|  |
| --- |
| OxCRF New Business Application Form |
| Thank you for applying to undertake research in the Oxford Clinical Research Facility.  Refer to the Guidance for Applicants Document  If you have any questions please contact us[**oxcrf@ndorms.ox.ac.uk**](mailto:oxcrf@ndorms.ox.ac.uk) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Your details | | | | | | | | | | | | | | | | | |
| **Investigator’s Name** |  | | | | | | | **Job title:** | | | | |  | | | | |
| **Work email:** |  | | | | | | | **Work phone:** | | | | |  | | | | |
| **Department** |  | | | | | | | **PID (if known)** | | | | |  | | | | |
| **Describe your role in the study below (e.g. CI, PI etc.):** tick one |  | | Chief Investigator | | |  | | | Principal Investigator | | | | |  | Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Main Employer ✓** |  | Oxford Univ. | |  | OUH Trust | | | | |  | Oxford Health Trust | | | | |  | Other**1** |
| **Honorary contracts ✓** |  | Oxford Univ. | |  | OUH Trust | | | | |  | Oxford Health Trust | | | | |  | Other**2** |
| **1 Specify employer:** |  | | | | | | **2 Specify contract** | | | | |  | | | | | |
| **Principal Investigator’s**  **Speciality**  **✓ one** |  | VACCINES | | | | | | | |  | NEUROSCIENCES | | | | | | |
|  | DIABETES ENDOCRINE & METABOLISM | | | | | | | |  | MENTAL HEALTH | | | | | | |
|  | GASTROENTEROLOGY | | | | | | | |  | RESPIRATORY | | | | | | |
|  | INFECTIOUS DISEASES | | | | | | | |  | RHEUMATOLOGY | | | | | | |
|  | Other (please specify)  Free text | | | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Your study*Please also provide a copy of the current protocol or equivalent (e.g.: funding application, synopsis ) other supporting documentation* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Full Research Title:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Expected sample size:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | **Multi-centre study** | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | **Single site** | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Funding status**  tick one | | | | | | |  | | | | | | Expression of Interest | | | | | | | | | | | | | | | | | |  | | Preparing application | | | | | | | | | | | | | | |  | | | | | Fully funded | | | | |
|  | | | | | | |  | | | | | | Other or part funded (specify): | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Protocol status**  tick one | | | | | | |  | | | | | | Early draft | | | | | | | | |  | | | | | | | | Final, awaiting approvals | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | |  | | | | | | Close to final | | | | | | | | |  | | | | | | | | Final, fully approved | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Planned start date in CRF:** | | | | | | | | | | | | |  | | | | | | | | **End date if CRF Activity (approx)** | | | | | | | | | | | | |  | | | | | | | | | | | | | |  | | | | | Or NK/NA | | | | |
| **Are there any deadlines or constraints the OxCRF review need to consider?**  *We will do our best to work within these timelines but this may not always be possible* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Please give details of the studies independent peer review status below:** tick one | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ☐ No Peer Review | | | | | | | | | | ☐ Peer review will be completed as part of funding application | | | | | | | | | ☐ Peer review completed & attached | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ☐ Other (please provide details) | | | | | | |
| Organisational and funding Details | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Funding sources**  Tick all that apply | | | | | | | | |  | | | | BRC | | | | | | | | |  | | | | Charity (UK) | | | | | | | | | | |  | | | Wellcome | | | | | | | | |  | | | MRC | | | |  | NIHR |
|  | | | | | | | | |  | | | | Industry (IIS) | | | | | | | | |  | | | | Fully Industry | | | | | | | | | | |  | | | Other\* | | | | | | | | | | | | | | | | | |
| **Sponsorship**  Tick all that apply | | | | | | | | |  | | | | OUH | | | | | | | | |  | | | | Oxford Uni. | | | | | | | | | | |  | | | Oxford Health | | | | | | | | |  | | | Industry | | | |  | Other |
| **Are you working with a CTU on this study?** | | | | | | | | | | | | | | | | | | | |  | | | | | | | Yes | | | | |  | | | | No | | | | | | | | | |  | Unsure | | | | | | | | | | |
| **If yes, give CTU name & contact details** | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Collaboration and cross department working | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Please indicate if you are collaborating with any other specialities on this study*** *(✓ all that apply)* | | | | | | | | | | | | |  | | VACCINES | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | NEUROSCIENCES | | | | | | | | | | | | | |
|  | | | | | | | | | | | | |  | | DIABETES ENDOCRINE & METABOLISM | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | MENTAL HEALTH | | | | | | | | | | | | | |
|  | | | | | | | | | | | | |  | | GASTROENTEROLOGY | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | RESPIRATORY | | | | | | | | | | | | | |
|  | | | | | | | | | | | | |  | | INFECTIOUS DISEASES | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | RHEUMATOLOGY | | | | | | | | | | | | | |
|  | | | | | | | | | | | | |  | | Others (please specify) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Interventions | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Phase:** | | | | |  | | | | | | | | Phase Ia | | | | | | | | |  | | | | | | Phase Ib | | | | | | | | | | |  | | | Phase II | | | | | | | |  | | | | Phase III | | | |
| **Is this a Clinical Trial of Investigational Medicinal Product (CTIMP) needing MHRA Clinical Trials Authorisation?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Yes | | | | | |  | | | | | No | | | | | | | | |  | | | | | | | | | | Unsure | | | | | | | | | | | | | | | | | | | | | | | | | |
| **What is the current IMP manufacturing/ import status?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Not yet manufactured | | | | | | | | | | | | | | | Being manufactured | | | | | | | | | | | | | | | | Released | | | | | | | | | | | | | | Received by pharmacy | | | | | | | | | | | | |
| Other, provide details: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Who is supplying the IMP?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Is the project an Advanced Therapy Investigation Medicinal Product (ATIMP)?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Yes | | | | | |  | | | | | No | | | | | | | | |  | | | | | | | Unsure | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Is the project a Clinical Trial of a Medical Device?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Yes | | | | | |  | | | | | No | | | | | | | | |  | | | | | | | | | | Unsure | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Is the project a Human Challenge study?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes | | | | | |  | | | | | | | No | | Unsure | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Your study team **OxCRF will work with your team to deliver the study – details will be finalised during set up.** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Medical Cover in OxCRF: All studies must have a medically qualified person who has agreed to be responsible for ensuring that immediate medical assistance is available for participants during their visits to the CRF. Please ensure this issue is discussed with the CRF. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Will you be able to allocate a named person to provide medical cover for OxCRF visits?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Yes | | | | | | | | | |  | | | No | | |  | | | | | | Unsure | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Do you have Research Nurse (RN) support from within your department or the Network to cover CRF activity?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Yes | | | | | | | | | |  | | | No | | |  | | | | | | Unsure | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **If YES please give name** | | | | | | | | | | | | | | | Name | | | | | | | | | | | | | | | | | | | | | | | Email | | | | | | | | | | | | | | | | | | | |
| **Nominated Study Contact**  *who will assist with study set-up* | | | | | | | | | | | | | | | Name | | | | | | | | | | | | | | | | | | | | | | | Email | | | | | | | | | | | | | | | | | | | |
| **Will the study involve specialist staff (e.g. for oscopy or other specialist procedures)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Yes | | | | | | | | | |  | | | No | | |  | | | | | | Unsure | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **If YES please give details of the proposed staff cover arrangements (with names & contact details if known)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Free text | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CRF Activities | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **What activities will be undertaken in the CRF? (tick all that apply)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Informed consent | | | | | | | | | | | | |  | Screening | | | | | | | | | | | | | | | | | | |  | | | Recruitment/ enrolment | | | | | | | | | | | | | | | | | | | |
|  | | Intervention/procedure | | | | | | | | | | | | |  | Follow up | | | | | | | | | | | | | | | | | | |  | | | Data entry | | | | | | | | | | | | | | | | | | | |
|  | | Other (Please provide details) : | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clinical resources and research support | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Please select which OxCRF resources you require** (tick all that apply). | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Patient bed | | | | | | | | | | | | |  | Oscopy suite | | | | | | | | | | | | | | | | | | |  | | | Clean minor procedure room | | | | | | | | | | | | | | | | | | | |
|  | | Out-patient rooms | | | | | | | | | | | | |  | Lab processing | | | | | | | | | | | | | | | | | | |  | | | Protocol development and design | | | | | | | | | | | | | | | | | | | |
|  | | In-patient room (for overnight stay) | | | | | | | | | | | | |  | PPI support | | | | | | | | | | | | | | | | | | |  | | | Other - please provide details below | | | | | | | | | | | | | | | | | | | |
| **Does your study require the use of the whole facility at one time?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | Yes | | | | | | | | | |  | | | | No | | | | | | | | | | | | | | | | |  | | | | Unsure | | | | | | | | | | | | | | | | | | | | | |
| **Do you require additional CRF Core staff support to cover the study visits?** *E.g: Research Nurse* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Yes | | | | | | | | | |  | | | No | | |  | | | | | | Unsure | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **If yes or unsure, please list below, the role(s) and/ or key duties to be delegated to CRF staff on this study** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3) Study specific equipment | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Is there any study specific equipment required to be used or stored in OxCRF?**  Please note – a separate Risk Assessment and procurement process will be completed for any equipment coming into the facility. Training, size, storage, and post-study arrangements will need to be considered. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | Yes | | | | | | | | | | | | |  | No | | | | | | | | | |  | | | | | Unsure | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **IF yes, please provide details:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Patient & Public Involvement (PPI) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **What PPI has there been in the development of your study?** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Have requested PPI support from OxCRF. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Do you have a PPI representative in your trial team?** | | | | | | | | | | | | | | |  | | | | Yes | | | | | | | | | | | | | | | | | | |  | | | | | No | | | | | | | | | | | | | | |
| NIHR Resources | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Will your study utilise other NIHR resources? | | | | | | | | | | | | | | | | |  | | | | | | Yes | | | | | | | | |  | | | | | | No | | | | | | | | | | | | |  | | | | Unsure | | |
| If yes, please indicate which below and details of resource (name, location): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | NIHR BRC \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | NIHR Local Clinical Research Network \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | Other NIHR Clinical Research Facilities (if multicentre study)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | Other – please provide details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Supporting Documents Required | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Item** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Attached** | | | | | | | | | | | | **Not Applicable/ available** | | | | |
| 2 page CV from Applicant (CI or PI) *For first time users of OxCRF* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | |  | | | | |
| Latest GCP certificate | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | |  | | | | |
| Peer review of study proposal | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | |  | | | | |
| Investigator Brochure/SmPC *For CTIMPs/ATIMPs* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | |  | | | | |
| Clinical Investigation Plan *For Device Trials* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | |  | | | | |
| Specialist Protocols *For Lab processing, procedures, pharmacy stores etc* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | |  | | | | |

**Thank you, the final section below asks for details of the protocol visits.**

## Please use this Visit Schedule if not already included in your proposal/protocol document

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Procedures** | **Timings** (indicate when these visits are planned ie: Visit 1 = Day 0, Visit 4 = Day 120) | | | | | | | | | | | |
| Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | Visit 7 | Visit 8 | Visit 9 | Visit 10 | Visit 11 | Visit 12 |
| **Indicate activity**  *Screening/Recruitment/Consent/*  *Intervention/Follow up* |  |  |  |  |  |  |  |  |  |  |  |  |
| **Anticipated length of visit (hours)** |  |  |  |  |  |  |  |  |  |  |  |  |
| Bed |  |  |  |  |  |  |  |  |  |  |  |  |
| Recliner chair |  |  |  |  |  |  |  |  |  |  |  |  |
| Consulting room |  |  |  |  |  |  |  |  |  |  |  |  |
| In-patient room |  |  |  |  |  |  |  |  |  |  |  |  |
| Clean procedure room |  |  |  |  |  |  |  |  |  |  |  |  |
| Oscopy room |  |  |  |  |  |  |  |  |  |  |  |  |
| Lab |  |  |  |  |  |  |  |  |  |  |  |  |
| Other…. |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

This refers to protocol visits that will be performed in OxCRF

**Please send the completed application form and accompanying documents to** [**oxcrf@ndorms.ox.ac.uk**](mailto:oxcrf@ndorms.ox.ac.uk)