North West London Data Access Request Form

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| **Document owner:** | | | Co-Chairs of the Data Access Committee | |
| **Document author:** | | | Information Governance Services Limited | |
| **Date updated:** | | | 08 December 2022 | |
| **Current Stage:** | | | Final | |
| **Version Number:** | | | 4.0 | |
| **Version History Below** | | | | |
| **Version** | **Date** | **Modified** | | **Updates** |
| 1.1 | 12/01/2021 | Robin Johnson (IGS) | | Full review (adding commercial section, conflict of interest section) |
| 1.2 | 15/01/2021 | Barrie Newton and Raj Seedher | | Review with the Co-Chairs to get feedback |
| 1.3 | 18/01/2021 | Dusan Saska (ICHP) | | Feedback on the Form |
| 1.4 | 22/01/2021 | Robin Johnson (IGS) | | Incorporate changes |
| 1.5 | 21/02/2021 | Taj Sallamuddin  (IGS) | | Review the Agreement |
| 1.6 | 11/03/2021 | Robin Johnson (IGS) | | Implementing the form feedback |
| 1.7 | 17/03/2021 | Taj Sallamuddin  (IGS) | | Final legal review |
| 2.0 | 18/03/2021 | Data Access Committee | | Approved the form for use. |
| 2.1 | 12/03/2021 | Robin Johnson (IGS) | | Small tweaks and amendments |
| 2.2 | 16/02/2022 | Robin Johnson (IGS) | | Removed honorary contracts requirement, added email field for individuals requiring access for WSIC team, updating role information. Amending typos |
| 2.3 | 30/03/2022 | Robin Johnson (IGS) | | Amendments to form following feedback from Data Access Committee following Acceptable Use Policy introduction |
| 3.0 | 09/06/2022 | IG Board | | Approved the form for use. |
| 3.1 | 06/12/2022 | Viktoria Hodson (IGS) | | Amending form to incorporate cohort recruitment. Quality of life changes to the form. |
| 4.0 | 06/04/2023 | IG Board | | Approved the form for use. |

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| **(1) Key project information** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(1.1) Project Title:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **INTERNAL USE ONLY - Project reference number:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(1.2) Does your project amount to Research, Service Evaluation or Cohort Recruitment for future research?\***  ***\*(see Annex A for definitions below)*** | | | | | | | | | **Research** | | | | | | | | | | |  | | | | | | | | | | |
| **Service** **Evaluation** | | | | | | | | | | |  | | | | | | | | | | |
| **Cohort Recruitment** | | | | | | | | | | |  | | | | | | | | | | |
| **(1.3) Is this project application a new request or extension request?** | | | | | | | | | **New** **Request** | | | | | | | | | | |  | | | | | | | | | | |
| **Extension Request** | | | | | | | | | | |  | | | | | | | | | | |
| **For extension requests, please provide the study ID number which it was previously approved under (e.g., ID-107)** | | | | | | | | | | |  | | | | | | | | | | |
| **(1.4) Is the project relevant to COVID-19 or a COVID-19 vaccination?** | | | | | | | | | **Yes** | | | | | | | | | | |  | | | | | | | | | | |
| **No** | | | | | | | | | | |  | | | | | | | | | | |
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| **(2) Clinical Sponsor details FOR RESEARCH PROJECTS ONLY:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(2.1) Clinical Sponsor (‘Relevant Partner’):** *The name of the Head of Service, Clinical Director or Divisional Director responsible for overseeing the project and ensuring that data use is appropriate and in line with the approval application* | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(2.2) Clinical Sponsor's Role Within Project:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(2.3) Clinical Sponsor’s Organisation:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(2.4) Clinical Sponsor’s Role Within Their Organisation:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(2.5) Clinical Sponsor's Email Address:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
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| **(3.1 – 3.5) Project Lead/Principal Investigator (“Requestor” and/or “Proposed Recipient”) Details:** | | | | | | | | |  | | | |  |  | | | | | | | | | |  |  | | |  | |  |
| **(3.1) Title:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(3.2) Name:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(3.3) Email Address:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(3.4) Phone Number:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(3.5) Employer:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(3.6 – 3.7) Project Sponsor and day-to-day contact:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(3.6) Which organisation is the data controller, who is signatory to the NWL Statement of Data Sharing, sponsoring this project (“Relevant Partner”)?** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(3.7) Who should the day to day contact point be for the project?** (This should be a staff member who can provide additional details and answer questions.) | | | | | | | | | **Contact name:** | | | | | | |  | | | | | | | | | | | | | | |
| **Job post:** | | | | | | |  | | | | | | | | | | | | | | |
| **Contact email:** | | | | | | |  | | | | | | | | | | | | | | |
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| **(4)** **Project purpose and patient benefits** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(4.1) Please describe the main purpose of the research project which you are requesting access to the data. If this application is related to cohort recruitment, please also specify the type/s of study and/or the disease area(s) the recruitment is for:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **(4.2) In clear and plain English, please provide details as to how the outcome of your project will directly benefit patients.   For any extension requests, please state any additional benefit, or, if the benefits are the same as the original request, then please state the benefits are the same:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **(4.3) For extension requests only, please confirm that the benefit to patients are the same as your previous successful application. If the patient benefits are different, please explain what those differences are.** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **The patient benefits are the same as the previous application:** | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
| **The patient benefits are different than the previous application. The explanation around the new patient benefits are as follows:** | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
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| **(5) Dataset requirements** | | | | | | | |  | | | | | | | | | | | | | | | | | |  | | | | |
| **(5.1) Description of Information Required:**  *Please include dates/timeframes for any analysis, and other specific indicators/categories required in the data such as specific codes/metrics.*  *For multiple Projects, Please title each project.* | | | | **Categories of data processing:** | | | | **Sub-Categories (where applicable):** | | | | | | | | | | | | | | | | | | **Tick as appropriate:** | | | | |
| **COVID data** | | | | * COVID vaccinations * COVID testing * COVID hospital admissions data | | | | | | | | | | | | | | | | | |  | | | | |
| **Demographic Information** | | | |  | | | | | | | | | | | | | | | | | |  | | | | |
| **Finance Data** | | | |  | | | | | | | | | | | | | | | | | |  | | | | |
| **Service Usage** | | | | * Acute data (SUS/SLAM); * Mental Health data; * Community data; * Primary care usage data; | | | | | | | | | | | | | | | | | |  | | | | |
| * Social care data | | | | | | | | | | | | | | | | | |  | | | | |
| **Prescription data** | | | | * Primary care; * High cost drugs in acute. | | | | | | | | | | | | | | | | | |  | | | | |
| **Special data** | | | | * Q-Administration; * Electronic Frailty Index; Patient Activation Measure (PAM); * Long term condition; * Risk Segmentation; * WSIC Segmentation. | | | | | | | | | | | | | | | | | |  | | | | |
| **Diagnostics data** | | | |  | | | | | | | | | | | | | | | | | |  | | | | |
| **Patient history** | | | |  | | | | | | | | | | | | | | | | | |  | | | | |
| **Reference data** | | | | * UK Health dimensions reference tables (if so please list the ones to be used): | | | | | | | | | | | | | | | | | |  | | | | |
| **(List if ticked):** | | | | | | | | | | | | | | | | | |
| **Other data\*** | | | |  | | | | | | | | | | | | | | | | | |  | | | | |
| **If you answered Other data\*, please provide the relevant details in the box below:** | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **(5.2) Please specify the full dataset and data categories that you require, having referenced the available metadata catalogue. Please see the following link to the metadata catalogues** [**https://ichp.qpuk.net/discover-now/north-west-london-covid-19-data-repository/**](https://ichp.qpuk.net/discover-now/north-west-london-covid-19-data-repository/) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **(5.3) Please confirm that the metadata catalogue has been accessed for reference:** | | | | | **Yes** | | | | | | | | | | | | | | | | |  | | | | | | | | |
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| **No** | | | | | | | | | | | | | | | | |  | | | | | | | | |
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| **(5.4) Is there a specific geographical area within North West London (e.g. Brent, Harrow etc.) whose data you are interested in for the project?** | | | | | **Yes** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **If yes, please indicate which geographical area/s you are interested in:** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **No** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **(5.5) For recruitment applications only: Please list the inclusion and exclusion criteria for patient cohorts to be recruited** | | | | | **Inclusion Criteria:** | | | | | | | | | | | | | **Exclusion Criteria:** | | | | | | | | | | | | |
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| **(6) Data Access Support** | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| **(6.1) Please note that the de-identified data will be made available in a SQL data warehouse. Some, or all of your users will need to have SQL skills to be able to extract the data.**  **Please confirm whether you have users with the necessary skills to extract the data:** | | | | | | | | | | | | | | | | | | | | | **Yes** | | | | |  | | | | |
| **No** | | | | |  | | | | |
| **(6.2) Do you already have access to the de-identified server?** | | | | | | **Yes** | | | | | | | | | |  | | | | | | | | | | | | | | |
| **If ‘Yes’, please provide details:** | | | | | | | | | |  | | | | | | | | | | | | | | |
| **No** | | | | | | | | | |  | | | | | | | | | | | | | | |
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| **(7) Data Linkage and DPIA** | | | | |  | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **(7.1) Are there any intentions to link the data with any other data sets, especially personal data?** | | | | | **Yes** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **No** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **(7.2) If you answered ‘Yes’, please confirm whether such processing meets the test set out in Article 35(1) UK GDPR, therefore requiring a Data Protection Impact Assessment to be completed:** | | | | | **Yes** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **No** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **(7.3) If you answered ‘Yes’ to the above question, please confirm whether a Data Protection Impact Assessment has been carried out, and provide a copy of it with your application.**  **If you have not carried out a Data Protection Impact Assessment despite such processing meeting the test in Article 35(1) UK GDPR, please explain why:** | | | | | **We have carried out a Data Protection Impact Assessment for linking the data sets, and I have attached a copy of it to this application:** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **We have not carried out a Data Protection Impact Assessment because… (explain):** | | | | | | | | | | | | | | | | |  | | | | | | | | |
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| **(8) Access Duration and users requiring access** | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| **(8.1) For new data requests only, please specify how long you require access to the requested data?**  **(Maximum permitted duration is 6 months)** | | | | | **Length requested:** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **Proposed start:** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **Proposed end:** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **(8.2) For extension requests only, please specify how much longer you require access to the previously requested data?**  **(Maximum permitted duration is 6 months)** | | | | | **Length requested:** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **Proposed start:** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **Proposed end:** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **(8.3) For extension requests only, please justify and explain why you require the additional time:** | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| **(8.4) For extension requests only, has there been any material change to the scope or usage of the data obtained in the original decision? If yes, please explain what these changes are.** | | | | | **Yes** | | **(Explain:)** | | | | | | | | | | | | | | | | | | | | | | | |
| **No** | |  | | | | | | | | | | | | | | | | | | | | | | | |
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| ***\*Please note: anyone accessing data will need to sign the Acceptable Use Policy, have completed their Information Governance training and signed the relevant Terms of Use for Data before they can have access to the data*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **(8.5) Please list all users who will require access to the data:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Name of user who will have access to the data, and the organisation they are employed on behalf of:** | | | | | | | | | | | **Please confirm that the User:**   * **Has completed their Information Governance Training;** * **Has read, understood and signed the relevant Terms of Use for Data;** * **Acknowledges that they will need to have read, understood and signed the relevant Acceptable Use Policy in order to be granted access to the data.** | | | | | | | | | | | | | | | | | | | |
| **Name of User** | | | **User’s Organisation** | | | | | | | |
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| **(8.6) Please provide the email address for each user who is required access to the data:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Name of Requested User:** | | | | | **Email address of Requested User** | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **(9) Funding arrangements** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(9.1) Is your project Commercially/Third Party Funded?\***  ***\*(please see Annex A) for a definition on Commercially/Third Party Funded*** | | | | | | | | | **Yes** | | | | | | | | | | | | | |  | | | | | | | |
| **No** | | | | | | | | | | | | | |  | | | | | | | |
| **(9.2) If required, have you paid or agreed to pay the required data access fee to ICHP?** | | | | | | | | | **Yes** | | | | | | | | | | | | | |  | | | | | | | |
| **No** | | | | | | | | | | | | | |  | | | | | | | |
| **If ‘No’, please explain why not (e.g. non-Commercially Funded study, access free of charge with agreement of data controller etc.)** | | | | | | | | | | | | | |  | | | | | | | |
| **(9.3) If you are funded by a research/ non-profit organisation, are there any relevant terms attached to the funding which restrict or are contrary to the terms of conditions below?** | | | | | | | | | **Yes** | | | | | | | | | |  | | | | | | | | | | | |
| **If ‘Yes’, please specify the relevant restrictions:** | | | | | | | | | |  | | | | | | | | | | | |
| **No** | | | | | | | | | |  | | | | | | | | | | | |
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| **(10) Project and Organisation Assurances** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **FOR RESEARCH AND COHORT RECRUITMENT PROJECTS ONLY (10.1 & 10.2)** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(10.1) Does your project require research ethics or other ethics approval?**  Please see the following link for guidance by the Health Research Authority as to whether your project requires review by the NHS Research Ethics Committee (REC)<http://www.hra-decisiontools.org.uk/ethics/> | | | | | | | | | **Yes** | | | | | | | | | | |  | | | | | | | | | | |
| **No** | | | | | | | | | | |  | | | | | | | | | | |
| **If ‘No’, then please explain why:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(10.2) Research Ethics Approval number:** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(10.3) Has your organisation reached a minimum level of ‘standards met’ in your most recent Data Protection Security Toolkit?** | | | | | **Yes** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **No** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **(10.4) Is your organisation a signatory to the WSIC Interoperability Service Specification?** | | | | | **Yes** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **No** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **If ‘No’, have you been sponsored by a data controller?** | | | | | | | | | | | | | | | | | **Yes** | | | | |  | | | |
| **No** | | | | |  | | | |
|  | | | | | **If you ticked ‘Yes’, please specify the data controller organisation who is sponsoring your organisation** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **(10.5) Please explain how staff are appropriately vetted at your organisation:** | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| **(10.6) Please confirm that staff who will be accessing the data have standard confidentiality clause in their contracts that prevents disclosure of confidential information outside the organisation:** | | | | | **I confirm that staff have appropriate confidentiality clauses.** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **The staff do not have appropriate confidentiality clauses.** | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **(10.7) Please note that any data quality issues must be reported to the WSIC de-identified mailbox at** [**nwlccgs.wsic.deidentified@nhs.net**](mailto:nwlccgs.wsic.deidentified@nhs.net) | | | | | **I understand the requirement for data quality issues to be reported and agree that I will report them to the email address provided.** | | | | | | | | | | | | | | | | |  | | | | | | | | |
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| **(11) Patient consent, safety and project feasibility FOR COHORT RECRUITMENT STUDIES ONLY** | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| **(11.1) Please confirm that you have attached the following documentation with your application…** | | | | | **Patient Consent Forms**  N.B – The consent form patients will sign in order to participate in the study, not the consent to contact register | | | | | | | | | | | |  | | | | | | | | | | | | | |  |
| **Patient Privacy Notices/ Study Transparency Materials** | | | | | | | | | | | |  | | | | | | | | | | | | | |
| **(11.2) If you are recruiting outside the Sponsor’s Trust/Centre, outline your plans to ensure patient safety** | | | | | **N/A – Not recruiting outside the Trust/centre** | | | | | | | | | | | |  | | | | | | | | | | | | | |
| **If yes, how will you maintain and ensure patient safety?** | | | | | | | | | | | |  | | | | | | | | | | | | | |
| **(11.3) What feasibility findings you have undertaken for the proposed study?** | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **(12) Study publication** | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
| **(12.1) Please indicate where you plan to publish the results of the project after it is completed:** | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
| **(12.2) Please note, that you are required to acknowledge Whole Systems Integrated Care (WSIC) / DISCOVER-NOW as per the terms and conditions below.** | | | | | | | | | | | | **I hereby acknowledge that I have read and understood the terms and conditions set out below and agree to acknowledge WSIC and Discover in any papers or publications as a result of the project.** | | | | | | | | | | | | | | | | |  | |
| **I also acknowledge that I will share the paper or publication with the Data Access Group and Discover once I am in a position to do so.** | | | | | | | | | | | | | | | | |  | |
|  | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
| **(13) Conflicts of Interest FOR RESEARCH PROJECTS AND COHORT RECRUITMENT ONLY** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
| **(13.1) Does the clinical sponsor have any conflicts of interest in this Project? *(Please see the description of Conflict of Interest in Definitions below before completing this section)*** | | | | | | | | | **Yes** | | | | | | | | | | |  | | | | | | | | | | |
| **No** | | | | | | | | | | |  | | | | | | | | | | |
| **If ‘Yes’ then please provide details of the relevant conflicts below:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **(13.2) I (the clinical sponsor) hereby confirm that the statement above (relating to Conflict of Interest) is true and complete to the best of my knowledge and accept any penalties imposed by the Agreement below should it transpire this was not the case.** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Name:** |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Signature:** |  | | | | **Date:** | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **(14) Project Lead data access request form sign-off**  **TO BE COMPLETED BY THE PROJECT LEAD ONLY** | | | | | | | | | |
| **(14.1) By signing this form, I confirm that all information included in this form is accurate (to the best of my knowledge), that all users who will be accessing data are listed in 8.5 of the form have completed their Information Governance training and have agreed to the Terms and Conditions listed below and have either signed, or intend to sign, an Acceptable Use Policy. I also confirm that my clinical sponsor also holds a substantive contract with one of the data controllers within North West London sector and a signatory of the ISA.** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Name:** | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Signature:** | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Date:** | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

**Appendix A: Definitions**

|  |  |
| --- | --- |
| **(Patient) Cohort Recruitment** | The enrolment of a cohort of patients to a study or clinical trial. Access to the data platform will determine what patients are eligible/suitable for the study. Only patients who are eligible and have signed up to the consent-to-contact register can be contacted for recruitment onto the study. |
| **Commercially/Third Party Funded** | A project is considered as being Commercially/Third Party Funded if it is being funded by a private organisation in any form and/or the project has been allocated funds to carry out research by a governmental/non-profit body (e.g. NIHR/MRC/British Heart Foundation etc.). This arrangement can take a number of different forms and may well include a number of different bodies (including public sector bodies) who involved in the transaction.  For example, a data analytics/pharmaceutical organisation sponsors a research study which is going to be delivered by a public sector body who has the necessary expertise to deliver it. Even if that public sector body is making the application, the project can reliably be considered as Commercially Funded because the outputs will be used by the aforementioned data analytics/pharmaceutical organisation. |
| **Conflict of Interest** | A potential or actual conflict of interest exists when your role in sponsoring this application is likely to be compromised by other material interests, or relationships (especially economic), particularly if those interests or commitments are not disclosed.  This Conflict of Interest statement (in the form above) should be completed if the Clinical Sponsor has an economic interest in, or acts as an officer or a director of, any outside entity whose financial interests would reasonably appear to be affected by the approval of this application. The Clinical Sponsor should also disclose any personal, business, or volunteer affiliations that may give rise to a real or apparent conflict of interest. In deciding whether a conflict is likely, the Clinical Sponsor should consider any relevant policy guidance available by their employer, any regulations and guidelines in financial conflicts and they must be abided by. Clinical Sponsor’s with a conflict of interest should refrain from sponsoring a project for consideration. |
| **Research** | Put simply, research concerns itself with the attainment of new knowledge. It involves the attempt to expand upon the already existing and available knowledge by means of a systematically defensible process of enquiry. The aim of research is to generate new hypotheses as well as studies that aim to test those hypotheses or explore them in order to answer questions with scientific methods. Research projects can include simply descriptive studies (which can be literature reviews) but the findings of the research should be generalisable beyond the project setting.  If you are unsure whether your project is research or a service evaluation, you can use the Health Research Authority’s tool which should assist you with the definition:  <http://www.hra-decisiontools.org.uk/research/> |
| **Service Evaluation** | Unlike research, service evaluations do not have a hypothesis and are undertaken to benefit the people using a particular health/social care service. They seek to assess how well a service is achieving its intended aims by analysing, defining, judging, or evaluating that service. Often a current service is measured without referencing a particular standard and they are almost exclusively relevant to the population or setting in which the evaluation takes place, and the results are not generalisable. The results of service evaluations are mostly used to generate information that can inform local decision making.  If you are unsure whether your project is research or a service evaluation, you can use the Health Research Authority’s tool which should assist you with the definition:  <http://www.hra-decisiontools.org.uk/research/> |

Data Access Contract

**TERMS AND CONDITIONS FOR USE OF DISCOVER DataSET**

**Whenever accessing the Discover Dataset, the Relevant Partner and the entity named in the De-Identified Data Request Form as the “Proposed Recipient” agree to these Terms and Conditions.**

## **THE AGREEMENT**

## This Agreement incorporates the following documents by reference: The Digital North West London De-Identified Data Request Form and these Terms and Conditions and any other terms referenced within them (collectively, the "**Agreement**"). The Agreement is effective from the date specified in section 13 of the North West London De-Identified Data Request Form.

## This Agreement shall only be used when use of the Discover Dataset complies with the terms and conditions of the ISA.

## **INTERPRETATIONS**

## In this Agreement, unless the context otherwise requires, the following words and expressions shall have the following meanings:

|  |  |
| --- | --- |
| “**Agreement**” | has the meaning given in Clause 1.1; |
| "**Applicable Law**" | means any court order or any common law, statute, statutory instrument, order or regulation issued by a governmental body with authority over any relevant Party, applicable to any relevant Party from time to time in the context of its relevant rights and obligations under this Agreement; |
| **“Commercial”** | means anything which does have a commercial objective and is intended to make a profit; |
| “**Data Access Committee**” | means the North West London data access group that consider applications for access to the Discover Data; |
| “**Data Controller(s)”** | has the same meaning as one in the Data Protection Act 2018 and/or Regulation (EU) 2016/679 of the European Parliament and of the Council; |
| "**Data Privacy Law**" | Means the laws and regulations, in any jurisdiction, that apply in relation to the Processing of Personal Data including the Data Protection Act 2018, UKGDPR and the Privacy and Electronic Communications (EC Directive) Regulations 2003 (21 2003/2426), any relevant/successor legislation/regulations, and all other applicable laws and regulations relating to processing of personal data and privacy in effect in any relevant territory from time to time, including where appropriate the guidance and codes of practice issued by the Information Commissioner’s Office; |
| "**De-Identified Data Request Form**" | means the North West London Data Request Form preceding this Agreement which sets out the out the details and disclosure of the Discover Dataset to the Recipient; |
| “**Deliverables”** | means any outputs which are developed as a result of accessing the Discover Dataset; |
| "**Discover Dataset**" | is the WSIC record after it has been de-identified/anonymised in line with the most up-to-date Information Commissioner’s Office’s Code of Practice on Anonymisation. The Discover Dataset is ready after the 2.3+ records from WSIC has gone through a robust de-identification/anonymisation procedure to protect people confidentiality. The Discover Dataset is hosted in a separate data centre to the one where WSIC is hosted; |
| "**DPA**" | means the Data Protection Act 2018; |
| "**Effective Date**" | means the date identified as the effective date in Section 13 of the De-Identified Data Request Form and from when the Parties’ respective rights and obligations hereunder shall be deemed binding; |
| "**FOIA**" | means the Freedom of Information Act 2000; |
| "**FOIA Request**" | means a request for information or an apparent request under FOIA; |
| **“ICHP”** | means Imperial College Health Partners Limited, a private company limited by guarantee and incorporated in England and Wales under registered number 08109403, whose registered office is at Mills & Reeve LLP, 4th Floor, Monument Place, 24 Monument Street, London EC3R 8AJ; |
| “**Intellectual Property**” | means (i) patents, designs, trade marks and trade names (whether registered or unregistered), copyright and related rights, database rights, Know-How and confidential information, (ii) all other intellectual property rights, in each case whether registered or unregistered and similar or equivalent rights anywhere in the world which currently exist or are recognised in the future; and (iii) all applications, renewals or extensions (including supplementary protection certificates) in relation to any such rights; |
| "**ISA**" | means the Digital North West London Statement of Data Sharing Agreement and the Whole Systems Integrated Care Interoperability Service Specification; |
| “**ISS**” | means the WSIC [Interoperability Service Specification](https://www.nwlondonccgs.nhs.uk/application/files/2115/9853/4738/20200819_WSIC_ISS_Reviewed_URL_changed.pdf); |
| “**Know-How**” | shall mean any technical and other information which is not in the public domain, including information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, assays, research plans, procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), processes (including manufacturing processes, specifications and techniques), laboratory records, chemical, pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports, manufacturing data or summaries and information contained in submissions to and information from ethical committees and regulatory authorities and computer programs or algorithms. Know-How includes documents containing Know-How, including but not limited to any rights including trade secrets, copyright, database or design rights protecting such Know-How. The fact that an item is known to the public shall not be taken to preclude the possibility that a compilation including the item, and/or a development relating to the item, is not known to the public; |
| “**Non-Commercial**” | means anything which does not have a commercial objective and is not intended to make a profit; |
| “**NWL Data Controllers”** | means the Data Controllers signatory to the ISA and ISS; |
| **“NWL IG Board”** | means the North West London Information Governance Board which has ISA Data Controller representation; |
| "**Overall Purpose**" | means such purpose(s) which are permitted by the ISA and applicable to the Relevant Partner's organisation type; |
| "**Party**" or "**Parties**" | meaning the Relevant Partner and/or the Recipient individually being the two parties to this Agreement; |
| "**Personal Data**" | shall have the meaning given to it under section 3 of the DPA; |
| “**Process, Processed and/or Processing**” | means any operation or set of operations which is performed on Discover Dataset, whether or not by automated means. |
| “**Project Intellectual Property**” | means any Intellectual Property created, devised, or arising out of the Purpose which has relied on or any part of the Discover Dataset; |
| "**Purpose(s)**" | means the purpose the Recipient will use the Discover Dataset for, as expressly set out in section 4.1 of the De-Identified Data Request Form; |
| "**Recipient**" | means the organisation or person identified as the Proposed Recipient in the De-Identified Data Request Form; |
| "**Relevant** **Partner"** | means an organisation which is a signatory to the [NWL Statement of Data Sharing](https://www.nwlondonccgs.nhs.uk/application/files/7515/9706/4593/190617_Statement_of_Data_Sharing_1_1.pdf), the ISS and who is sponsoring the Recipient to access the Discover Dataset; |
| “**Security Breach”** | a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to the disclosed Discover Dataset; |
| "**Terms and Conditions**" | means the terms and conditions contained in this document comprising the terms and conditions applicable to the use and disclosure of the Discover Dataset; |
| “**VDI**” | shall mean the virtual desktop infrastructure; |
| “**Virus**” | means any piece of code which is capable of copying itself and typically having a detrimental effect, such as corrupting the system or destroying data; and |
| “**WSIC**” | means Whole Systems Integrated Care record, WSIC is an identifiable care record, based in North West London, that holds health and social care data of people and is used by health and social care professional to only provide direct care to each patient/service user. WSIC receives Personal Data from over 400 Data Controllers in North West London under an legal data sharing framework, these Data Controllers are General Practices, Hospital Trusts, Mental Health Trusts and Local Authorities. |

* 1. A reference to a statute or statutory provision is a reference to it as amended or re-enacted. A reference to a statute or statutory provision includes any subordinate legislation made under that statute or statutory provision, as amended or re-enacted.
  2. Any words following the terms including, include, in particular, for example or any similar expression shall be construed as illustrative and shall not limit the sense of the words, description, definition, phrase or term preceding those terms.
  3. A reference to writing or written includes email.
  4. unless otherwise specified, the singular includes the plural, and the masculine includes the feminine and vice versa.
  5. A reference to a company shall include any company, corporation or other body corporate, wherever and however incorporated or established.
  6. Any obligation on a Party not to do something includes an obligation not to allow that thing to be done.
  7. For the avoidance of doubt, references in this Agreement to the use of the Discover Dataset includes the use or reproduction of any Part thereof and the use or reproduction of any the Discover Dataset. "Use" includes any action which would constitute Processing.
  8. A reference to a Party in this Agreement, shall also include, where evidently relevant, the NWL Data Controllers.

## **INFORMATION TO BE SHARED**

## Based on the sponsorship from the Relevant Partner, the NWL Data Controllers have agreed to share the specific data requested in the De-identified Data Request Form, from the Discover Dataset, to the Recipient.

## The Recipient acknowledges that the Discover Dataset is derived from the WSIC and warrants that he/she will only use it for the purposes expressly set out in section 4.1 of the De-identified Data Request Form.

## The Parties agree and acknowledge it is not intended that any Personal Data will be shared under this Agreement. If the Recipient receives any data from the Relevant Partner which it considers may constitute Personal Data or identifies a patient then, the Recipient will:

## immediately notify the Relevant Partner;

## immediately notify the WSIC team at [nwl.infogovernance@nhs.net](mailto:nwl.infogovernance@nhs.net) ; and

## immediately destroy any Personal Data unless explicitly told otherwise by the Relevant Partner and/or the Data Access Committee.

## Prior to disclosure of the Discover Dataset, the Relevant Partner will inform the Recipient if there are any additional terms and conditions of use over and above those set out in this Agreement. If there are any additional terms and conditions of use, and before the Discover dataset is shared, the Recipient must agree to those additional terms in writing and such terms shall be deemed to be incorporated into this Agreement.

## No term of this Agreement shall oblige the Relevant Partner to disclose any of the Discover Dataset to the Recipient. The Relevant Partner does not guarantee access or that the Discover Dataset and/or that it will be fit for the Purpose(s) that the Recipient requires.

## Notwithstanding the fact that data quality is an important priority under the ISA, the Relevant Partner does not warrant and shall have no liability for the quality, accuracy, completeness and validity of the Discover Dataset.

## **RETENTION OF INFORMATION**

## Unless otherwise specified in the De-Identified Data Request Form or an extension has been granted, the Discover Dataset may be only Processed for a maximum of 6 months.

## If the Recipient requires an extension to the permitted period of access, then the Recipient will request an extension in writing by making an application to the Data Access Committee. To continue access, to the Discover Dataset, this extension request must be made, and approved, before the expiration of the current period of access.

## No term of this Agreement shall oblige the Data Access Committee to extend the period of access and the Data Access Committee will determine at their own discretion whether to accede to such a request, and shall notify the Recipient of its decision in line with its own procedures.

## **CONDITIONS OF DISCLOSURE**

## In return for the Data Access Committee granting the Recipient access to the Discover Dataset, the Recipient warrants, represents and undertakes that:

## the De-identified Data Request Form has been completed accurately and the statement in section 13 of the same form is true to the best of their knowledge;

## will only use the Discover Dataset for the Purpose set out in section 4.1 of the De-Identified Data Request Form;

## no one, other than those named in the De-identified Data Request Form, from the Recipient’s organisation will be permitted access,

## he/she will not knowingly permit anyone include to attempt and/or circumvent the security and access controls that are already in place for the data;

## the Discover Data will not be exploited for any other commercial purposes other than those disclosed within the De-Identified Data Access Form or permitted by a license;

## he/she/they will only use the Discover Dataset for scientific and medical research purposes only, this research always with the aim of benefit the public and society in general;

## will not seek or attempt to re-identify any individual whose Personal Data has been de-identified and whose data is contained within the Discover Dataset or combine the aforementioned dataset with any other data in an attempt to identify any individual;

## shall not link or attempt to link the Discover Dataset, whether in whole or in part, with any other dataset, especially ones who may contain Personal Data;

## shall comply with all Applicable Law in his/her use of the Discover Dataset and shall not discharge his/her obligations under this Agreement in such a way as to cause the Relevant Partner to breach any of its obligations under Data Privacy Law;

## shall ensure that any outputs are attributed the Relevant Partner and source of the information they use, as per section 11.2 of the De-Identified Data Request Form;

## will fully co-operate with the Relevant Partner, the NWL IG Board and/or the Data Access Committee if they require any information;

## On expiry of the retention period the Recipient will delete all copies of the Discover Dataset and if applicable hard copies will be shredded;

## The Recipient shall not do anything that may materially damage the reputation of the Relevant Partner and/or NWL Data Controllers; and

## The Recipient shall not make, or permit any person within his/her organisation and/or named in the De-Identified Data Request Form, to make any public announcement concerning the subject matter of this Agreement without the Relevant Partner's and Data Access Committee’s prior written consent.

## **SECURITY**

### The Recipient agrees to adhere to any security controls mandated by the NWL Data Controllers, the NWL IG Board and/or the Data Access Committee. This to include any specific security controls in place within the system, platform and/or software that hosts the Discover Dataset and using a VDI.

### If applicable and only when strictly permitted to do so, the Recipient will store the Discover Dataset on a secure system and apply the adequate technical and organisational measures to protect the dataset from unauthorised disclosure, copying and/or use.

### The Recipient must ensure that any device used to access the Discover Dataset is Virus free and take precautions to prevent a Virus being imbedded within the device.

## **AUDITS**

### During the Agreement period, the Relevant Partner reserves the right at any time to undertake an audit in respect of the Recipient's Processing of the Discover Dataset and compliance with the terms of this Agreement. This can include, but not limited to, checking:

### Destruction of the Discover Dataset; and/or

### Whether on expiry of the retention period the Recipient will delete all copies of the Discover Dataset; and

### The Recipient will also provide any assurances in writing, to the Relevant Partner, the NWL IG Board and/or the Data Access Committee, with any confirmation required in lieu of an actual audit .

## **RETURN OF THE DATA**

### The Recipient shall comply with any request from the Relevant Partner, the NWL IG Board and Data Access Committee requiring the Recipient to:

### securely return all or part of Discover Dataset; and

### do so within a timeframe specified and in accordance with any specified security measures.

## **FREEDOM OF INFORMATION and DISCLOSURE**

## The Recipient acknowledges that the Relevant Partner and/or NWL Data Controllers are subject to the requirements of FOIA and shall assist and co-operate with the Relevant Partner and/or NWL Data Controllers to enable them to comply with the FOIA disclosure requirements.

## The Recipient shall:

## transfer any FOIA Request received to the Relevant Partner as soon as practicable after receipt and in any event within three (3) days of receiving a FOIA request;

## disclose the Relevant Partner and/or any NWL Data Controllers the information they require in order to be able to respond to the request; and

### provide all necessary assistance as reasonably requested by the Relevant Partner to enable the Relevant Partner to respond to a FOIA Request within the time for compliance set out in section 10 of FOIA.

## The Party who has received the FOIA request shall be responsible for determining at its absolute discretion whether the requested data:

## is exempt from disclosure in accordance with the provisions of FOIA; and/or

## is to be disclosed in response to a FOIA Request.

## The Recipient is prevented, unless the Recipient is also under obligations of FOIA, from responding directly to a FOIA Request, made in respect of the Discover Dataset, unless expressly authorised to do so by the Relevant Partner and the Data Access Committee.

## If any Party takes a decision to comply with the FOIA Request, it shall notify the Recipient of this decision not less than three (3) days in advance of the disclosure being made and provide the Recipient with a copy of the information that it intends to disclose.

## For any other requests to release the Discover Dataset, the Recipient must obtain the written permission of the Relevant Partner and Data Access Committee prior to its release.

## **SECURITY BREACH AND BREACH OF CONDITIONS**

10.1 The Recipient must report any known or suspected Security Breach concerning the Discover Dataset to the Relevant Partner and by emailing: [nwl.infogovernance@nhs.net](mailto:nwl.infogovernance@nhs.net) within twenty-four (24) hours of that known or suspected Security Breach.

10.2 In the event of a Security breach and/or breach concerning any terms of this Agreement, the Relevant Partner and/or the NWL Data Controllers may at their absolute discretion take the following actions:

10.2.1 Suspend access to the Discover Dataset;

10.2.2 terminate any obligations to the Recipient under this Agreement; and/or

10.2.3 terminate any rights afforded under clause 11 of this Agreement.

## **Proprietary Rights in the Data**

## Any and all Intellectual Property Rights owned by, or licensed to, either the Relevant Partner and/or the Recipient, together with any and all improvements to them which are used, improved, modified or developed prior to and after the date of this Agreement, will remain and become the sole property of that Party (‘**Background IPR’**).

## Other than a limited, non-exclusive and time restricted license to use the Discover Dataset for the Purpose, nothing in this Agreement should be interpreted as transferring or shall be deemed to grant any right, title, or interest whatsoever (including any Intellectual Property rights whatsoever) in or to the Discover Dataset or any part thereof.

## Where an application has not been defined as Commercially/Third Party Funded as per section 9.1 of the De-Identified Data Request Form, any Intellectual Property Rights shall be owned wholly by the Relevant Partner. This shall not affect the Requestor’s ‘Moral Rights’ as set out in the Copyright, Designs and Patents Act 1988.

## Where clause 12.3 is applicable, the Relevant Partner hereby grants to the Recipient, and the Recipient in turn accepts, a non-exclusive, perpetual, royalty free license to use the Deliverables for Non-Commercial use(s)/purpose(s).

## Where an application has been defined as Commercially/Third Party Funded as per section 9.1 of the De-Identified Data Request Form, any Intellectual Property Rights in the Deliverable shall be owned, subject to clause 12.6, wholly by ICHP.

## ICHP shall ensure that any use of the Intellectual Property Rights in Deliverables, which may include any subsequent assignment and/or licensing to a third party, is in line with United Kingdom Research Innovation’s ‘Principles of Participation’. Furthermore, ICHP shall also ensure that any assignment and/or license would not restrict the Recipient and/or North West London Collaboration from using the Project Intellectual Property for Non-Commercial purpose(s).

## Any license granted under this clause 12 is subject to the conditions of disclosure set out in clause 5.1, if the Recipient is found to be in breach of any of those conditions then the Relevant Partner, the NWL IG Board and/or the Data Access Committee shall at their own discretion be entitled to revoke any such license.

## **Term and Termination**

## This Agreement shall commence on the Effective Date and shall continue until the Recipient has ceased:

## to use the Discover Dataset for the Purpose; or

## the date specific in section 8.2 of the De-Identified Data Access Request Form.

Whichever is sooner.

## The Agreement may be terminated by the Relevant Partner and/or NWL Data Controllers with immediate effect in the event it would contravene any new Applicable Law that those organisations are subject to.

## This Agreement may be terminated by the Relevant Partner and/or NWL Data Controllers with immediate effect if the Recipient:

## is in breach of any obligation under this Agreement;

## is made the subject of a winding up order or an administrator or receiver is appointed;

## ceases to trade in the UK; or

## is subject to a change of control.

## Termination of the Agreement, for any reason, shall not affect any accrued rights, remedies, obligations and/or liabilities of either Party up to the date of termination, including the right to claim damages in respect of any breach of the Agreement which existed at or before the date of termination.

## **INDEMNITY**

## The Recipient shall indemnify the Relevant Partner and NWL Data Controllers fully and keep them indemnified against all costs, regulatory fines, losses, charges, claims, proceedings, actions, damages, legal costs, expenses and any other liabilities which those parties suffer or for which they may become liable, where they are caused directly or indirectly by any breach of this Agreement by the Recipient.

## **ASSIGNMENT**

## Neither Party may assign, transfer, or otherwise dispose of its rights or obligations under this Agreement without the prior written consent of the other Party.

## **NO WAIVER**

## No failure or delay by either Party to exercise any right or remedy provided under the Agreement or by law, shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such a right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.

## **SEVERABILITY**

## If any provision or part-provision of the Agreement is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification to or deletion of a provision or part-provision shall be deemed deleted. Any modification to or deletion of a provision or part-provision under this clause shall not affect the validity and enforceability of the rest of the Agreement.

## If any provision or part-provision of the Agreement is deemed deleted under clause 17.1, the parties shall negotiate in good faith to agree a replacement provision that, to the greatest extent possible, achieves the intended result of the original provision.

## **STATUS OF THE PARTIES**

## Nothing in this Agreement is intended to or shall operate to create a partnership or joint venture of any kind between the Parties or to authorise either Party to act as agent for the other and neither Party shall have authority to act in the name or on behalf of or otherwise bind the other in any way.

## **THIRD PARTY RIGHTS**

## 19.1 Save for the fact that the NWL Data Controllers are permitted to enforce any rights under this Agreement to protect their own interest, nothing in this Agreement will be construed as conferring any rights or benefits on any person or legal entity who or which is not a Party to this Agreement. The Contracts (Rights of Third Parties) Act 1999 and any other legislation applicable to this Agreement that confers contractual rights on third parties, is hereby excluded to the fullest extent permitted by law.

## **VARIATION**

## No variation or modification of this Agreement shall be valid unless in writing and signed by both parties.

## **ENTIRE AGREEMENT**

## 21.1 This Agreement constitutes the entire agreement and supersedes all previous verbal or written proposals and agreements between the Parties. Except as expressly stated in writing in this Agreement, neither Party has relied upon any statement or representation made by the other in agreeing to enter into this Agreement.

## **COUNTERPARTS**

## This Contract may be executed in any number of counterparts, each of which will be regarded as an original, but all of which together will constitute one agreement binding on all of the parties, notwithstanding that all of the parties are not signatories to the same counterpart.

## **GOVERNING LAW**

## This Agreement and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the laws of England and Wales.

## **GOVERNING LAW AND JURISDICTION**

## Each Party irrevocably agrees that the courts of England and Wales shall have non-exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with this Agreement or its subject matter or formation.

|  |  |
| --- | --- |
| **SIGNED** for and on behalf of **[INSERT DETAILS]** (the “**Recipient**”) | ……………………………………………………….. |
| Name: |  |
| Position: |  |
| Date: |  |

|  |  |
| --- | --- |
| **SIGNED** for and on behalf of **[INSERT PARTNER DETAILS]** (the “**Relevant Partner**”) | ……………………………………………………….. |
| Name: |  |
| Position: |  |
| Date: |  |