**Registration of Interest/Site Feasibility Assessment**

PROTECT-V for the addition of monoclonal agents to the platform

**Site Name: ……………………………………………………………………………………………**

**Address: ………………………………………………………………………………………………**

**The study protocol and synopsis for monoclonal arm is sent as an attachment, please keep it confidential.**

**Details of Principal Investigator:**

|  |  |  |
| --- | --- | --- |
| Title: | Name: | |
| Qualifications: |  | |
| Address: | | Tel: |
| Email: | | Fax: |

|  |  |
| --- | --- |
| Is your site already active in the PROTECT-V trial?  Is your site in the set-up phrase for PROTECT V, with your R&D actively reviewing the study? | Yes/No  Yes/No |
| Do you want to consider running a monoclonal arm (s) in the trial at the trial at your site?  If no, please email back to inform us. There is no need to complete the remainder of the questionnaire. Many thanks for your ongoing support and recruitment to the existing arms of the study.  If yes, please answer the following questions to ensure that this is feasible at your site. | Yes/No |
| Do you have a record of patients who have mounted sub-optimal responses to vaccination at your centre? E.g. the OCTAVE study or other similar local initiatives? | Yes/No |
| Which of the following patient groups could you recruit from:   1. Solid organ transplant 2. Haematopoietic stem cell transplants 3. Autoimmune disease receiving long-term immunosuppression 4. Primary immune deficiency 5. Individuals receiving chemotherapy 6. Other patients who are likely to have a sub-optimal response to a COVID vaccine (if yes please specify below)   Other: | Yes/No  Yes/No  Yes/No  Yes/No  Yes/No  Yes/No |
| If yes, please indicate an estimate of the number of patients your site would be able to recruit per group:  Solid organ transplant \_\_\_\_\_\_\_\_\_\_  Haematopoietic stem cell transplants \_\_\_\_\_\_\_\_\_  Autoimmune disease receiving long term immunosuppression \_\_\_\_  Primary immune deficiency \_\_\_\_\_\_\_\_  Individuals receiving chemotherapy \_\_\_\_\_\_\_\_\_  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ |  |
| Do you have access to a clinical research facility (CRF) at your site?   * Will it have capacity to accommodate patients in this trial in August 2022 - September 2023? * How many patients could be seen each day at the CRF? * Did your CRF conduct COVID-19 vaccine trials, and could a similar model be used for this study? * Within what timeframe would you envisage your site would be able to recruit the number of patients you have suggested above? In months * If you do not have a CRF or you do not plan to use a CRF, does your site have the capacity to screen, recruit and perform the face-to-face visits for the number of patients you have stated above? | Yes/No  Yes/No  Yes/No  Yes/No |
| Do you have sufficient medical cover for the trial (particularly time for consent, SAE reporting)? | Yes/No |
| Do you have sufficient research nurse cover for screening, drug administration and follow up (4 F2F visits over 6 months with 2 weekly phone call f/u for the duration of the study)?  Do you have CRN nurse and admin support at your unit? | Yes/No  Yes/No |
| Would blinding at the level of pharmacy or research nurse be preferable at your site? NB.IMP is a single IV injection. | Yes - Pharmacy  Yes - RN |
| Does your site have the facility/capability to bring in COVID positive patients in order to take blood tests? | Yes/No |
| Have you contacted your local R&D department about this significant amendment to the study, and have they the capacity to review quickly? | Yes/No |
| Please give the name of the sub-investigators who would lead each of the cohorts in your centre. Put N/A if you do not plan to enrol a sub-group.  Solid organ transplant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Haematopoietic stem cell transplants \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Autoimmune disease \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Primary immune deficiency \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Individuals receiving chemotherapy \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Renal patients \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other patients who are likely to have a sub-optimal response  (please specify cohort and Sub-investigator) |  |
| ***If your site is already recruiting, please sign the last page.***  ***If your site is not already active in the PROTECT-V trial***  ***Please complete the following additional details*** |  |
| Are you aware of any competing studies either ongoing or in set-up at your site (looking at the same patient population as this trial or similar IMP)  If yes, please give details | Yes/No |
| Do the laboratories at your site or likely to be processing samples from the trial have valid UKAS accreditation or equivalent? | Yes/No |
| Do you have the following equipment accessible at your site?  Centrifuge  Fridge  -70C Freezer | Yes/No  Yes/No Yes/No |
| Do you have the following necessary facilities to be able to conduct the study?  Pharmacy  Clinical Biochemistry Lab  Microbiology/virology lab (capacity to perform COVID PCR swab)  Access to Lateral Flow tests | Yes/No  Yes/No  Yes/No  Yes/No |
| Are you aware of all financial implications for your site in participating in this study?  IMP is free of charge  Provided fees:  £2823 site set up fee  £2160 site pharmacy setup/close out fee  £100 for each patient screened (up to a maximum of 30% screen fail rate)  £1000 for each randomised participant that receives IMP.  £500 Archiving fee. | Yes/No |

**Details of the Site R&D Contact:**

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| Title: | Name: | |
| Address: | | Tel: |
| Email: | | Fax: |

**Details of the Site Research Team Main Contact:** (this can be a research nurse, research fellow, PI, site coordinator etc.)

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| --- | --- | --- |
| Title: | Name: | |
| Job Title: |  | |
| Address: | | Tel: |
| Email: | | Fax: |

**Details of the Site Trial Pharmacy Department Contact:**

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| --- | --- | --- |
| Title: | Name: | |
| Job Title: |  | |
| Address: | | Tel: |
| Email: | | Fax: |

Signature: Print Name: Date:

Please send to: Francis Dowling, Emmanuel Sappor, Phoebe Vargas

Cambridge Clinical Trials Unit, Box 401 Coton House Level 6 Addenbrooke’s Hospital, Hills Road, Cambridge CB2 0QQ

Email: add-tr.protect@nhs.uk

**Thank you**