRB website (<https://www.hrb.ie/funding/manage-a-grant/grant-policies/>), as the same is amended, supplemented or replaced by the HRB from time to time.
- 1.32. **“Infrastructure Director” («Lead Applicant»)** means the individual employed or otherwise engaged by the Host Institution nominated as such by the Host Institution and named in the letter of outcome as being the relevant director or clinical lead applicant (or similar) for the Grant, as amended by the Host Institution by notice in writing to the HRB but only where such replacement person is approved of by the HRB in writing.
- 1.33. **“Intellectual Property”** means all intellectual property rights including copyright, patents, design rights, trade secrets, confidential information, trade marks, trade names, domain names, service marks, utility models, moral rights, topography rights, rights in databases and know-how, in all cases whether or not registered or registrable and including registrations and applications for registration of any of these rights and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these anywhere in the world.
- 1.34. **“Interim Report”** means the report to the submitted by the Host Institution to the HRB in accordance with Clause 5.6 of Schedule 2.
- 1.35. **“Misconduct”** means fabrication (including the making up of data or results and recording or reporting them), falsification (including manipulating research materials, equipment or processes or changing or omitting data or results such that the research is not accurately repre-

sented in the research record), plagiarism (the appropriation of another person's ideas, processes, results or words without giving appropriate credit) or other serious deviation from accepted practices.

- 1.36. **"No Cost Extension"** means an extension of the duration of the Term of this Agreement pursuant to Clause 16.3.
- 1.37. **"Open Access"** means free availability on the public internet, permitting any users to read, download, copy, distribute, print, search, or link to the full texts of these articles, crawl them for indexing, pass them as data to software, or use them for any other lawful purpose, without financial, legal, or technical barriers other than those inseparable from gaining access to the internet itself. The only constraint on reproduction and distribution, and the only role for copyright in this domain, should be to give authors control over the integrity of their work and the right to be properly acknowledged and cited.
- 1.38. **"Other HRB Funded Infrastructure"** means any other clinical infrastructure, network or other similar supports funded in whole or in part by the HRB from time to time.
- 1.39. **"Personal Data"** shall have the meaning given to the term in the GDPR.
- 1.40. **"Relevant External Policy"** means any non-HRB third party policy, framework, protocol or similar document relating to research which has been endorsed by the HRB; and is published on the HRB website (<https://www.hrb.ie/funding/manage-a-grant/grant-policies/>), as the same is amended, supplemented or replaced by the HRB from time to time. The term Relevant External Policy shall also include any non-HRB third party policy, framework, protocol or similar document named in this Agreement and stated as requiring the compliance of the Host Institution.
- 1.41. **"Relevant Third Party Agreement"** means any agreement or arrangement with any third party (including with any member of the Core Team) which relates directly to the Grant Funded Activities or any Co-Investment.
- 1.42. **"Research Data"** are the evidence that underpins the answer to the research question and can be used to validate findings regardless of its form (e.g. print, digital, or physical). The primary purpose of research data is to provide the information necessary to support or validate a research project's observations, findings or outputs.
- 1.43. **"Research Integrity Training"** means the minimum level of training required is that provided by EPIGEUM as part of the National Online Training Pilot, or equivalent from time to time.
- 1.44. **"Special Conditions"** means the terms and conditions set out in Schedule 3 and as referred to in Clause 4.
- 1.45. **"Sponsor(s)"** means a company, institution or other organisation which takes ultimate responsibility for the initiation, for the management and for setting up the financing and reporting of a clinical trial (or other intervention) (whether regulated or unregulated), clinical study, clinical research or other activity, or other non-clinical research (or similar).
- 1.46. **"Team"** means the Infrastructure Director, co-applicants, funding collaborators (including Co-Investors), staff, students, visiting researchers and other third parties employed, involved or otherwise engaged by the Host Institution (or by any such named third parties) for the purposes of the Grant Funded Activities.

- 1.47. “**Term**” means the period of **«Grant Duration months»** months commencing on the Commencement Date.
- 1.48. “**Underlying Research Activity**” means any and all clinical trials (or other interventions) (whether regulated or unregulated), clinical study, clinical research or other activity, or other non-clinical research (or similar) facilitated, or intended to be facilitated by the Grant Funded Activities. For the avoidance of doubt, the term Underlying Research Activity shall not include the provision of healthcare services (other than such research) in the ordinary course of the activities of a Host Institution of any member of the Team and the obligations under this Agreement shall not be construed to extend to any such healthcare services.
- 1.49. “**Variation Notice**” means written notice from the HRB to the Host Institution to vary the terms of this Agreement.

## 2. Interpretations

- 2.1. All references to a statutory provision shall be construed as including references to: -
- 2.1.1 Any statutory modification, consolidation or re-enactment (whether before or after the date of this Agreement) for the time being in force;
  - 2.1.2 All statutory instruments, regulations or orders from time to time made pursuant to any of them; and
  - 2.1.3 Any statutory provisions of which a statutory provision is a modification, consolidation or re-enactment.
- 2.2. Any reference to a person shall be construed as a reference to an individual, firm, company, corporation, government, state or agency of a state or any association or partnership (whether or not having separate legal personality) and shall include that person’s legal personal representatives, successors and permitted assigns.
- 2.3. Any reference to the HRB includes, where appropriate, its successors and assigns.
- 2.4. Except where the context otherwise requires words denoting the singular include the plural and vice versa and words denoting any one gender shall include all genders.
- 2.5. Where any word or phrase is given a defined meaning any other form of that word or phrase has the corresponding meaning.
- 2.6. Headings are for convenience of reference only and do not affect the construction or interpretation of any provision.
- 2.7. Unless the context otherwise requires, general words, including those introduced by the word “other”, shall not be given a restrictive meaning by reason of the fact that they are preceded by words indicating a particular class of acts, matters or things and general words and phrases followed by the terms “including”, “include” and “in particular” or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.
- 2.8. Any reference to any named HRB Policy or Relevant External Policy is a reference to that policy (or similar document) as amended, superseded or replaced from time to time.
- 2.9. In the case of conflict or inconsistency between the Special Conditions and the General Terms and Conditions then the Special Conditions shall prevail.



**3. General Terms and Conditions**

3.1. The Host Institution shall comply with the General Terms and Conditions.

**4. Special Conditions**

4.1. The Host Institution shall comply with the Special Conditions.

**SCHEDULE 1**

**THE HOST INSTITUTION**

**«Grant Host Institution Legal Name»**

**«Host Inst Contract Address New Line»**

## SCHEDULE 2

### GENERAL TERMS AND CONDITIONS

#### 1. The Grant

- 1.1. The HRB in reliance on the warranties and undertakings given by the Host Institution in this Agreement agrees to provide the Grant to the Host Institution, subject to the terms and conditions set out in this Agreement.
- 1.2. The Grant shall be paid to the Host Institution and used exclusively for the Grant Funded Activities in accordance with the terms of this Agreement and paid in accordance with Clause 3 of this Schedule 2.
- 1.3. The Parties shall have the rights and comply with the obligations as set out in Schedule 5 in respect of the HRB Engagement Forum.
- 1.4. As requested by the HRB, the Host Institution shall make use of GEMS or such other system or process as required by the HRB in its operation of the Agreement.

#### 2. The Approved Use of the Grant

- 2.1. The Host Institution will apply the Grant as set out in this Agreement and will not deviate in any respect without the prior written consent of the HRB.

#### 3. Payment of Grant

- 3.1. The HRB will make payment of the amounts specified in the Budget in accordance with the payment profile and associated conditions or methodologies set out in the Special Conditions or as otherwise outlined in Schedule 4, subject to compliance with any conditions precedent set out in the this Agreement.
- 3.2. Where this Agreement contains payment-related milestones or a specified funding model as set out in the Special Conditions or Schedule 4, no payment will be made where the relevant milestone has not been achieved or where the funding model specified does not provide or allow for relevant payments or claims outside of any specified period that has expired.
- 3.3. The HRB shall be entitled to withhold a scheduled payment if the Host Institution has not complied with its reporting obligations as set out in this Agreement. The HRB shall not unreasonably withhold payments in that regard. In connection with the foregoing, it is acknowledged and agreed by the Host Institution that it shall not be unreasonable for the HRB to withhold payment(s) in circumstances where the Host Institution has not complied with the relevant form of reporting, or omitted to provide any material information, as required by the HRB from time to time.
- 3.4. If the costs incurred by the Host Institution in carrying out the Grant Funded Activities amount to less than the maximum amount of the Grant, the HRB shall be obliged to pay only such

amount as may be necessary to discharge the actual costs incurred by the Host Institution or relevant member of the Team.

- 3.5. Any part of the Grant paid that remains unused or uncommitted at the end of the Term or earlier termination of this Agreement shall be returned to the HRB within sixty days of the HRB's request. The Host Institution is not entitled to 'carry over' or defer any unspent or unclaimed monies into any subsequent application(s) made to, or grants funded by, the HRB.
- 3.6. The Host Institution shall be obliged to repay to the HRB within thirty days of demand any amounts of Grant monies paid by the HRB and not used to discharge actual costs incurred in carrying out the Grant Funded Activities.
- 3.7. The HRB shall have the right to seek reimbursement in the event of an overpayment of the Grant including the right to set off such overpayment against further payments of the Grant or any other grant or other payment from the HRB to the Host Institution.
- 3.8. Any foreign exchange loss arising on the payment of the Grant or any part of it shall be borne in full by the Host Institution and any gain shall be for the account of the HRB.

#### **4. Financial Records and Other Records**

- 4.1. The Host Institution shall maintain separate Financial Records for the Grant identified by a reference code which is specific to the Grant and all costs and income properly relating to the Grant (including all disbursements of Grant monies) shall be accounted for through such records.
- 4.2. The Financial Records shall be maintained in accordance with good accounting practice.
- 4.3. The Host Institution shall maintain such other records as may be reasonably necessary, or as may be reasonably required by the HRB from time to time, to satisfy the HRB that the Host Institution has complied with this Agreement including records relating to the outputs, outcomes, impacts and other results of the Grant Funded Activities.
- 4.4. The Host Institution shall ensure that an appropriate business continuity/disaster recovery plan is in place in respect of the Grant Funded Activities.
- 4.5. The Host Institution shall ensure that any agreement it may enter into with a third party in relation to any Co-Investment provides for the right of the HRB or any other body or individual appointed by it to inspect the Financial Records and other records as if such third parties were party to this Agreement.
- 4.6. The Host Institution shall retain, or arrange for the retention of, the Financial Records and other records referred to above and shall make them available to the HRB or its authorised representatives upon seven days' notice during the Term and for a period of seven years following submission of the Final Financial Report or for such longer period as the HRB may require, in each case whether they are located on premises owned or occupied or systems used by the Host Institution or otherwise.
- 4.7. The HRB or its authorised representative(s) shall be entitled to enter any premises owned or occupied by the Host Institution or over which the Host Institution have control or right of access in which any Grant Funded Activity is being conducted and/or the Financial Records or other records are being stored for the purposes of inspecting the premises, observing procedures,

inspecting the Financial Records and other records and doing all things necessary to satisfy itself that the Host Institution has complied with the terms of this Agreement.

## **5. Reports**

- 5.1. In addition to the reporting set out in this Clause 5, the Host Institution shall provide the summary reporting and information as required by Schedule 4 and Schedule 5.
- 5.2. The Host Institution shall furnish a Bi-annual Report to the HRB, covering the respective bi-annual calendar periods of January to June and July to December (or part thereof if shorter in the case of the first such report) in any given year in the Term (or as otherwise as requested by the HRB), within three months of each such six month reporting period. For the avoidance of doubt a Bi-annual Report will be required where the Grant Funded Activity is temporarily suspended.
- 5.3. The Host Institution shall furnish a Final Report on outputs, outcomes and impacts of the Grant Funded Activities on or before the 31<sup>st</sup> of March each year for awards completed in the previous calendar year and shall provide updates on request on an annual basis for a period of up to three years after the Term.
- 5.4. The Host Institution shall furnish the Final Financial Statement of Expenditure to the HRB within sixty days of the termination or determination of the Grant Funded Activities.
- 5.5. On request from the HRB, the Host Institution shall furnish an Approvals Declaration (and a copy of any relevant Approval) to the HRB.
- 5.6. The Host Institution shall furnish to the HRB an Interim Report at such other times and within such periods during the Term as it may reasonably require.
- 5.7. All such reports shall conform strictly to the form or template (if any) prescribed by the HRB from time to time and shall contain such information as the HRB may reasonably require and shall be completed to the satisfaction of the HRB. The Host Institution shall ensure that the reporting it provides shall be completed with reasonable care, skill and diligence and shall be complete and accurate in all material respects and not misleading, in each case as at the time of its submission to the HRB. Any and all issues identified by the HRB with any reporting provided by the Host Institution in respect of the Grant Funded Activities shall be addressed promptly and fully by the Host Institution.
- 5.8. The Host Institution shall, if so required by the HRB, procure that any report required pursuant to this Clause 5 is audited by the Host Institution's auditors at the expense of the Host Institution.
- 5.9. The HRB shall be entitled as often as it may reasonably require to have any such report audited at its expense by its nominated auditors and the Host Institution shall fully co-operate with such auditors and shall allow them full access to all Financial Records and other records referred to above and all statistical, administrative, scientific and other relevant supporting papers and records in both paper and electronic form.
- 5.10. The Host Institution shall furnish to the HRB within such period as may reasonably be required by it such further information as it may reasonably request following receipt by the HRB of a Bi-annual Report, an Interim Report, the Final Report or the Final Financial Statement including information for the purpose of evaluating the outputs, outcomes and impacts of the Grant Funded Activities.

5.11. The HRB shall be entitled to reduce, suspend, terminate or revoke the Grant in whole or in part with immediate effect:

5.11.1 for so long as any of the reports or reporting referred to in Clauses 5.1 to 5.6 above or any audited report referred to in Clause 5.9 above or any additional information requested in relation to any such report or requested pursuant to Clause 5.10 above or otherwise is outstanding; or

5.11.2 in circumstances where the Host Institution is not, in the opinion of the HRB, in material compliance with any other obligation under this Agreement;

## **6. Warranties**

6.1. The Host Institution warrants that: -

6.1.1 It has full power and authority and all necessary resources to carry out the Grant Funded Activities and to comply with the provisions of and perform all of its obligations under this Agreement.

6.1.2 The acceptance of the award of Grant has been executed by its duly authorised representative with full power and authority to bind it.

6.1.3 It has obtained or will obtain all necessary consents, approvals, authorisations, licences and permissions which are required to enable it comply with its obligations under this Agreement.

6.1.4 It shall throughout the Term maintain all such consents, approvals, authorisations, licences and permissions and shall not commit any act or omission which might invalidate, breach or otherwise impair the effect of any of them.

6.1.5 Every statement, representation or information provided in the Application, any documents furnished therewith, any Bi-annual Report, Final Report or Interim Report or financial statement is or will be, to the best of its knowledge and having made in advance appropriate enquiries, true, complete and accurate.

6.1.6 If relevant, it is registered with the Charities Regulatory Authority and has charitable status approved by the Revenue Commissioners.

6.1.7 It is authorised by its Constitution/Memorandum and Articles of Association to carry out the Grant Funded Activities.

6.1.8 No member of the Core Team is applying for, holding or currently employed under a research grant from the tobacco industry.

6.1.9 There is no other information of which the Host Institution or its agents is aware that is relevant to the Application or the interests of the HRB concerning the Application or the Grant which has not been disclosed to the HRB.

## **7. Responsibilities of the Host Institution**

7.1. The Host Institution has full responsibility for the Grant and the Grant Funded Activities and for adherence by the Team with the terms and conditions of this Agreement and with Applicable Laws.

- 7.2. The Host Institution shall ensure that it maintains appropriate and effective governance structures and procedures in respect of the Granted Funded Activities, which shall seek at all times to promote the principles of accountability, responsibility and transparency. The Host Institution shall notify the HRB of the members of any governance body or committee maintained for these purposes, including any executive or scientific advisory committees or groups, and any proposed change thereto shall be subject to the prior written consent of the HRB, not to be unreasonably withheld or delayed.
- 7.3. The Host Institution shall (and, as applicable, shall procure that the Team shall): -
- 7.3.1 Comply in full with the terms and conditions of this Agreement.
  - 7.3.2 Comply, and ensure that any Relevant Third Party Agreement requires compliance, with all of the HRB Policies and the Relevant External Policies, to the extent that they are relevant to the Grant Funded Activities.
  - 7.3.3 Supply a copy of any Relevant Third Party Agreement to the HRB on request.
  - 7.3.4 Use the Grant monies solely and entirely for the Grant Funded Activities and for no other purpose whatsoever and strictly in accordance with the Budget.
  - 7.3.5 Perform or ensure that the Grant Funded Activities are performed with due skill, care and diligence and by appropriately qualified personnel and are completed within the Term.
  - 7.3.6 Ensure that all monies claimed and paid are allowable, necessary and reasonable for the conduct of the Grant Funded Activities.
  - 7.3.7 Not permit or effect a significant change to the Grant Funded Activities, unless otherwise agreed in writing by the HRB;
  - 7.3.8 Ensure that all members of the Core Team receive a copy of this Agreement and any subsequent binding variations and procure that the Grant Funded Activities are carried out under the supervision of the Infrastructure Director.
  - 7.3.9 Ensure that all members of the Team directly involved in the Grant Funded Activities are sufficiently qualified or will receive all training appropriate for their duties including health and safety training.
  - 7.3.10 Ensure that the Team fully complies with the obligations on the part of the Host Institution contained in this Agreement.
  - 7.3.11 Ensure that all members of the Team in receipt of salary or other financial support from the Budget have or undertake Research Integrity Training within 6 months of the Commencement Date or within three calendar months of a member of the Team commencing involvement on the Grant Funded Activities, whichever is the later.
  - 7.3.12 Ensure that certification of Research Integrity Training undertaken is available for inspection on request.
  - 7.3.13 Ensure that appropriate direction and supervision of the Team directly involved in the Grant Funded Activities is provided.
  - 7.3.14 To the extent that the Grant Funded Activities involve patient contact, ensure that the appropriate medical indemnity insurance is in place.
  - 7.3.15 Take part in and ensure that the Infrastructure Director takes part in a review or reviews of the progress of the Grant Funded Activities, its organisation and financing and any other relevant issues when so required by the HRB.

- 7.3.16 Implement and ensure that the Infrastructure Director implements any conditions for the continuation of the Grant made by the HRB arising out of any such review or out of any report furnished pursuant to Clause 5 of this Schedule 2.
  - 7.3.17 Comply with all Applicable Laws relating to the Grant and the Grant Funded Activities including all such relating to the employment, involvement or engagement of the members of the Team.
  - 7.3.18 Not accept or receive funding (including any Co-Investment) for the same Grant Funded Activities from any other source unless set out in the Application or previously approved of in writing by the HRB.
  - 7.3.19 Use best endeavours to ensure that any and all Co-Investment is obtained and maintained at the level or ratio specified in the Application for the duration of the Term, and to notify the HRB in writing where the Host Institution considers that it is likely that any such Co-Investment is not or will no longer be forthcoming, or not at such levels or ratios.
  - 7.3.20 Provide the HRB in a timely way with all reasonably requested information in relation to any Co-Investment and discuss the same with the HRB.
  - 7.3.21 Not enter into any Relevant Third Party Agreement with a party which is not identified on the Application without the prior written consent of the HRB and shall not in any material respect alter or amend any such agreement without the further written consent of the HRB.
  - 7.3.22 Without prejudice to the foregoing, ensure that any Relevant Third Party Agreement does not contain any clauses which are inconsistent with the terms of this Agreement.
  - 7.3.23 Pay interest on such monies, if any, as may from time to time be payable by the Host Institution to the HRB hereunder at the rate from time to time specified pursuant to Section 1080 of the Taxes Consolidation Act, 1997 such interest to be payable within fourteen days of a written demand and to be in respect of the period from the date of the demand to the date of actual payment.
  - 7.3.24 Ensure that it has not contractually committed to any party for the supply of services or entered into any contract for services or for the supply or provision of an Asset without ensuring such obligation or commitment is conditional on Grant monies (unless the Host Institution is prepared to lease any Asset from a finance party irrespective of the Grant monies) and further that such obligation or commitment contains a provision for termination in the event of the Grant monies being no longer available for any reason whatsoever.
  - 7.3.25 Not alter the principal objects provision of its Constitution/Memorandum and Articles of Association without the prior written consent of the HRB save for Host Institutions created by Statute PROVIDED ALWAYS any such amendment to the Statute shall not prevent the Host Institution from complying with this Agreement.
  - 7.3.26 Not do any act, or omit to do any act, which may bring the HRB or the Grant Funded Activities into disrepute.
- 7.4. The Host Institution shall notify the HRB of any of the following matters: -
- 7.4.1 Any proposed change in the objectives of the Grant Funded Activities (which proposed change for the avoidance of doubt shall not be made without the written consent of the HRB).



- 7.4.2 Any proposed or actual change in the funding of, or relevant direct or indirect contribution of any third parties to, the Grant Funded Activities (other than in respect of HRB funding).
- 7.4.3 Any material adverse occurrence or anticipated occurrence relating to the Grant Funded Activities.
- 7.4.4 If the Infrastructure Director or any other member of the Core Team directly involved in the Grant Funded Activities: -
  - 7.4.4.1 severs or intends to sever his connection with the Host Institution;
  - 7.4.4.2 has been absent for a continuous period of three months or more; or
  - 7.4.4.3 has relinquished or intends to relinquish active direction of the Grant Funded Activities;
- 7.5. The Infrastructure Director shall be employed or otherwise engaged by the Host Institution and the Host Institution shall ensure in the Infrastructure Director's agreement that the Infrastructure Director is responsible to the Host Institution for the direction, management and pursuit of the Grant Funded Activities in all of its objectives and the efficient, proper and appropriate conduct of the Grant Funded Activities.
- 7.6. The Host Institution shall, without limiting the generality of any of the foregoing provisions of this Clause 7 in respect of the Grant Funded Activities:-
  - 7.6.1 Be responsible for entering into a contract of employment or engagement with the Infrastructure Director and each member of the Core Team (if applicable) and shall forthwith inform the HRB if any such contract is terminated during the Term and shall furnish to the HRB such information as it may reasonably require in relation to any replacement or additional member of the Core Team.
  - 7.6.2 Ensure that each such contract for the Core Team contains such terms and conditions as the Host Institution may require to enable it to comply with its obligations under this Agreement.
  - 7.6.3 Ensure that the term of each such contract for the Core Team is strictly limited to the Term of this Agreement unless the Host Institution wishes to retain the services of the Infrastructure Director or any member of the Core Team for its own purposes and its own expense.
  - 7.6.4 Ensure that all salary payments are appropriately adjusted to reflect any changes in personnel, as well as any circumstances such as absences, illness or resignation.
  - 7.6.5 In the event that the duties of any member of the Core Team involve travel out of Ireland ensure that all necessary permits, licences and other approvals necessary to facilitate such travel are obtained and complied with.
  - 7.6.6 Ensure that all costs incurred in relation to travel, attendance at conferences, subsistence and other similar costs comply with guidelines and rates from time to time issued by any relevant Irish Government department.
  - 7.6.7 Where relevant, in the event of the Infrastructure Director or any other member of the Core Team resigning during the Term, as applicable, take all reasonable steps to ensure that post graduate students supported by the Grant are given every opportunity to complete their degrees.
  - 7.6.8 Ensure that the Infrastructure Director and the members of the Core Team are aware that the contract under which they are employed or otherwise engaged is with the

Host Institution and not with the HRB and indemnify the HRB on demand against any claim by the Infrastructure Director or the members of the Core Team that they are an employee of, have otherwise been engaged by the HRB or have any on-going right to employment as a result of HRB funding beyond the Term.

- 7.7. The Host Institution shall use best endeavours to ensure, and shall as necessary procure that the Team use best endeavours to ensure, that any and all Underlying Research Activities:
- 7.7.1 are conducted in accordance with good clinical practice, good research governance and all Applicable Law;
  - 7.7.2 are conducted in accordance with all applicable HRB Policies and Relevant External Policies as if such Underlying Research Activities were being funded by the HRB; and
- 7.8. The Host Institution acknowledges that the Grant Funded Activities form a key part of the HRB's strategy to support the design, conduct and evaluation of healthcare intervention studies in order to improve health outcomes and health service delivery and further that the HRB grants monies to Other HRB Funded Infrastructure. To that end, the Host Institution shall, and shall procure that the Team shall:
- 7.8.1 provide any and all reasonable information, co-operation and assistance to the HRB in furtherance of any HRB general strategy from time to time and of the HRB Policies and Relevant External Policies); and
  - 7.8.2 as far as possible, and in conjunction with the HRB, co-ordinate with, and not unnecessarily duplicate, any Other HRB Funded Infrastructure.
- 7.9. The Host Institution shall perform, or procure the performance of, all further acts and things, and shall deliver, or procure the execution and delivery of further documents which are required by or are necessary or reasonably desirable to give effect to the terms of this Agreement.

## **8. Intellectual Property**

- 8.1. The Host Institution acknowledges that it has a duty to the public to ensure that discoveries and advancements in knowledge arising from the Grant Funded Activities are translated for public benefit including commercial development of new therapies, diagnostics, materials, methodologies, devices and software for health.
- 8.2. The Host Institution must subscribe to, and in respect of the Grant Funded Activities ensure compliance with, the National Intellectual Property Protocol.
- 8.3. The Host Institution shall: -
- 8.3.1 Devise, publish, implement and maintain procedures for the management of any Grant IP and shall use all reasonable endeavours to ensure that the Grant IP: -
    - 8.3.1.1 is identified, clearly defined, recorded and carefully distinguished from the other outputs of other research;
    - 8.3.1.2 is appropriately protected prior to any publication; and
    - 8.3.1.3 is translated and commercialised, where appropriate.
  - 8.3.2 Assist with the development of the appropriate commercial strategies referred to above.

- 8.3.3 Inform the HRB of, and provide reasonable details on, any outputs which are capable of exploitation or reuse, whether patentable or not.
  - 8.3.4 Inform the HRB of any outcomes and impact arising from translation (including commercialisation).
  - 8.3.5 Permit the HRB to audit the Host Institution and the Core Team's policies and procedures for the management of the Grant IP.
- 8.4. The HRB makes no claim to the Grant IP or any Intellectual Property in and to the Underlying Research Activities, except in respect of the rights expressly set out in this Clause 8.

## **9. Liability, Indemnity and Insurance**

- 9.1. The parties acknowledge and agree that:-
- 9.1.1 as between the HRB and the Host Institution, the Host Institution shall be wholly responsible for the conduct of the Grant Funded Activities; and
  - 9.1.2 as between the HRB, the Host Institution and the Sponsor(s), the relevant Sponsor(s) shall be wholly responsible for the conduct of individual Underlying Research Activities; and
  - 9.1.3 the HRB shall have no obligation, responsibility or any liability financial or otherwise of any kind to the Host Institution, the Infrastructure Director or any member of the Team or any third party arising directly or indirectly from the Grant, the Grant Funded Activities or the Underlying Research Activities or payment of the Grant or any part thereof or any representation or other act or omission connected with the Grant, save and except for the payment of the Grant in accordance with the terms and conditions of the Agreement.
- 9.2. The Host Institution shall use reasonable endeavours to ensure that the Host Institution shall enter into relevant contractual arrangements with each relevant Sponsor which provide that the Sponsor(s) is responsible for the conduct of the relevant Underlying Research Activities.
- 9.3. The Host Institution shall fully indemnify and keep indemnified the HRB, its officers, members, servants and agents on demand against all liabilities, losses, damages, costs (including legal and/or professional costs) and claims of any kind arising from any act or omission of the Host Institution, the Infrastructure Director or any member of the Team in connection with the Grant Funded Activities, the use of the Grant or from the provision of any funds, advice or assistance of any kind given by the HRB pursuant to the terms and conditions of this Agreement or otherwise howsoever including in relation to: -
- 9.3.1 the management monitoring and control (including the requirements of all regulatory authorities governing the use of radioactive isotopes, animals, pathogenic organisms, genetically manipulated organisms, toxic and hazardous substances and research on human or animals subject(s)) of any research funded by the Grant; and
  - 9.3.2 any claims by any member of the Team whether during or after the termination of this Agreement and whether under terms and conditions of this Agreement, tort, common law, statute or otherwise, including claims relating to the European Communities (Safe-guarding of Employee Rights on Transfer of Undertakings) Regulations, 2003;
- 9.4. Without limiting Clauses 9.1 and 9.2 above, the Host Institution shall fully indemnify, keep indemnified the HRB its officers, members, servants and agents on demand from and against all

proceedings, actions, costs (including legal and/or professional costs), charges, claims, expenses, damages, liabilities, losses and damages in respect of any injury, sickness, disease, personal injury to or the death of any person whatsoever or in respect of any loss of, destruction or damage to any property or any part of both, caused by or howsoever arising from any act, negligence, error, default, omission, breach of this Agreement or breach of statutory duty of the Host Institution, the Infrastructure Director or any member of the Team in connection with the performance of the Grant Funded Activities.

- 9.5. The Host Institution shall maintain the following insurances at all times during the Term with a well-established and reputable insurer or underwriter authorised to provide insurance in Ireland and shall furnish to the HRB details of such insurance on request: -
- 9.5.1 A public liability policy insuring against liability for any claims, losses, damages and expenses (including legal and/or professional costs) due to damage or destruction of property or death or personal injury of any person arising as a result of the Grant Funded Activities for an amount of not less than €6.5 million any one occurrence. The Host Institution's policy shall provide for indemnity to principals.
  - 9.5.2 An employer's liability policy insuring against liability for any claims, losses, damages and expenses (including legal and/or professional costs) due to the injury to or disease or death of any person employed or otherwise engaged by the Host Institution arising as a result of or in connection with the Grant Funded Activities for an amount of not less than €13 million any one occurrence. The Host Institution's policy shall provide for indemnity to principals.
  - 9.5.3 The Host Institution shall increase the insurance limits set out above and/or obtain additional cover at its own expense when reasonably required so to do by the HRB.
- 9.6. The insurances required to be obtained by the Host Institution pursuant to Clause 9.4 shall not limit the obligations, liabilities or responsibilities of the Host Institution under this Agreement or otherwise and the Host Institution shall discharge all of its obligations which are insurable under the terms and conditions of this Agreement whether or not it has the requisite insurance or has received payment in respect of the insured obligations from its insurers.
- 9.7. The HRB acknowledges that the Host Institution is not covered by the Clinical Indemnity Scheme and does not maintain medical malpractice insurance. The Host Institution shall use best endeavours to ensure that the Grant Funded Activities are covered by such insurance as is appropriate depending on the nature of the human participant activity concerned and obtain confirmation to its satisfaction that such insurance covers the Grant Funded Activities.
- 9.8. The Host Institution shall be liable to pay the full amount of any deductible or excess amounts arising under the insurance policies in respect of each and every claim.
- 9.9. The Host Institution shall notify the HRB of any claims made under its Public and Employers Liability policies such as they relate to the operation or performance of the Grant Funded Activities.
- 9.10. The Host Institution shall as soon as possible furnish to the HRB full details in writing of any event, occurrence or non-occurrence which is material to the indemnities and insurances provided for in this Clause 9.

## 10. Procurement

- 10.1. The Host Institution shall ensure that the procurement of Assets and services funded by the Grant is carried out in accordance with procurement law and policy including any guidelines issued by the Department of Public Expenditure and Reform (or similar) from time to time in relation to public sector procurement.

## 11. Assets

- 11.1. The Host Institution shall procure that at all times it has full and unencumbered title to all Assets and shall not dispose of or grant any security or otherwise deal with any Asset without the prior written consent of the HRB. Notwithstanding the foregoing, Host Institution shall be entitled:

- 11.1.1 to enter into asset leasing arrangements using the Grant to support the Grant Funded Activities in the ordinary course of its activities where these leases do not extend beyond the Term; and

- 11.1.2 to make use of, including to permit access by a third party to, any Asset funded by the Grant, but only to the extent the same is directly in support of the Grant Funded Activities (or clause 11.4 below) and only where permitting such access does not give rise to any potential for liability on the part of the HRB to that third party.

- 11.2. The Host Institution shall be responsible for ensuring that all such Assets have adequate insurance cover. If an Asset is damaged or destroyed, the Host Institution shall repair or replace it.

- 11.3. Any loss resulting from payments made for an Asset in advance of delivery will be entirely the responsibility of the Host Institution.

- 11.4. The Assets shall be used solely for the purpose of Grant Funded Activities and if during the Term or thereafter an Asset is not required for use in connection with the Grant Funded Activities the Host Institution shall so notify the HRB in writing and shall make it available for use in the following order of priority:

- 11.4.1 to any other grant funded activity within the Host Institution funded by the HRB;

- 11.4.2 to any research in Ireland in receipt of funding from the HRB;

- 11.4.3 to any other research within the Host Institution which is in receipt of funding from any agency of the Irish Government or the European Commission;

- 11.4.4 to any other research in Ireland which is in receipt of funding from any agency of the Irish Government or the European Commission;

- 11.4.5 to any research or use nominated or directed in writing by the HRB;

- 11.4.6 as the Host Institution itself may reasonably desire in furtherance of its educational research objectives;

provided that where any such Asset is made available for other use the Host Institution may require payment of a reasonable market fee in respect of such use which shall be treated as income of the Grant Funded Activity.

- 11.5. The Host Institution shall ensure effective asset management and maintenance standards and in particular shall maintain detailed and accurate records containing the following information (as relevant):

- 11.5.1 a description of each Asset;
  - 11.5.2 manufacturer's serial number and model number;
  - 11.5.3 source and/or supplier;
  - 11.5.4 details regarding the funding by which each Asset was acquired;
  - 11.5.5 details regarding title to each Asset;
  - 11.5.6 details of acquisition and cost;
  - 11.5.7 information from which one can calculate the percentage of the Host Institution's participation in the cost of the Asset;
  - 11.5.8 location and condition of the Asset and the date upon which that information was reported;
  - 11.5.9 ultimate disposition data, including date of disposal and sale price and the method used to determine current fair market value.
- 11.6. HRB shall be entitled to request the Host Institution designate or label certain specified Assets to acknowledge the support of the HRB.

## **12. Transfer of Grant**

- 12.1. The Grant is made personally to the Host Institution and the Host Institution shall not, without the prior written consent of the HRB, assign, transfer, sub-contract, charge or in any other manner deal with the benefit and/or burden of the Agreement.
- 12.2. The Grant shall not be transferred to another institution without the prior written consent of the HRB, the Host Institution and the new host institution, and any such transfer shall only be permitted in accordance with the HRB Policy on the Transfer of Awards.

## **13. Publication and Naming**

### **13.1. Publishing your research**

In accordance with the HRB Policy on Open Access and any Relevant External Policy, the Host Institution shall and shall ensure that any relevant member of the Team shall:

13.1.1 Subject to any Intellectual Property entitlement of third parties, deposit electronic copies of any research papers that have been accepted for publication in a peer-review journal, which are supported in whole or in part by the Grant Funded Activities, in an Open Access repository ideally at the time of acceptance by the journal and no later than the date of formal publication; and

13.1.2 Whenever possible, grant licences in respect of research papers such that they can be freely copied and re-used for, amongst other things, text and data-mining purposes, provided that such uses are fully attributed.

### **13.2. Communicating your research outcomes**

It is essential that the Host Institution ensures that any relevant member of the Team shall fulfil communications requirements in relation to Grant Funded Activities in line with the following:

- 13.2.1 Disseminate any findings, results or products of the Grant Funded Activities and/or the Underlying Research Activities in peer review publications through the media and among the general public as far as possible or practicable (unless this would undermine Intellectual Property or other rights/entitlements of the Host Institution, Infrastructure Director or the Team).
- 13.2.2 Prominently reference the HRB when publicising (publication, presentation, report, advertising, press release or media interview) any findings, results or products from any research studies included in or supported by the Grant Funded Activities as part of the wider responsibility to promote the value of health research to the public. This shall include, but is not limited to: -
- 13.2.2.1 Up to two agreed days during each successive twelve-month period of the Term when the Infrastructure Director or a relevant member of the Core Team will be available to promote and publicise its work, if required by the HRB.
- 13.2.3 Inclusion of the following statement within any press release issued by the Host Institution or the Infrastructure Director or related communications office.
- “The Health Research Board (HRB) is Ireland’s lead funding agency supporting innovative health research and delivering data and evidence that improves people’s health and patient care. We are committed to putting people first, and ensuring data and evidence is used in policy and practice to overcome health challenges, advance health systems, and benefit society and economy.”*
- or shall be in such other form as the HRB shall notify to the Host Institution from time to time.
- 13.2.4 Inclusion of the following footnote in any publication or presentation *“This research was [part] funded by the Health Research Board Ireland [insert HRB Grant Number].”*
- 13.2.5 All media releases involving, or supported by, the Grant Funded Activities must be sent to the HRB communications office ([communications@hrb.ie](mailto:communications@hrb.ie)) two days prior to general circulation.

### 13.3. Conditions related to use of HRB branding

- 13.3.1 Any advertisement or tender notice which is produced for the press, world-wide web or internal notice boards shall carry an acknowledgment of the HRB as a funding source and the logo of the Host Institution and the HRB. The HRB logo must be used in line with the HRB logo guidelines which are listed in the communications section of the HRB website (the **“HRB Branding Guidelines”**).
- 13.3.2 The Host Institution shall ensure that the HRB name is used [**INSERT AGREED NAME and TAGLINE-SEE NAMING CONVENTION SHEET**] In such circumstances:
- 13.3.2.1 the Host Institution shall comply strictly with the HRB Branding Guidelines and any relevant written directions given by the HRB regarding the use of the HRB name and logo. Where any such written directions conflict with the terms of the HRB Branding Guidelines, the specific written directions shall prevail.
- 13.4. Except as expressly set out in this Agreement, the Host Institution has no right to use, and no ownership right in respect of, any Intellectual Property in or to the HRB logo and name. Any and all goodwill in the HRB logo and name shall accrue to the benefit of the HRB and the Host Institution shall execute any document required to give effect to this clause.

- 13.5. During the Term, the Host Institution shall not change the name of any HRB Branded Infrastructure without the prior written consent of the HRB.
- 13.6. Following the Term, the Host Institution shall ensure that it ceases any and all further use of the HRB name and logo (and/or anything confusingly similar to the HRB name or logo) within a period of 20 Business Days after the Term, provided that it is acknowledged and agreed that the Host Institution shall not be obliged to put any written materials which are the subject of this clause beyond use by having them destroyed.

#### **14. Research Governance (Responsible Conduct of Research)**

- 14.1. It is the responsibility of the Host Institution to ensure that the Underlying Research Activities and any other research carried out in the course or with the support of the Grant Funded Activities is organised and undertaken within a framework of best practice and in accordance with the highest standards of scientific integrity and research methodology including ensuring adherence to HRB Policies, Relevant External Policies and all Applicable Law. The following shall be considered as minimum requirements in achieving the aforementioned high standards: -
- 14.1.1 The Host Institution shall have in place procedures for governing good research practice and reliable systems for the prevention of Misconduct and clearly defined procedures for the investigation of allegations of Misconduct. Such policies and procedures shall be publicly available and accessible to all research and administrative staff through the institution website and by all other means.
  - 14.1.2 The Host Institution shall as soon as possible furnish to the HRB in writing details of any proven allegation of Misconduct directly or indirectly relating to the Grant Funded Activities.
  - 14.1.3 The Host Institution shall be responsible for ensuring that issues of an ethical nature relating to research are identified at the earliest opportunity and where necessary approval obtained from an ethics committee(s) recognised by the Host Institution.
  - 14.1.4 The Host Institution must have in place effective and verifiable systems for managing research quality, progress and the safety and well-being of patients and other research participants. These systems must promote and maintain the relevant codes of practice and all relevant statutory review, authorisation and reporting requirements.
  - 14.1.5 Where the HRB has requested an Approvals Declaration and it has not been provided within a reasonable period of time thereafter, the HRB may suspend payment or further payment of the Grant until receipt by HRB of: (i) an up to date Approvals Declaration confirming that regulatory approvals are in place or (ii) confirmation in writing that the Grant Funded Activities which requires regulatory approval shall not begin until such approvals are in place.
  - 14.1.6 Where the Host Institution has more than one site, all clinical procedures involving the handling of samples must be carried out using standard operating procedures on all its sites with minimum common data-sets and striving towards best practice.
  - 14.1.7 Subject to compliance with Applicable Law, the Host Institution shall, as soon as possible furnish to the HRB details of any proven Bullying and/or Harassment directly or indirectly relating to the Grant Funded Activities.



## 15. Government Funding and State Aid

- 15.1. The Host Institution acknowledges that the HRB is dependent on the Irish State for funding of its Grant activities and that, if sufficient funding is not forthcoming from the State, the HRB may not be in a position to fund all of its grant commitments including the Grant. Accordingly, the Host Institution agrees that if the HRB does not have sufficient funding to cover all of its Grant commitments as aforesaid: -
- 15.1.1 The HRB shall be entitled in its sole discretion to determine which grant commitments it will continue and which commitments it will reduce, suspend, terminate or revoke; and
  - 15.1.2 The HRB shall be entitled in its sole discretion to forthwith reduce, suspend, terminate or revoke the Grant by written notice to the Host Institution.
- 15.2. The Parties acknowledge and agree that:
- 15.2.1 State aid law may apply to the Grant, this Agreement and the Grant Funded Activities; and
  - 15.2.2 HRB has agreed to award the Grant on the basis that the Host Institution complies with applicable State aid law.
- 15.3. In the event of an investigation by the European Commission or proceedings before any court or tribunal of competent jurisdiction are commenced or threatened concerning an allegation that the Host Institution's receipt of the Grant or the Grant Funded Activities are contrary to applicable State aid law ("**State Aid Investigation**"), then the Host Institution shall co-operate fully and promptly with any such State Aid Investigation and, if so requested by the HRB, promptly provide to the HRB all assistance, information and data in connection with any such State Aid Investigation.
- 15.4. In the event of any State Aid Investigation, the Host Institution shall keep the HRB fully and promptly informed and, to the fullest extent permitted by Applicable Law, liaise with the HRB concerning any response(s) to any such State Aid Investigation.
- 15.5. The obligations set out in Clauses 15.2 to 15.4 shall continue in full force and effect for a period of ten (10) years from the date of completion of the Grant Funded Activities, notwithstanding any earlier termination or expiry of this Agreement.

## 16. Term/Termination

- 16.1. The Term shall commence on the Commencement Date and, unless terminated earlier in accordance with the terms of this Agreement, shall continue for the Term.
- 16.2. The HRB will be entitled to reduce, suspend, terminate or revoke the Grant in whole or in part with immediate effect by written notice to the Host Institution if: -
- 16.2.1 any of the information in the Application is inaccurate in any material respect or any other information supplied for the purpose of drawing down the Grant or any instalment thereof is inaccurate in any material respect or if the Host Institution fails to disclose any information which the HRB reasonably regards as material for the purposes of determining whether the Host Institution is entitled to be paid any part of the Grant;

- 16.2.2 the Host Institution commits a material breach of the terms and conditions of the Grant and in the case of a breach capable of remedy fails to remedy the breach within thirty days of the date of written notice thereof containing reasonable details of the breach;
- 16.2.3 an encumbrancer takes possession of or a receiver or manager is appointed over any of the property or assets of the Host Institution or an application is made for the appointment of an examiner or an examiner is appointed to the Host Institution;
- 16.2.4 the Host Institution makes a voluntary composition with its creditors or is subject to an administration order;
- 16.2.5 the Host Institution goes into liquidation;
- 16.2.6 anything analogous to any of the foregoing under the law of any other jurisdiction occurs in relation to the Host Institution or;
- 16.2.7 the Host Institution is unable to pay its debts as and when they fall due within the meaning of Section 570 of the Companies Act, 2014;
- 16.2.8 distress or execution is levied on or issued against any property of the Host Institution;
- 16.2.9 any warranty or representation by the Host Institution is untrue or inaccurate;
- 16.2.10 the Host Institution or other member of the Core Team is unable to obtain any relevant permits, approvals, permissions or consents necessary for the carrying out of the Grant Funded Activities, any part of them or any activities supported by them;
- 16.2.11 the Host Institution ceases or threatens to cease to carry on the whole or any material part of its business.
- 16.2.12 if the Infrastructure Director or any member of the Core Team: -
  - 16.2.12.1 commits an act of bankruptcy;
  - 16.2.12.2 is convicted of any criminal offence;
  - 16.2.12.3 has devoted or intends to devote substantially less effort to the Grant Funded Activities;
  - 16.2.12.4 severs or intends to sever their connection with the Host Institution;
  - 16.2.12.5 has been absent for a continuous period of three months or more;
  - 16.2.12.6 has relinquished or intends to relinquish active direction of the Grant Funded Activities; or
  - 16.2.12.7 has their employment or engagement by the Host Institution terminated.
- 16.3. The Host Institution acknowledges that Grant must be spent during the Term or otherwise as set out in the Budget and/or as permitted by the Special Conditions. The HRB shall be entitled, but shall not in any circumstance be obliged, to approve a once-off No Cost Extension for a maximum period of 12 months beyond the end of the Term.
- 16.4. A request for a No Cost Extension, if desired, must be made in writing by the Host Institution and must comply with the HRB Policy on No Cost Extensions.

## **17. Effects of Termination**

- 17.1. In no event will the total of the Grant payments under a terminated Grant exceed the Grant.

- 17.2. Where the Grant is terminated in accordance with Clause 16 of this Schedule 2 the Host Institution shall be entitled to retain any part of the Grant already paid but the HRB shall have no liability to pay further amounts of the Grant but without prejudice to the liability of any party for any antecedent breach of this Agreement.
- 17.3. Where the Grant is terminated by the HRB in accordance with Clause 16 of this Schedule 2 the Host Institution shall repay to the HRB such sum as the HRB may demand (but not to exceed the amount of the Grant already paid to the Host Institution) in respect of the Grant and if the Grant is reduced the Host Institution shall repay to the HRB the amount by which the Grant has been reduced. The repayment shall be made within sixty days of the date of the demand and in default of payment within sixty days such sum may be recoverable by the HRB from the Host Institution as a simple contract debt.
- 17.4. The Host Institution shall repay to the HRB within thirty days any part of the Grant which remains unspent at the end of the Term or earlier termination thereof.
- 17.5. The right to terminate the Grant given by Clause 16 of this Schedule 2 is without prejudice to any other right or remedy of either Party under law or in respect of any antecedent breach of this Agreement.
- 17.6. Notwithstanding the expiration or earlier termination of the Term, all provisions of this Agreement designed to survive such expiration or earlier termination and all warranties and representations therein contained which shall not have been implemented and which shall be capable of continuing or taking effect shall endure and remain in full force and effect following such expiration or earlier termination.

## **18. Dispute Resolution/Arbitration**

- 18.1. The parties will use their best endeavours to resolve any dispute that may arise out of or related to the Grant, the Grant Funded Activities or this Agreement or any breach thereof. If any such dispute cannot be settled amicably through negotiations by authorised representatives of the HRB and the Host Institution, either Party may refer it to arbitration by a sole arbitrator to be appointed in default of agreement between the parties by the President or other Senior Officer for the time being of the Law Society of Ireland.
- 18.2. Any such referral shall be deemed to be a submission to arbitration within the meaning of the Arbitration Acts, 2010 and any award thereunder may be made a rule or order of the High Court in Ireland.
- 18.3. The award of the Arbitrator shall be final and binding on the parties.
- 18.4. The Arbitrator shall have power to determine all matters in dispute which shall be referred to him and the costs of and incidental to the reference and award respectively shall be at the discretion of the Arbitrator who may determine the amount thereof or direct the same to be taxed and any award made thereunder may be made a rule or order of the High Court in Ireland.
- 18.5. Nothing contained in this Clause 18 shall restrict the freedom of any party to commence legal proceedings to preserve any legal right or remedy or protect any Intellectual Property rights.

## **19. Entire Agreement and Counterparts**

- 19.1. Subject to the provisions of Clause 20 (Variation) of this Schedule 2, this Agreement and any documents referred to in it constitute the entire agreement between the Parties with respect to the Grant and supersede and replace any prior written or oral agreements, representations or undertakings between the HRB and the Host Institution relating to the Grant.
- 19.2. This Agreement may be executed in any number of counterparts and by the Parties on different counterparts. Each counterpart shall constitute an original of this Agreement but all the counterparts shall together constitute one and the same agreement.
- 19.3. Each Party consents to the execution by or on behalf of each other Party of this Agreement by electronic signature, provided that such manner of execution is permitted by law. The Parties also agree that an executed copy of this Agreement may be retained in electronic form and acknowledge that such electronic form shall constitute an original of this Agreement and may be relied upon as evidence of this Agreement.

## **20. Variation**

- 20.1. The HRB shall be entitled at any time to issue a Variation Notice. Any Variation Notice shall provide full details of the variation including the date (not being less than 30 days from the date of service of the Variation Notice) on which it becomes operative and the reasons for the change.
- 20.2. The Host Institution may within thirty days of receipt of a Variation Notice issue a notice of objection or refusal to the HRB setting out the reasons for such objection or refusal and the direct consequences (including breach of any contract directly related to the Grant Funded Activities between the Host Institution and a third party) that shall flow from the variation. If no such objection is received the Variation Notice shall thereupon become legally binding. The HRB shall give reasonable consideration to such notice of objection or refusal and within a reasonable period following receipt of the notice the HRB shall: -
  - 20.2.1 withdraw the Variation Notice in which event the Agreement shall continue in force unchanged;
  - 20.2.2 issue a revised Variation Notice having regard to the reasons given for any refusal or objection in which event the provisions of Clauses 20.1 and 20.2 shall apply mutatis mutandis to such revised Variation Notice; or
  - 20.2.3 terminate the Agreement by notice in writing to the Host Institution.
- 20.3. Where the notice of objection or refusal states that the variation specified in the Variation Notice would, if implemented, cause the Host Institution to be in material breach of a contract directly related to the Grant Funded Activities then the HRB shall act reasonably in good faith further consulting the Host Institution and shall give reasonable consideration to the matters raised by the Host Institution.
- 20.4. No variation of the Agreement or termination pursuant to Clause 20.2.3 shall give rise to any requirement for repayment by the Host Institution of the whole or any part of the Grant paid to it prior to the date of the Variation Notice save for any unspent part or incorrectly spent part of the Grant by reference to the Budget.

- 20.5. No Variation Notice shall affect any liability incurred by any party to the Agreement for a breach of the Grant incurred prior to the Variation Notice becoming effective.
- 20.6. The Host Institution shall be entitled to make a Host Institution Variation Request, subject to HRB Policies, on written notice to the HRB containing full details of the proposed variation and reasons for the Host Institution Variation Request. The HRB shall give reasonable consideration to the Host Institution Variation Request, in accordance with HRB Policies but unless it gives written notice accepting the Host Institution Variation Request within sixty days from receipt of the Host Institution Variation Request the Agreement shall remain in full force and effect.
- 20.7. Subject to Clauses 20.1 and 20.2 above, no variation of the Agreement shall be legally binding on either Party unless recorded in a written memorandum or letter signed on behalf of both Parties.

## **21. Severability**

- 21.1. If any provision or term of the Agreement or any part thereof shall become or be declared illegal, invalid or unenforceable for any reason whatsoever including by reason of the provision of any legislation or other provisions having the force of law or by reason of any decision of any court or other body or authority having jurisdiction over the parties including the EU Commission and the European Court of Justice such term or provision shall be severable from the Grant and shall be deemed to be deleted, provided always that if any such deletion substantially affects or alters the basis of the Agreement the parties shall negotiate in good faith to amend and modify the provisions and terms of the Grant as may be necessary or desirable in the circumstances in relation to the Agreement.

## **22. Nature of Relationship**

- 22.1. Nothing in this Agreement shall constitute: -
- 22.1.1 a partnership or joint venture or establish a relationship of agency between the parties;
  - 22.1.2 a contract of employment between the HRB, any member of the Team or any servant or agent of the Host Institution.
- 22.2. Neither the Infrastructure Director nor any member of the Team nor any servant or agent of the Host Institution shall be nor in any way represent himself to be an agent of the HRB and none of them shall have any authority to enter into obligation on behalf of the HRB or to bind the HRB in any way.

## **23. Waiver, HRB Approvals and other matters**

- 23.1. No failure or delay on the part of any party hereto to exercise any right or remedy under the Agreement shall be construed or operated as a waiver thereof nor shall any single or partial exercise of any right or remedy as the case may be.
- 23.2. The rights and remedies provided in the Agreement are cumulative and are not exclusive of any rights or remedies provided by law.

- 23.3. Neither the giving of any HRB Approval, knowledge of the terms of any agreement or document, review of any information, documents or other materials, or comment or absence of comments on any matter in the course of considering any request for HRB Approval by or on behalf of the HRB, shall relieve the Host Institution of any of its obligations under this Agreement or of its duty to ensure the correctness, accuracy or suitability of the matter or thing which is the subject of the HRB Approval, knowledge, review, comment or absence of comments.
- 23.4. Without limitation to the generality of the foregoing no examination or lack of examination by the HRB of any information, documents or other materials provided by or on behalf of the Host Institution generally under this Agreement nor any comment, rejection or HRB Approval expressed by such person in regard thereto, either with or without modifications, shall in any respect relieve or absolve the Host Institution from any obligations or liability under or in connection with this Agreement.

**24. Notices**

- 24.1. Any notice or document to be given under the Agreement shall be in writing and shall be deemed to have been duly given if delivered by hand, sent by ordinary prepaid post or email to the correct address (as may be amended from time to time by notice in writing to the other party) of the party to whom it is being sent.
- 24.2. The relevant addressee and address of each Party for the purposes of this Agreement are:

<b>Name of Party</b>	<b>Address, Addressee</b>
<b>HRB</b>	Grattan House 67-72 Lower Mount Street Dublin 2  FAO: Dr Teresa Maguire, RSF Director
<b>Host Institution</b>	[ • ]  FAO: [ • ] Email: [ • ]

- 24.3. Any notice or other document shall be deemed to have been received by the addressee as follows: -
  - 24.3.1 delivery by hand – day of delivery;
  - 24.3.2 ordinary post – two Business Days after posting
  - 24.3.3 email – when sent by email;

provided that if in accordance with the above provisions any such notice or other communication would otherwise be deemed to have been given or made outside working hours (being 9.00 a.m. to 5.00 p.m. on a Business Day) such notice, or other communication shall be deemed to have been given or made at the start of working hours on the next business day.

24.4. To prove the giving of a notice or other document it shall be sufficient to show that it was dispatched.

## **25. Law / Jurisdiction**

25.1. This Agreement, together with any non-contractual obligations arising in relation to it, shall be governed by and construed in accordance with the laws of Ireland and the parties exclusively submit to the jurisdiction of the Irish Courts.

## **26. Freedom of Information**

26.1. The HRB may be required to disclose information provided to it in response to a request under the Freedom of Information Act 2014 (the “FOI Act”).

26.2. If the Host Institution considers that any information supplied to the HRB is confidential and/or commercially sensitive it shall, at the time of providing the information, identify such information and give reasons for its confidentiality and/or commercial sensitivity. The HRB may, if it considers it appropriate or if it is obliged to do under the FOI Act, consult with the Host Institution prior to releasing or consenting to the release of such information in the circumstances mentioned in Clause 26.1.

26.3. If the Host Institution receives a request made under the FOI Act which relates to the Grant or to this Agreement, the Host Institution must (subject to applicable laws) notify and consult with the HRB on the response to the request.

26.4. The Host Institution acknowledges and agrees that the HRB shall be entitled to use information provided to it in the Application for the purpose of Grant, and reviews of the Grant Funded Activities including for the purposes of: -

26.4.1 registration of the Application;

26.4.2 operation of grant processing and management information systems;

26.4.3 preparation of material for use by referees and peer review panels;

26.4.4 administration, investigation and review of the Application;

26.4.5 sharing information furnished in the Application on a strictly confidential basis with other funding organisations;

26.4.6 statistical analysis in relation to the evaluation of research and the study of trends;

26.4.7 policy and strategy analyses;

26.4.8 Meeting the HRB’s obligations for public accountability and dissemination of information;

26.4.9 posting of details of the Grant Funded Activities on the HRB website and other publicly available databases and in reports, documents and mailing lists; and

26.4.10 furnishing the details and information referred to in Clauses 26.1 and 26.4.1 to 26.4.9 above to meet HRB Policies and Relevant External Policies.

## 27. Data Protection

### 27.1. Processing of Personal Data by HRB

27.1.1 HRB will collect, use and disclose Personal Data provided in the Application and otherwise obtained under or in connection with this Agreement for processing the Application, making a Grant, for the payment, monitoring, maintenance and review of the Agreement, for the performance of its statutory powers and functions and for the general activities of HRB.

27.1.2 Further details regarding HRB's collection, use and disclosure of Personal Data and individuals' rights in respect of Personal Data relating to them which is held by HRB are available in the privacy statement on the HRB website.

### 27.2. Processing of Personal Data by the Host Institution

27.2.1 The Host Institution acknowledges that the Grant Funded Activities may involve the processing of Personal Data. In such circumstances, the Host Institution warrants and undertakes that it shall process such Personal Data in accordance with Data Protection Law.

## 28. Legal Proceedings

28.1. The Host Institution shall and shall ensure that the Infrastructure Director and any member of the Core Team shall agree to be available to participate in any legal proceedings arising out of this Agreement including proceedings in connection with the ownership, exploitation, commercialisation and/or management of any Intellectual Property.

## 29. Confidentiality

29.1. In this clause "**Confidential Information**" means all information disclosed whether in writing, orally or by another means whether directly or indirectly and whether specifically designated as "confidential" or which ought reasonably to be regarded as confidential under or in connection with the Agreement by one party (the "**Disclosing Party**") to the other party (the "**Receiving Party**") whether before, on or after the date of this Agreement.

29.2. Subject to the provisions of Clause 8 (Intellectual Property), Clause 13 (Publication) and Clause 26 (Freedom of Information) all of this Schedule 2, during the Term and after termination or expiration of it for any reason the Host Institution shall: -

29.2.1 not disclose Confidential Information for any purpose other than the performance of its obligations in relation to the Agreement;

29.2.2 not disclose Confidential Information to any person except with the prior written consent of the Disclosing Party;

29.2.3 make every effort to prevent the use or disclosure of Confidential Information.

29.3. The Receiving Party may disclose Confidential Information to any of its directors, other officers and employees (a "**Recipient**") to the extent that the disclosure is reasonably necessary for the purposes of the Agreement.



- 29.4. Before disclosure to a Recipient the Receiving Party shall ensure that the Recipient is made aware of and complies with the Receiving Party's obligations of confidentiality as if the Recipient was a party to the Agreement.
- 29.5. The Receiving Party may disclose Confidential Information of the Disclosing Party if and to the extent that: -
- 29.5.1 it is required by the law of any relevant jurisdiction (including the Freedom of Information Act 2014) or pursuant to an order of a Court of competent jurisdiction;
  - 29.5.2 it is necessary for the professional advisors, auditors and bankers of the Receiving Party;
  - 29.5.3 the Confidential Information has come into the public domain through no fault of the Receiving Party;
  - 29.5.4 the Confidential Information was in the possession of the Receiving Party before such disclosure by the Disclosing Party;
  - 29.5.5 the Confidential Information was obtained by the Receiving Party from a third party who was free to divulge it;
  - 29.5.6 it is required to enable that party enforce its rights or perform its obligations (including the publication obligations in Clause 13 of this Schedule 2) under the Agreement; or
  - 29.5.7 it is disclosed to a bona fide current and/or potential purchaser, investor and/or lender of the Receiving Party and any legal and/or professional representative thereof provided that such potential purchaser, investor and/or lender shall be subject to a confidentiality agreement (on terms usual to such transactions) covering such Confidential Information.
- 29.6. The parties acknowledge and agree that in the event of a default of the obligations set out in this clause, damages may not be a sufficient remedy for the Disclosing Party. Accordingly, in addition to other remedies, such Disclosing Party will have the right to seek injunctive relief or specific performance of the other party's obligations. Any such remedy shall not be deemed to exclusive and shall be in addition to any and all other remedies which may be available to the other party at law or in equity.
- 29.7. Upon termination or expiry of the Agreement the Receiving Party shall at the option of the Disclosing Party either destroy or return to the Disclosing Party all records, documentation or other information of the Disclosing Party and all copies thereof which are held by the Receiving Party.
- 29.8. The obligations of each of the parties as to disclosure and confidentiality shall continue in force notwithstanding the termination of this agreement or expiration of the Agreement.

### **30. Taxation**

- 30.1. The payment of the Grant or where payment is to be made by instalments the payment of each instalment is subject to the Host Institution furnishing to the HRB a valid tax clearance certificate confirming that its tax affairs are in order as of the date of each such payment.

**31. Force Majeure**

- 31.1. Neither Party shall be liable to the other in contract, tort or otherwise for any failure or delay in the performance of any of its obligations under the Agreement that is caused by any event of force majeure including an act of God; labour dispute; or interruption or failure of utility service.

**SCHEDULE 3**

**SPECIAL CONDITIONS**

[ • ]

## SCHEDULE 4

### BUDGET AND FINANCIAL SCHEDULE

#### 1. Budget details

##### «Contract Budget Table»

- 1.1. Income tax and PRSI must be paid from the salary amount.
- 1.2. The salary contribution above includes a 5% employee's pension contribution.
- 1.3. Where applicable due to the Host Institution being a Higher Education body, pension provision up to a maximum of 20% of gross salary will be paid to Host Institutions to enable compliance with the Employment Control Framework for the Higher Education Sector 2011-2014 (as amended, superseded or replaced from time to time).
- 1.4. Any amounts in any Grant (including in the Budget table above) expressed to be payable in respect of pension contributions or provisions shall not be permitted to be applied by the Host Institution to disburse any other category of direct or indirect cost of the Host Institution or the Team.

#### 2. Details of agreed Co-Investment (if applicable)

- 2.1. As a condition to the provision of the Grant, the Host Institution has agreed to procure that the Co-Investment outlined in this Schedule be provided, or made available, by one or more named Co-Investors in further support of the Grant Funded Activities.
- 2.2. Where the table below additionally indicates that any element/line item of the Grant is payable only (in whole or in part) on the occurrence of a linked Co-Investment amount/contribution (including in any given ratio to any HRB Grant element), then any such element/line item is only payable by the HRB where the HRB is satisfied (based on documented evidence where requested) that any such Co-Investment has actually been made or is legally due to be made as envisaged in this table.

##### Co-Investment table

##### [CoInvestment Table]

- 2.3. Without prejudice to the foregoing, where under Clause 7.3.19 the Host Institution has notified the HRB in writing that the Host Institution considers it likely that any Co-Investment is not or will no longer be forthcoming, or not at such levels or ratios, the Host Institution and the HRB shall meet without undue delay to discuss the matter to agree in writing, but only where the HRB is agreeable to a revised Budget in its sole discretion, any consequential variations to the Budget.
- 2.4. Fulfilment of Co-Investment funding as per the agreed Co-investment contribution in the Budget in Schedule 4 shall be assessed and, if not in line with proposed commitments, the HRB reserves the right to adjust the Grant accordingly.

### 3. Payment Procedure

- 3.1. Payment will be made, subject to compliance with the terms and conditions of this Agreement and in accordance with the following:-
- 3.1.1 The Host Institution shall submit quarterly claims in writing for payment as set out in the Budget, such claims to be made in arrears setting out the details of the actual expenditure incurred and shall contain, or be accompanied by, such reasonable information (and where requested by the HRB, accompanying Financial Records) as may be required by HRB. Any such quarterly claims shall be made in the format or using the method as required by the HRB from time to time.
- 3.1.2 The first quarterly claim shall cover the period from the Commencement Date to the last day of the calendar quarter during which the Commencement Date occurs (i.e. 31 March, 30 June, 30 September or 31 December of the current calendar year) and shall be submitted no later than the 21st day of next calendar month after the relevant calendar quarter (i.e. 21 January, 21 April, 21 July or 21 October as applicable) and continue on a quarterly basis thereafter for the Term. The final quarterly claim for each calendar year during the Term should also include the annual cumulative claim for the elapsed calendar year and should be submitted by the 21st January of the current calendar year.
- 3.1.3 Where 10% of the Budget for the previous 12 month Budget year (or part of such period in the first 12 months of the Term) has either not been claimed, or over-claimed, HRB is agreeable to allow 10% of such elapsed Budget year to be adjusted into the next 12 month Budget year(s) provided that:-
- 3.1.3.1 the Host Institution submits such claim to HRB for approval with details of what line items of the Budget are to be adjusted in the next 12 month Budget year(s). The proposed Budget for the next 12 month Budget year shall accompany such request;
- 3.1.3.2 the Host Institution in submitting such request confirms that it will enter into a Variation Notice to adopt the revised Budget, if approved, to the Grant; and
- 3.1.3.3 at no time shall the total Budget exceed the original amount issued with the Grant, or most recent Variation Notice, in total or cumulatively.
- 3.1.4 The HRB shall be entitled to have the annual cumulative claim audited at its expense by its nominated auditors on a date agreed between the Host Institution and the HRB. Payment for the final quarter will follow completion of a satisfactory audit (where performed).
- 3.1.5 The Host Institution shall submit a financial forecast for each year of the Term by the 21st January of each year to include the budget with respect to the Grant and the Co-Investment funding element.
- 3.1.6 The Host Institution shall complete and provide along with the quarterly claims a financial report detailing the income and expenditure on Co-Investment to date in line with the quarterly claims and payment schedule, along with any other income and expenditure related to the Grant.

**«Payment Schedule Table System»**



## SCHEDULE 5

### HRB ENGAGEMENT FORUM

- 1.1 The Host Institution acknowledges and agrees that the HRB has a legitimate interest in the ongoing progress, and ultimate success, of the Grant Funded Activities with a view to furthering the HRB's overall aim of supporting the design, conduct and evaluation of healthcare intervention studies in order to improve health outcomes and health service delivery.
- 1.2 To this end, promptly following the date of this Agreement, the Parties shall establish and maintain a group to periodically review and discuss mutually beneficial actions related to the Grant and the Grant Funded Activities (the "**HRB Engagement Forum**"). Where one or more Co-Investors are providing investment or contributions in or to the Grant Funded Activities, the HRB Engagement Forum shall also include the participation of such Co-Investor(s).
- 1.3 The HRB Engagement Forum shall be comprised of individuals of sufficiently senior standing and no less than two representatives appointed by the Host Institution, no less than two representatives appointed by the Co-Investors (if applicable), and no less than two representatives appointed by the HRB. The Host Institution shall use best endeavours to procure that: (i) each relevant Co-Investor appoints two representatives to the HRB Engagement Forum; and (ii) each Co-Investor representative participates in the HRB Engagement Forum. Where the Host Institution is also a Co-Investor it shall not be necessary for any more than the minimum of such representatives of the Host Institution, detailed above, to be appointed.
- 1.4 As at the date of this Agreement, each of the Host Institution (including in respect of the Co-Investors (if applicable)) and the HRB confirms that the individuals set opposite its (or the relevant Co-Investor's) name in the following table are hereby authorised to represent it (or the relevant Co-Investor) on the HRB Engagement Forum from time to time (each, a "**HRB Engagement Forum Representative**"):

Host Institution HRB Engagement Forum Representatives	[ • ] (Infrastructure Director) [ • ]
Co-Investor HRB Engagement Forum Representatives	[ • ] [ • ]
HRB Engagement Forum Representatives from the HRB	RSF Director (Dr Teresa Maguire) RSF RAI HOU (Ms Oonagh Ward)

- 1.5 Each HRB Engagement Forum Representative acts as a representative of the Party (or Co-Investor) who nominated them and not in any personal capacity.
- 1.6 The HRB shall each have the right, at any time, to remove any of its respective HRB Engagement Forum Representatives and replace any such person with such other person as the HRB may, in its discretion, determine upon written notice to the other HRB Engagement Forum Representatives.
- 1.7 The Host Institution and the Co-Investor shall not have the right to remove and replace any of its respective HRB Engagement Forum Representatives, except with the prior written consent of the HRB (provided that at all times the Infrastructure Director shall be one of the Host Institution's representatives on the HRB Engagement Forum).

- 1.8 An HRB Engagement Forum Representative shall not be entitled to appoint an alternate or alternates to attend any HRB Engagement Forum meeting in their place.
- 1.9 If desired, the HRB may appoint one of the HRB Engagement Forum Representatives appointed by it as the chairperson.
- 1.10 The quorum for any meeting of the HRB Engagement Forum shall be two representatives from each of the Host Institution, each Co-Investor and the HRB.
- 1.11 A HRB Engagement Forum Representative is deemed to be present for the purposes of being counted in the quorum if he or she attends the meeting in person or is in communication with the other representative(s) by telephone or other communication equipment. Each Party shall use best endeavours to procure that its representatives (which, in the case of the Host Institution, shall also include any relevant Co-Investor representative) attend any such meeting.
- 1.12 The HRB shall be responsible for recording and circulating to the other HRB Engagement Forum members in advance of the next such meeting, outline meeting minutes which shall include, in particular, any agreed action items and outcomes from the previous meeting.

#### **Topics for discussion**

- 1.13 The HRB shall circulate an agenda for discussion for each meeting to the HRB Engagement Forum, however, it is envisaged that the HRB Engagement Forum shall from time to time consider and discuss matters which may include:
  - (a) the on-going performance of the Grant Funded Activities, including against any metrics specified by the HRB from time to time; and
  - (b) the outcomes of the Underlying Research Activities; and
  - (c) summary of expenditure in connection with the Budget, as applicable; and
  - (d) tracking progress of the Host Institution and Team against any agreed targets or milestones; and
  - (e) the potential for the Grant Funded Activities to further or better contribute to the HRB's overall current strategy and to find innovative and useful ways of furthering interactions between the Grant Funded Activities and other infrastructure or research funded by the HRB or taking place in Ireland or elsewhere; and
  - (f) risk identification and management; and
  - (g) on-going support of core functions (to include financing and funding); and
  - (h) any other matters as notified to the Host Institution from time to time by the HRB or agreed between the Parties as being suitable for discussion.
- 1.14 The HRB Engagement Forum must meet (unless otherwise agreed), by phone or other virtual communications method or in person, bi-annually to review, discuss and consider matters relating to Grant and the Grant Funded Activities.

#### **Input reporting**

- 1.15 At least ten Business Days prior to any meeting of the HRB Engagement Forum, the Host Institution must provide the following information to the HRB in outline or summary form, which shall be in the form of any HRB template summary reporting document issued from the HRB from time to time for these purposes:



- (a) any significant clinical and non-clinical developments in the Grant Funded Activities begun, anticipated or completed since the previous meeting of the HRB Engagement Forum;
- (b) performance against any metrics specified by the HRB in the period;
- (c) any change in membership of the Core Team or of any governance body or entity operating, or advisory group assisting, the Grant Funded Activities since the previous meeting of the HRB Engagement Forum;
- (d) information on identified risks and risk management; and
- (e) any other matters as notified to the Host Institution from time to time or agreed between the Parties.

1.16 The participation of the HRB in the HRB Engagement Forum is expressly without prejudice to the exercise of any of its other rights or remedies in this Agreement.

## SCHEDULE 6

### HRB CORE PERFORMANCE METRICS FOR CLINICAL TRIAL ACTIVITY

Domain/Area	Metric	Definition
<b>Start Up Speed</b>	Time from clinical trial agreement contract execution to PPFV	The time (days) between the date of an executed contract and the date of the First Patient First Visit
	Time from protocol submission to ethics committee to ethics decision (ethics completion time)	The time (days) between the dates of initial submission to the ethics committee and the protocol approval with no contingencies remaining
	Time from protocol submission to the HPRA to receipt of HPRA decision (approval completion time)	The time (days) between the dates of initial submission to the HPRA and the protocol approval with no contingencies remaining
<b>Patient Recruitment and Retention</b>	Total actual recruitment versus total target recruitment by month	The actual number of participants recruited into the trial by the sites by month, versus the target number that was contractually agreed with the sites by month prior to the trial commencing
<b>Data Management</b>	Percentage of randomised participants with complete data for primary and secondary outcome data	The percentage of randomised participants at the site with outcome data complete for both the primary outcome and all the agreed important secondary outcomes
<b>Protocol Compliance</b>	Percentage of randomised participants receiving allocated intervention as intended per protocol	The percentage of randomised participants at the site who completed the allocated intervention, as specified in the protocol

### HRB INFRASTRUCTURE AWARD METRICS – COMMON CORE METRICS

Domain/Area	Metric	Definition
<b>Enabling Scientific Excellence</b>	Number and percentage of successful grant proposals	Number and percentage of funded grant proposals with accepted users and provision of supports and services of total grant proposal applications
	Percentage of top (10%) cited publications	Percentage of publications based on research performed using facilities/resources of the RI that, compared with the publications in the

		same field and in the same year, belong to the top 10% most frequently cited.
<b>Delivery of Education and Training</b>	Number of master and PhD students using the RI	Number of master and PhD students who have performed some of their studies at or using the services of the RI in a particular year regardless of whether they are funded/hosted by the RI or access it as a user
	Training of people who are not RI staff	The total number of person hours for which people external to the RI have made use of training opportunities provided by the RI, through both real (e.g., face to face) events and on-line services
<b>Facilitating Economic Activities</b>	Share of users associated with industry and publications with industry	Number of users directly linked to industry
	Income from commercial activities and the number of entities paying for service	Share of revenue from the RI's economic activities (sale of services and goods, access provision) reported in the in the annual accounts
<b>Outreach to the Public</b>	Engagement achieved by direct contact (events, visitors, guided tours	Outreach by public relations/direct contact with specific target groups: organisation of (e.g., summer schools, events for industry, government)
	Outreach through printed, broadcast and web-based media	Impact of press and communication actions in raising awareness of RI mission, activities and societal relevance of results
	Outreach via the RI's own web and social media activities	Website popularity and level of social media engagement: Web (e.g., Google analytics) analytics and social media analytic tools (Twitter, LinkedIn, Youtube, Flickr, Facebook, etc.)
<b>Optimising Data Use</b>	Number of publicly available data sets used externally	Number of data sets produced as a consequence of access to the RI that are subsequently accessed by other users
<b>Provision of Scientific Advice</b>	Participation by RIs in policy related activities	Number of participations, reimbursed by the organisers, in policy related working groups, committees & advisory boards. In the case of working groups, etc, organised by intergovernmental organisations, the invitation suffices.
	Citations in policy related publications	Number of times the RI or its projects are cited in policy related publications
<b>Optimising Management</b>	Extent of Resources made available to users	Experimental time available or size of resources database made available to users to facilitate research.
	Revenues	Sources of revenue and their respective contributions to investments and operational costs

Signed on behalf of  
**«Host Institution»**  
by a duly authorised officer

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Full Name

\_\_\_\_\_  
Date Signed

Signed on behalf of the **HRB**  
by a duly authorised officer

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Full Name

\_\_\_\_\_  
Date Signed

**«Grant Reference»**