ORB ADM-038 OCHRe full application form & Terms and conditions

Section 1 Applicant details				
Research group / department				
Lead applicant *(e.g. Head of Department or Group, or clinical trial PI)*	Name			
	Job Title			
	Address	Department Building Street address Town and Postcode		
	Tel No.			
	Email			
Contact person *(if different from above) (i.e. the person who will coordinate the request(s) with OCHRe)*	Name			
	Job Title			
	Address	Department Building Street address Town and Postcode		
	Tel No.			
	Email			
Shipping details *(if different from above)*	Name			
	Address	Department Building Street address Town and Postcode		
	Tel No. & email			
Section 2 Funding details				
Research funder (*e.g. commercial company, NHS or University) (indicate if funder is ORB Stakeholder)*				
Contact person for quotation / funding questions *(including name and contact details, phone, email)*	Name			
	Address	Department Building Street address Town and Postcode		
	Tel No. & email			
Section 3 Approval details				
Ethical approval details *A copy of the approval letter is to be submitted with this application.* ***If you need ethical cover, you may use the phrase "request to come under ORB RTB ethics"***	Reference No.			
	Title			
	Approval date		Expiry date	
Consent for use of data/tissues in research *(RTB consent form, NHS consent form, study-specific consent form, exempt? Please justify if exempt)*				
R&D approval details *A copy of the approval letter should be submitted with this application (usually associated with ethical approval)*	Approval body			
	Reference no. (if applicable)			
	Other information			
Registration on portfolio *(NIHR, other –* ***clinical studies*** *only)*	Name of portfolio and reference number			
Sponsor	Organisation			
Has an MTA been arranged? ***(under ORB ethics this is required for samples being requested from Oxford to be sent outside Oxford or shared with a commercial company, for trials: sample shipment outside of Oxford should be covered in the clinical trial agreement or similar contract, including a clause regarding return of diagnostic material to the originating hospital)***				
Section 4 Project details				
Research project title				

Expected date of project completion	
Does this project need to be done in an accredited lab?	
Lay summary *(this may be made available on the OCHRe website, please advise if confidential so it is not shared other than with the research ethics committee for annual reporting)*	
Aims and objectives *(Scientific background, plan of investigation, methodology and any pilot data)*	
NHS Pathologist *(advise if you have discussed this specific project with an NHS pathologist and indicate name – if applicable; indicate if a named pathologist will be a named collaborator on publication or may charge for time spent)*	
Section 5 Samples, service and data	
Sample requirements *Total number of samples required (for clinical trials: expected number of patients to be recruited), sample/case numbers if known (e.g. path number or ORB sample ID; sample lists including patient identifiers such as NHS or hospital numbers must be emailed separately as password-protected files, or use OUH to OUH email or NHS.net to NHS.net email (orh-tr.ochre@nhs.net)), description of samples required (e.g. fixed tissue, frozen tissue, whole blood (include type of blood tube), blood derivatives, and is the tissue needed from biopsy samples or resection tissue?)*	
Prospective collections (ORB only) *What is the patient population (including eligibility criteria)? Please describe who will be doing the following and how: identification of suitable candidates, initial approach of patients about research, seeking consent, sample collection, labelling of samples, registration into ORB's inventory; please describe if any samples will need to be stored, how many and for how long.*	
Full details of histology services required from OCHRe team or ORB team *e.g. OCHRe: number of sections required, what thickness, what type of slide (charged or uncharged), staining, processing; any specific precautions required for preparation of samples; scanning of histology slides (if required please indicate preferred resolution, and confirm external hard drive will be provided for transfer of image files), ORB: collection and/or processing of body fluid samples and/ or tissue samples (fresh with or without culture medium; make into FFPE blocks; freeze to -80 or LN2). Use Data requirements for details of collection of clinical data.*	
How will material be used? *How will you use the materials requested in this application (i.e. what specific techniques, to justify the amount of sample being requested)?* ***For trials only****: describe what is being used for each category that is relevant: screening (eligibility assessment), primary or secondary outcome measures, and/ or exploratory objectives*	
Data requirements *Specify any accompanying data you require e.g. copy of pathology reports, other clinical information from the Electronic Patient Record and who will be obtaining this, what processes are in place to maintain security and confidentiality (data collected under ORB ethics must comply with the relevant SOPs and requires that data managers are included in the delegation log)*	

Thank you for completing this OCHRe application form. **Please remember to provide electronic or paper copies of ethics, consent documentation (PIS & consent form templates) and R&D approval documents (if not applying to come under ORB ethics) when you submit the form to OCHRe**:

NDCLS, Level 4, Academic Block, University of Oxford, John Radcliffe Hospital, Oxford, OX3 9DU
Email: ochre@ndcls.ox.ac.uk Tel: 01865 220557

Terms and conditions

By submitting this application form for review, you are agreeing to the following terms and conditions.

1. Human tissue research training

1.1. All University of Oxford staff must undergo training before working with human tissue, including human tissue issued through ORB/OCHRe.

1.2. Relevant training course(s) are signposted on the Human Tissue Governance team section of the University of Oxford Clinical Trials and Research Governance website: https://researchsupport.admin.ox.ac.uk/governance/human-tissue

2. Access to OCHRe services for processing of material(s) provided by the requestor

2.1. It is the responsibility of the service requestor to ensure that material provided to OCHRe for processing is:

- not contaminated with highly infectious agents such as hepatitis and HIV, or that any Health and Safety issues are highlighted in the application (including any considerations relating to COVID-19 or other pandemic agent); and
- available for research in accordance with applicable regulations.

2.2. Depending upon the origin of the material, requestors may be required to have approval from a Research Ethics Committee for the work requested and details of this should be supplied with the application. If ethical approval is not required the service requestor should provide details in their application.

2.3. OCHRe does not accept responsibility for material provided for processing which is lost or damaged in transit.

2.4. Requestors are required to pay a fee to cover the cost of the services provided by OCHRe. A quotation will be provided and no work will be undertaken until a Purchase Order or written confirmation of payment is received.

3. Terms and Conditions of Sample and / or Data Access

3.1. The requestor agrees that the samples and / or data provided by OCHRe or ORB will be used only for the purposes specified in this application. Further use of the same material for subsequent research must be sought independently of the original application.

3.2. Samples and / or data supplied **may only be transferred to collaborators named at the time of the original application or in subsequent applications and specified in the Material Transfer Agreement or later amendments.** This includes derivatives of the material (e.g. protein, RNA or DNA).

3.3. Samples will be supplied with a minimum dataset, unless additional data is available and requested. All samples are coded-linked and no donor identifiable data will be provided. The requestor agrees not to attempt to identify any individual from the materials supplied.

3.4. The requestor assumes all responsibility for ensuring that samples and / or data are used in accordance with:

3.4.1. the ethical approval and host organisation / sponsor approvals, including appropriate handling of material when approvals expire; and

3.4.2. the current requirements of the Human Tissue Authority or applicable regulations if outside England, Wales and Northern Ireland.

3.5. **Requestors external to the University of Oxford and Oxford University Hospitals NHS Foundation Trust may be required to complete a Material Transfer Agreement before samples and / or data are released**.

3.6. Once the project is completed, the samples must either be returned to the Biobank, destroyed (and a record made of the method, reason and date of disposal), or approval gained to use them in another project.

3.7. Requestors are required to pay a fee to cover costs associated with retrieval, processing and dispatch of samples and / or data. A quotation will be provided and no work will be undertaken until a Purchase Order or written confirmation of payment is received.

3.8. If patient consent is withdrawn for issued samples and / or data, recipients will be informed of the relevant numbers and asked to destroy any unused samples and / or associated data and certify that they have done so. Results obtained from samples that have already been used for research need not be destroyed. The fee is non-refundable if consent is withdrawn.

3.9. OCHRe and ORB attempt to avoid providing samples that are contaminated with highly infectious agents such as hepatitis and HIV, however all samples should be treated as potentially infectious. The requestor assumes all responsibility for training personnel in the procedures for safe handling of human samples.

3.10. The samples and/or data are provided as a service to the research community without warranty of merchantability or fitness for a particular purpose or use or any other warranty or representation, whether express or implied.

3.11. The requestor will ensure that any publication or presentation that is based (in whole or in part) on any materials obtained via OCHRe or ORB will include the following standard acknowledgement: "*We acknowledge the contribution to this study made by the Oxford Centre for Histopathology Research and the Oxford Radcliffe Biobank, which are supported by the University of Oxford, the Oxford CRUK Cancer Centre and the NIHR Oxford Biomedical Research Centre (Molecular Diagnostics Theme/Multimodal Pathology Subtheme), and the NIHR CRN Thames Valley network*." Recipients will be advised if samples have been sourced from a specific collection that must also be acknowledged. Recipients must provide a copy of any publications based on data or samples from the collection to ORB, and **ideally pathologists, sub-collection managers and members of ORB/OCHRe who have contributed significantly to delivery of a project, should be named as co-authors in publications**.

3.12. Study titles may be published on the ORB website, together with lay summaries and the names of institutions where the work is taking place (unless agreed otherwise e.g. for confidentiality purposes).

4. Additional information regarding release of diagnostic material

4.1. The original diagnostic formalin-fixed paraffin-embedded tissue blocks from the Oxford University Hospitals NHS Foundation Trust Cellular Pathology archive will NOT be released for research, unless the patient has specifically consented for use of their diagnostic material (e.g. within some clinical trials). Material (e.g. sections / cores / scrolls) from the original diagnostic tissue blocks will be offered as an alternative.

4.2. If specific patient consent is in place and tissue blocks are required, the material from the Oxford University NHS Foundation Trust Cellular Pathology diagnostic archive will be loaned for the

period of the ethical approval for the study, or as stated in the clinical trial / study contract. Requestors are required to return samples prior to the end of the stated loan period or ethical approval.

4.3. Requestors will be required to return samples if they are required for clinical purposes at any point. Samples must be returned within 5 working days of the request being made.

4.4. Samples must not be used to extinction by the requestor, unless this is specifically stated in advance and agreed in writing.

5. Terms of payment

5.1. Services provided by OCHRe will be charged according to the work involved.

5.2. A estimate will be provided upon approval of application. This estimate is valid for a period of 30 days and is exclusive of VAT.

5.3. The estimate price is approximate, and representative of the services requested in the application. If additional costs are anticipated once the estimate has been issued, this will be agreed with the requestor before further work is undertaken.

5.4. Depending upon the size and complexity of the request, OCHRe or the requestor may request that a contract is put in place before work is undertaken.

5.5. Each application will incur a handling charge and this will be included on the quotation. Subsequent requests / amendments to the original application will usually incur a further handling charge.

5.6. No material will be provided or work undertaken until OCHRe is in receipt of a Purchase Order to cover at least 50% of the estimate costs. Purchase orders should be addressed to University of Oxford, Nuffield Department of Surgical Sciences, Level 6, Rm 6607, John Radcliffe Hospital, Headington, Oxford, OX3 9DU.

5.7. Payment terms are strictly 30 days from receipt of invoice. Invoices will be issued by the University of Oxford.