MRC/Wellcome-funded Human Developmental Biology Resource (HDBR)

Registration Form

Project Title:	
Principal Investigator:	
Position Held:	

Institution:			
Address:			
Telephone No:		**Ext No:**	
E-mail address:			

I am applying to use the HDBR In House Gene Expression Service (IHGES): ☐ **Yes** ☐ **No**
This is an extension of a previous project: ☐ **No** ☐ **Yes, project number:**

For official use only

Project Number:		**Date project-specific ethics received:**	
Date Project Registered:		**Date MTA Agreed:**	
Date Project Started:		**Date Project Finished:**	

This form consists of 3 sections:

1. Project background and finance details.
2. Materials requested.
3. Conditions of use of the HDBR, contact details and signatures.

Section 1. Project Description

1. To allow the HDBR Steering Committee to review your project, please give a short summary (maximum of 500 words) of the background/history to your proposed research.

Please include details of:

a. Background and introduction to project.

b. Will the proposed project involve any of the following:

☐ Create neuronal “assembloids” derived from more than one tissue type – for example neuronal-sensory cell types (e.g. eye, ear) or neuronal-motor (muscular) cell types?

☐ Produce germ cells (including primordial germ cells)?

☐ Culture cells or their derivatives indefinitely, or plan to freeze down cultures to be resurrected in the future?

☐ Operate a ‘biobank’ of HDBR-derived cellular material (e.g. organoids), to be provided to secondary users?

☐ Transfer HDBR tissue into animals?

☐ Use HDBR derived tissue for commercial purposes?

c. Objectives of proposed study.

- List the main objectives of your proposed study in order of priority.

d. Technical summary.

- Outline the techniques and experiments planned.
- If culturing tissue (cells or organoids) include details on the maximum length of time the cultures will be maintained and what will happen to the cells/tissue once the project has been completed.

e. Justification of numbers of samples being requested.

- Attention should be given to the number of samples required to complete the study. Sample numbers required to produce statistically meaningful results must be considered alongside the understanding that the samples are scarce,

f. What data will be generated and where will it be stored?

- It is strongly encouraged by our funders to deposit all data generated in open access databases.

- Whenever generating data on microscope slides, please record the experimental details using the Slide Experimental Details form (http://hdbr.org/uploads/default/factsheets/1529682017_f53_hdbr-slide-record.pdf). The data will be uploaded to the HDBR Atlas website (www.hdbratlas.org) - a publicly available resource for sharing human gene expression data.

- When returning your results slides to the HDBR (see Section 3 HDBR Terms and conditions) please include a completed Slide Submission form (http://hdbr.org/uploads/default/factsheets/1529682017_f53_hdbr-slide-record.pdf).

g. Describe who will benefit from the proposed research.

2. Project description suitable for lay person review (150 word summary).

Please note this information will be included in the HDBR's annual ethics report, to be reviewed by the Health Research Authority.

3. Project funding (ongoing or planned). Please specify:

a. Funding body:
b. Grant start date:
c. Grant end date:

4. Collaborators:

Please provide details of any project collaborators and provide full details of their part in the proposed project (continue on a separate page if there is more than one collaborator).

a. Name:
b. Institution:
c. Address:
d. Telephone number:
e. Email address:
f. Role in project:
g. Will HDBR tissue, its derivatives or data be shared with this collaborator, please provide details:

5. Where did you hear about us?

a. HDBR Website (www.hdbr.org): ☐
b. MRC/Wellcome Trust information: ☐
c. Personal recommendation: ☐
d. Conference: ☐
e. HDBR flyer: ☐
f. Paper citation: ☐
g. Other, please specify: ☐

6. Will the material requested, or any data generated from this study, be used for commercial purposes or used in support of a filed patent application? If yes, please provide further details.

Finance Details

Upon registration of an HDBR project an initial administration fee of £500 (plus VAT) for academic users and £1,000 (plus VAT) for commercial users will be payable for each registered project. A purchase order (or internal grant code/cost centre number) for this payment will be requested upon registration of the project.

An annual administration fee of £500 plus VAT (academic) and £1,000 plus VAT (commercial) will be payable per annum for the duration of the project and is non-transferable upon renewal or completion of the project.

Other costs may be incurred during the project lifecycle (i.e., prepaid courier shipment fees, dry ice and shipments costs, solution/reagents, other agreed costs, IHGES fees).

All financial transactions external to Newcastle University require the provision of a purchase order made payable to Newcastle University and a copy provided to hdbr@newcastle.ac.uk. Invoices cannot be raised, and payments cannot be allocated to projects if this document is not provided by the user.

UK Credit card payments for the £500 (plus VAT) administration fee can be made via our webstore without a purchase order. A webstore receipt will be supplied upon completion of the transaction. However, if an invoice is required, a purchase order will need to be supplied.
https://webstore.ncl.ac.uk/product-catalogue/faculty-of-medical-sciences/medical-sciences/hdbr

HDBR material can only be provided once payment is received.

Please provide the following information:

Full contact details of your Finance Department: Postal address: Tel. number: Fax number: Contact person (+ email address): PO Number / Grant Code (internal)	
International users: Bank Name and Address: Bank Account No: Sort Code: IBAN Swift Code	
VAT registration number: (UK/EU Countries only)	

Commercial organisations can address queries to the Resource Manager at either hdbr@ncl.ac.uk or hdbr@ucl.ac.uk.

I confirm that I have read and understood the financial requirements outlined in the project registration form.

Name:	Signature:

Section 2. Materials Requested

In most cases, a maximum of 25 tissue samples will be released from the HDBR in the first instance. A project update form will need to be completed and returned before further tissues can be provided, and again after every 25 samples to a maximum of 100 tissues. When requesting slides, up to 20 slides may be requested from each wax block from a maximum of 25 wax blocks.

The total number of samples requested across tables 1a (archived tissue) and 1b (fresh tissue) must not exceed 100. In the case of slide requests, the wax block from which the slides were sectioned is considered to be one sample.

Table 1a: for receiving archived material (fixed, wax-embedded or frozen tissue, sectioned material on microscope slides, cDNA, RNA OR DNA).

*Please complete table **1b** on the following page if you are applying to access material from the ongoing collection (fresh tissue).*

Source of materials requested		**Material preparation**						
Tissue or Organ	***Stage (specify CS or pcw)**	**Number of slides (maximum of 20 slides per wax block)**	**Number of wax blocks**	**Number of formalin fixed tissues**	**Number of frozen tissues**	**Number of genomic DNA aliquots**	**No of RNA aliquots**	**No of cDNA aliquots**
		Sub total	**Sub total**	**Sub total**	**Sub total**	**Sub total**	**Sub total**	**Sub total**
Total number of tissues requested (wax blocks, frozen tissues, or cDNA/RNA/DNA aliquots) =								
Total number wax blocks / slides requested =								

*Please refer to staging guides on HDBR website (http://hdbr.org/factsheets).

Table 1b: for receiving material from the ongoing collection (fresh tissue)

*Please complete table **1a** on the previous page if you are applying to access archived material (fixed, wax-embedded or frozen tissue, sectioned material on microscope slides, cDNA, RNA or DNA). Please indicate the TOTAL number of samples required to complete the project.*

Tissue Requested			Sample Processing			Comments
Number of samples	**Organ/Fetal abnormality**	***Stage from** **Please indicate CS or pcw**	**Fixative**	**Media (L15 is standard, if not please specify)**	**Storage temperature**	**(e.g. if all organs must come from same fetus, or if any special instructions are required for tissue processing)**

The total number of samples requested (tables 1a and 1b) should not exceed 100. Samples will be dispatched in batches of no more than 25 following which a completed feedback form must be returned in order to receive the next batch of samples.

Total number of samples requested =

Total number of archived samples requested (table 1a) =

Total number of fresh tissues request (table 1b) =

*Please refer to staging guides on HDBR website (http://hdbr.org/factsheets).

1. Receiving tissue from the HDBR.

Do you wish to receive tissue from:

Newcastle: collect in person ☐ Arrange for collection by courier ☐
London: collect in person ☐ Will arrange a courier ☐

Note:

EU: EORI Number required for shipments: **EORI Number:**
USA: CDC Declaration required for the import of UN3373 Category B samples into the USA

Contact Details

Please confirm the contact details of two members of staff who will arrange for couriers or collection of material from the HDBR. Ideal candidates are post-docs or research assistants who are working directly on the proposed project.

Name 1st Contact:			
Telephone No:		**Ext. No:**	
E-mail address:			

Name 2nd Contact:			
Telephone No:		**Ext. No:**	
E-mail address:			

3. Material Transfer Agreement (MTA)

Before any material can be released from the HDBR you will need to enter into an MTA to cover the transfer of material to your Institution. Separate MTAs will be required from the two HDBR centres: Newcastle (Newcastle University) and London (UCL). Once your project has been officially registered with the HDBR, draft MTA documents will be sent to your institution to agree and countersign.

Tissue must not be sent to collaborators without prior discussion with the HDBR and a Material Transfer Agreement being in place to cover the movement of the material, even to researchers within the same institution (please see operating principles – https://hdbr.s3.eu-west-2.amazonaws.com/downloads/hdbr-operating-principles.pdf).

Name of person who will prepare MTA
(usually within Contracts Dept.):

Position:

Postal Address:

Telephone number:

Email:

4. Project ethics approval

Most UK-based HDBR projects are covered by the HDBR research tissue bank ethical approval. Confirmation of favourable ethical opinion can be downloaded here: http://hdbr.org/ethical-approvals.

Please specify which of the following apply:

a. The project will be based solely within the UK and it will be undertaken using the HDBR research tissue bank ethics. ☐

b. The project will be based outside the UK and local ethics approval has been obtained: ☐

   i) Please forward a copy of a letter confirming favourable ethical opinion.

c. The project is based within the UK and has received local ethical approval ☐

Section 3. Conditions of use of the HDBR

On signing this form, the applicant agrees to be bound by the following conditions, which have been established by the Joint Steering Committee, which oversees and regulates the operation of the HDBR:

I understand that HDBR samples are not screened for viruses or other pathogens and should be treated as potentially pathogenic. A comprehensive risk assessment must be performed and documented acknowledging this risk before receiving any tissue from the HDBR. Whilst some limited donor information is recorded and can be supplied to researchers, all samples are collected anonymously which means there is no possibility of returning to donors for additional clinical testing or to obtain identifiable patient data.

Additional information can be found in our factsheet "Limitations of working with human material" (http://www.hdbr.org/factsheets/).

HDBR Terms and Conditions

The following Terms govern use of HDBR material. Please read these carefully you agree to be bound by these Terms and Conditions when registering your project with the HDBR and signing below.

I agree to:

- respect the value of this human material.
- abide by the Human Tissue Authority codes of practices www.hta.gov.uk, ISSCR guidelines and conditions laid out in the ethics approval of the HDBR research tissue banks.
- use the material only for the approved purpose described in my HDBR registration and shall not transfer this material (or derivatives including cell lines) to any third party without the prior written consent of the HDBR.
- submit a new project application if I wish to use HDBR material for a different purpose.
- perform a laboratory risk assessment before any HDBR material is used.
- pay the annual HDBR registration fees and, if appropriate, ensure MTAs are in place to cover transfer of the material.
- submit a project report to the HDBR every 6 months following project registration or after, 25 tissue samples have been received.
- inform the HDBR once a manuscript has been accepted for publication.
- inform the HDBR if I change institution or university.
- inform the HDBR before commercialising any results or materials provided by the HDBR.
- use the following wording in any publications arising from this work (including presentations and posters), "The human embryonic and fetal material was provided by the Joint MRC/Wellcome Trust (grant# MR/R006237/1) Human Developmental Biology Resource (www.hdbr.org)." Any subsequent secondary publications arising from data generated from HDBR material should similarly acknowledge the HDBR.
- give appropriate acknowledgement to the HDBR in any subsequent secondary publications arising from data generated from HDBR material.

I also agree to:

- the HDBR withholding material until a project report has been received.

- the HDBR refusing my application or terminating the supply of HDBR material without prior notice, and without giving a reason for this decision.
- the tissue requested being released in a staged manner depending upon satisfactory and demonstrable research progress being made.
- the project being terminated if a project report is not submitted when requested.
- the project registration continuing for a maximum of five years.
- my HDBR project title and institutional affiliation being published on the publicly accessible HDBR website www.hdbr.org/projects

Following publication, or one year after the submission of a final report to the HDBR, I agree to:

- return all gene and protein expression images taken from microscope slides.
- provide details of antibodies and probes used for all slides returned http://hdbr.org/uploads/default/factsheets/1529682017_f53_hdbr-slide-record.pdf
- HDBR capturing images from returned slides and adding them to the HDBR gene expression database www.hdbratlas.org.
- submit all sequencing data and data generated from all high through-put studies to a publicly accessible database.

Please note that publication of manuscripts in Open Access journals is strongly encouraged by our funders; for example, see www.doaj.org. Our funders Open Access policy can be found on their websites - https://wellcome.ac.uk/funding/managing-grant/open-access-policy and https://mrc.ukri.org/research/policies-and-guidance-for-researchers/open-access-policy/.

The HDBR provides human embryo/fetal tissue to all users on an equal access basis, however, I acknowledge that the HDBR, the funders and all users of the resource accept no liability for any overlap of the project aims, methods, outcomes or outputs (including publications) that arise from use of HDBR material. The HDBR policy on potentially overlapping research projects is available at https://hdbr.org/policy-on-overlapping-projects.

☐ **I agree** to have my contact details forwarded to other researchers where my project may share overlapping research outcomes with another HDBR project to discuss potential collaboration and shared use of resources.

☐ **I do not agree** to have my contact details forwarded to other researchers where my project overlaps with another HDBR project.

From time to time we would like to contact you with details of services we provide, and updates to service provision due to holidays or exceptional events (such as the COVID-19 pandemic).

☐ **I agree** ☐ **I do not agree**

Information regarding how your information will be processed can be found in our privacy notices here https://www.ncl.ac.uk/data.protection/dataprotectionpolicy/privacynotice/ and here https://www.ucl.ac.uk/legal-services/privacy/general-privacy-notice

To be completed by the Principal Investigator:

The Principal Investigator is expected to be the grant holder and will take overall responsibility for the project and ensure that the above conditions are adhered to.

I agree that I have read and understand and will abide by the HDBR terms and conditions outlined above.

Name:	
Signature:	
Date:	

Statement of Support from the Applicant's Head of Department

I have discussed the proposed project with the applicant and support his/her use of human embryonic/fetal material to be supplied by the HDBR.

Note: If the applicant is also the head of department, please ask a deputy or a person in an equivalent position to complete this section.

Name:			
Department:			
Institution:			
Address:			
Telephone No:		**Ext. No:**	
E-mail address:			
Signature:		**Date:**	

Please return the completed form to:

Dr S. Lisgo
Biosciences Institute, Newcastle University, International Centre for Life, Central Parkway, Newcastle upon Tyne. NE1 3BZ.
Email: HDBR@ncl.ac.uk

OR

Dr N. Solanky
Developmental Biology & Cancer Programme, UCL, Great Ormond Street Institute of Child Health, 30 Guilford Street, London. WC1N 1EH.
Email: HDBR@ucl.ac.uk