Imperial Health Knowledge Bank

Access Committee Request Form

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| **Study Name:** |  |
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| **Contact Details -** |
|  | **Principal Investigator**  | **Main Contact** |
| **Name:** |  |  |
| **Email Address:** |  |  |
| **Phone Number:** |  |  |
| **Address:** |  |  |
| **Substantive Organisation Name:** |  |  |
| **Organisation Type:** |  |  |
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| **How is your project funded?** |  |
| **Is your project Commercially / Third Party Funded?\*** | **Yes** |[ ]  **No** |[ ]
| *\*If yes, a further discussion will need to be had regarding commercial Terms and Conditions* |
| **Will any of the samples or data requested be directly used for a project with commercial intent?** |
| **Yes** [ ]  **Please provide details below.** | **No** [ ]  |
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| **Will any of the samples or data requested, or its outputs, project data, methodologies, know how, or inventions generated from the project be commercially exploited or used for commercial purposes** **now or in the future?** |
| **Yes** [ ]  **Please provide details below.** | **No** [ ]  |
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| 1. **Study summary – Introduction and Aims(s) (please clearly state the aim(s) of your project)**

**(min. 300 characters)** |
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| 1. **Lay Summary - please provide a short lay summary of your project proposal (maximum 300 words): ): *Please note that this summary will be published on our website. It should be a stand-alone explanation of the project and not refer to any other information or acronyms referred to elsewhere in this form.***
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| 1. **Public Benefit Statement - how have you identified that this research question is a priority/of benefit for patients/the public? *Please note that this summary will be published on our website. It should be a stand-alone explanation of the project and not refer to any other information or acronyms referred to elsewhere in this form. Please write this section in lay language as public members of the committee review this section.***
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| 1. **What plans do you have to involve and engage with members of the public as part of this research project proposal? *Please see this*** [***guidance document***](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fimperialbrc.nihr.ac.uk%2Fwp-content%2Fuploads%2F2022%2F03%2FImperial-PERC-Guidance-on-Involving-the-Public-in-health-data-research-.pdf&data=05%7C01%7Cdimitri.papadimitriou%40nhs.net%7C19140a9e5f074d3b27f108db561aebe2%7C37c354b285b047f5b22207b48d774ee3%7C0%7C1%7C638198447275578024%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=DzFQeRlG9NHxvUxWDFSbslVutim7mA07FTzQn3b7Bhw%3D&reserved=0) ***on involving the public in health data research or the*** [***Public Involvement Resource Hub***](https://www.imperial.ac.uk/patient-experience-research-centre/ppi/ppi-resource-hub/) ***for guidance or contact the Imperial Patient Experience Research Centre on*** ***publicinvolvement@imperial.ac.uk******. Please write this section in lay language as public members of the committee review this section****.*
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| 1. **Equality, Diversity and Inclusion (EDI)**

*Have you considered EDI in your proposal? Please provide a short overview of your consideration and how these have been implemented where possible.* |
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| 1. **Request type**
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| 1. **Consent to contact** – the IHKB team will search our database to identify and re-contact suitable participants for prospective studies
2. **Samples** – request use of samples already collected from IHKB participants
3. **Data** – IHKB data set available on request

*Which type of request applies to your application?* *Please note you can request all three or both consent to contact and samples together or separately within this application.* *Data only requests are processed by NIHR Imperial BRC Data Access and Prioritisation Committee.* |
| **Consent to Contact** [ ] (Please complete section 7 and 13 onwards) | **IHKB pre-existing Samples** [ ] (Please complete section 8, 9 and 13 onwards) | **Data required** [ ] (Please complete section 10 onwards) |

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| 1. **Consent to contact**
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| **Please attach current copies of your Protocol, Patient information Sheet and Consent form with this application** [ ] * Which institution will be contacting and consenting patients, where will this take place?
* Where will the patient identifiable data be held?
* How many patients are you looking to recruit?

**Data Protection and security links** [data-protection-confidentiality-and-information-sharing-policy.pdf (imperial.nhs.uk)](https://www.imperial.nhs.uk/-/media/website/about-us/publications/policies/data-protection-confidentiality-and-information-sharing-policy.pdf?rev=68dd3552d3724f898cf921388f643ea6&hash=F7405AA03D9975EF86F3F958D74E336C)[privacy-notice-patients.pdf (imperial.nhs.uk)](https://www.imperial.nhs.uk/-/media/website/patients-and-visitors/privacy-notice-patients.pdf?rev=8a9e54f0899a4092b18666332bca559a&sc_lang=en&hash=EAEE38FDDCF54BD124766C0F54EDAE9E) |

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| 1. **IHKB Samples requests**

Scientific validity of your study of the proposed research on the samples you are requesting from the IHKB. Please fully address ALL the headings below (min. 300 characters). |
| 1. **Experience of group and/or company** carrying out analysis (please provide information to indicate that your research group has experience in the techniques you intend to use, either by use of preliminary data from other work carried out in your group or by providing references to publications from your group/company that are relevant to this application)
2. If hypothesis generation is the specific purpose of your application, what do you envisage its **application in the clinical setting** will be? Please give as much detail as possible on target identification, validation etc.
3. **Methods** (please detail the methods you intend to use, indicating controls and the experimental design you will use where relevant include statistical information). It is important that you provide details of the methods you will use to study your gene/pathway of interest. Phrases such as “we will investigate the genomics/epigenomics of xx” are not specific enough. Please be specific but concise.
4. **Justify number of samples requested** (statistical analysis)
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| **Clinical Sponsor's Signature:** |  |
| **Date:** |  |

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| 1. **Specimens Requested.**

Please specify **exactly** what you require e.g. 1 x0.5mL aliquots plasma, 1 x 0.5mL whole blood, 2 x 0.5mL serum. All samples are provided in 1mL cryovials with 2D barcodes.*A shipping list will be included with the samples, please complete, scan and send back by email to the IHKB team (imperial.healthknowledgebank@nhs.net).*  |
|  | **Number of samples required** | **Volume per sample (µl)** |
| **Plasma** |  |  |
| **Serum** |  |  |
| **Shipping location:*****Please note: sample transport costs will be rechargeable to the research project***  |
| **Point of contact for MTA execution:** |

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| 1. **IHKB Data Requests**

Technical Summary - please tell us the main purpose of the research project for which you are requesting the data including methods and data analysis: (Tools available on iCARE website) |
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| 1. **Please confirm which of the following you require**
2. Access to data requested
3. A report generated from the data requested
4. Sample analysis data associated with this application to be linked to clinical data (if so, specify data sizes and analysis requirements)
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| **12. Please confirm that the metadata catalogue for IHKB has been accessed for reference** | Yes  |  |
| No |  |
| Please specify which IHKB data category or catergories you require having referenced the available metadata catalogue.Please also specify if you require data that is not included in the current IHKB metadatacatalogue. If so, have you discussed this with the IHKB / iCARE team?  |
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| 1. **Other Approval Committees - list all other decision-making bodies that the project has already been authorised by:**
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| 1. **Any other Collaborators**
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| 1. **Does your project currently have research ethics?**

*Please note: ICHNT service evaluations and clinical audits do not require research ethics* | Yes |[x]   |  |  |  |  |
|  | No |[ ]   |  |  |  |  |
| **If yes please provide IRAS number:** |  |  |  |  |  |

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| 1. **Does you project need to link to other external datasets?**

**If so, please provide details below** | Yes |[ ]   |  |  |  |  |
|  | No |[ ]   |  |  |  |  |
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| 1. **Please list all users who require have access to the data (Project Lead or otherwise):**

*Please note: anyone accessing data will need to meet the criteria for* [*Accredited Researcher Status*](https://www.gov.uk/government/publications/digital-economy-act-2017-part-5-codes-of-practice/research-code-of-practice-and-accreditation-criteria#section-b-accreditation-of-researchers-and-peer-reviewers)*. We will provide support for applicants to complete mandatory Information Governance training and then sign the relevant Terms of Use for Data. All applicants will be expected to have an undergraduate degree (or higher), including a significant proportion of mathematics or statistics, or be able to demonstrate at least 3 years quantitative research experience and be proficient in using data analysis and programming tools (such as SQL, R-Studio or Python).* *If you are requesting access for more than two applicants, please provide the justification for this below.* |
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| **Publication Policy**  |
| **Notification of Publication**IHKB and/or the NIHR Imperial BRC should be acknowledged in all publications resulting from any study that IHKB have supported. Any press releases including social media posts based on studies that IHKB have supported should include appropriate acknowledgement.All manuscripts that make use of data, samples or consent to contact from the IHKB must be reviewed by the IHKB team prior to submission to imperial.healthknowledgebank@nhs.net **Acknowledgement**Please use the following wording in the acknowledgements section of any publications making use of IHKB participants, samples and or data:"We thank Imperial Health Knowledge Bank volunteers for their participation, and gratefully acknowledge NHS Trusts and staff for their contribution. We thank the National Institute for Health and Care Research Biomedical Research Centre at Imperial College Healthcare NHS Trust. *The research was enabled by the Imperial Clinical Analytics Research and Evaluation (iCARE) environment and used the iCARE team and data resources. IHKB is approved by Wales REC3 to release human material for research (22/WA/0214).* The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care."**Press release and Social Media**All social media posts regarding a study that the IHKB and/or the NIHR Imperial BRC has supported should acknowledge the IHKB and/or the NIHR Imperial BRC by including our hands **@IHKB @ImperialNHS @ImperialBRC****Publication Costs**Where the IHKB and/or the NIHR Imperial BRC is acknowledged, the IHKB and/or the NIHR Imperial BRC is unable to pay or contribute to the costs associated with publications arising from studies. |

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| **Project Amendments** *If submitting an amendment to an already approved project, please provide a summary of changes* |
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| **By signing this form I confirm that all information included in this form is accurate, that all users who will be accessing data are listed in the form have completed Information Governance training and have agreed to the terms and conditions listed below. The clinical sponsor must hold a substantive or honorary contract with Imperial College Healthcare NHS Trust.** |
| **Name:** |  |
| **Signature:** |  |
| **Date:** |  |

Please email completed forms to imperial.healthknowledgebank@nhs.net

Access Committee meetings take place monthly, usually on the last Friday of each month. To ensure review at the next Committee meeting, you will need to submit the form by 5pm of the Wednesday 16 days before the meeting.