**Appendix 7: Application to use the CPFT Research Database (Project)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***Please return to Kristel.Klaus@mrc-cbu.cam.ac.uk*** | | | | | |  |
| **Section 1 - Details of Researcher** *To be completed by the Researcher* | | | | | |
| a | Surname: | | Prof Dr Mr Mrs  Miss  Ms Other | | |
| Forename(s): | |
| Work Address: | | | | |
| Work Tel: Email: | | | | |
| b | Employer: or place of study: | | | | |
| Work Address/Place of Study: | | | | |
| Post or status held: | | | | |
| c | Do you hold a contract with the CPFT?  Substantive employee  Honorary Clinical Contract  Research Passport  Honorary Research Contract  Letter of Access  Date issued: Date of expiry: | | | | |
| **Section 2 – Research Study** *To be completed by the Researcher* | | | | | |
| a | Summary of research project: | | | | |
| b | Full title of the study:  Chief Investigator:  Proposed end date: | | | Sponsor:  Research Ethics Committee and Reference number: | |
| Does the study have CPFT R&D Approval? Yes  No  N/A  Ref number:       Date of approval       Service area | | | | |
| Who is the Principal Investigator at the Trust? | | | | |
| **Section 3 – Search Criteria** *To be completed by the Researcher* | | | | | |
| a | Please set out your search methods. | | | | |
| **Section 4 – Type of study** *To be completed by the Researcher* | | | | | |
| Our study is of the following type (*please tick one*): | | | | | |
| **( )** | | **Research based on anonymous information only (epidemiology, population-based studies, audit, or service development).**  Normally, such research may be conducted under the auspices of the generic ethics approval given to the CPFT Research Database. If your study needs and has additional ethical approval from a Research Ethics Committee, please enclose a copy of your application and approval.  If you do not have independent research ethics approval, then the following conditions apply:   * You may publish your findings freely EXCEPT that you may not publish, or share outside your research team, any information that might inadvertently identify a patient or be recognizable by an individual patient (for example, extremely rare combinations of diseases, or free-text information, that might lead to inadvertent de-anonymisation). Give sufficient detail in your methods regarding data extraction and publication (in the boxes above, or attach further information) that the Committee may be assured of this.   The following conditions also apply:   * In general, the Committee will not approve requests where information relating to individuals, or to groups of fewer than 10 people, is sent outside an NHS secure environment at any time. * You must keep data secure, and store data in accordance with CPFT’s information governance policies, your institution’s policies (if your CPFT contract is honorary) and the Department of Health Research Governance Framework for Health and Social Care and its Annex (see http://www.dh.gov.uk).   Please skip to Section 7. | | | |
| **( )** | | **Patient-contact research.** **We wish to contact patients based on our searches.**  Please complete Section 5, then move to Section 7. | | | |
| **( )** | | **Commercial trials feasibility**  Please complete Section 6, then move to Section 7. | | | |
| **Section 5 – For patient-contact studies ONLY: Type of patient contact** *To be completed by the Researcher* | | | | | |
| a | Do you plan to include patients under the age of 16? | | | | Yes  No |
| b | Do you plan to include patients who lack the capacity to consent? | | | | Yes  No |
| c | Is your research a clinical trial governed by the Clinical Trials Regulations? | | | | Yes  No |
| d | Do you plan to include patients who have been discharged from CPFT? | | | | Yes  No |
| e | When always approaching via the patient’s clinician: Do you wish to include a form to collect data from the patient’s clinician? | | | | Yes  No |
| f | Researchers involved in taking face-to-face consent for participation in a study must be trained in the assessment of capacity. Please list these researchers and provide evidence of capacity training (such as CPFT’s basic capacity training for researchers). | | | | |
| **Researcher 1:** | | | | MCA module |
| **Researcher 2:** | | | | MCA module |
| **Researcher 3:** | | | | MCA module |
| **Section 6 – For commercial feasibility** *To be completed by the Researcher* | | | | | |
| a | Is R&D aware of the expression of interest from the company? | | | | Yes  No |
| b | Is your research a clinical trial governed by the Clinical Trials Regulations? | | | | Yes  No |

|  |  |  |
| --- | --- | --- |
| **Section 7 – Declaration** *To be completed by the Researcher* | | |
|  | I confirm that I will:   * comply with ethics approval and R&D approval for my study * follow the guidance of the Principal Investigator for CPFT * comply with CPFT’s Information Governance rules * comply with the Data Protection Act * conform to CPFT’s policies regarding the Research Database, and the conditions in this application form * follow any additional requirements specified by the Research Database Oversight Board | |
| Signed: | Dated: |

|  |  |  |
| --- | --- | --- |
| **Section 7 – Declaration** *To be completed by the Researcher* | | |
|  | As an approved researcher accessing the Affective Disorders Research Database (ADRD), I agree to adhere to the CPFT information governance regulations.  Any data accessed from the ADRD will be stored, retained and disposed of in line with their data protection and confidentiality policies and will remain within the CPFT network. No data will be removed from a CPFT server (including printing, saving onto an external USB, emailed ect).  **Breach of confidentiality**  If a breach of data protection is found to have occurred, it is the responsibility of the researcher to notify the ADRD Committee, who will ensure the data breach is reported appropriately and the necessary reporting requirements and timescales are adhered to.  **ADRD Contacts:**   |  |  | | --- | --- | | Dr Caitlin Hitchcock | Caitlin.Hitchcock@mrc-cbu.cam.ac.uk | | Dr Tim Dalgleish | Tim.Dalgleish@mrc-cbu.cam.ac.uk | | Dr Rajini Ramana | rajini.ramana@cpft.nhs.uk | | Rachel Elliott | Rachel.elliott@mrc-cbu.cam.ac.uk | |  |  | | |
| Signed: | Dated: |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 8 – *To be completed by the Research Database Administrator*** | | | |
| a | Does the study have R&D Approval or Trust approval in the case of Audit or service evaluation | | Yes  No |
| b | Is the study’s Ethics Approval compatible with the use of the Research Database to recruit participants? | | Yes  No  N/A |
| c | Applicant has honorary/substantive contract in place? | | Yes  No |
| d | Applicant has completed Good Governance Module? | | Yes  No |
| e | All researchers taking consent have completed MCA Module? | | Yes  No  N/A |
| Completed by: | | | Dated: |
| **Section 9 – *To be completed by the Research Database Oversight Committee*** | | | |
| a | Study approved for use of Affective Disorders Research Database  Research Database Project Approval Number: | Yes  No  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Signed by: | | Dated: | |

**Documents to include in your application**

|  |  |  |
| --- | --- | --- |
|  | **Patient contact** | **Epidemiological studies** |
| NHS Ethics Letter | Required | N/A |
| REC Form | Required | N/A |
| Insurance letter | Required | N/A |
| Sponsorship letter | Required | Required |
| R&D Approval Letter | Required | Required |
| Patient information sheet (PDF) | Required | N/A |
| Research team CVs | Required | PI Only |
| MCA training certificates | Required | N/A |
| Data collection form for completion by clinicians (PDF) | optional | N/A |