|  |
| --- |
| **Please complete the minimally required information below** |
| Chief Investigator or Primary Collaborator | Name: |
| Position: |
| Institution/Department: |
| Email address: |
| Individual submitting (if different from above) | Name:  |
| Email Address: |
| Proposed research title (full) |  |
| Proposed research title (short/acronym) |  |
| Brief outline of research question and case of need | Or attach synopsis if available assuming no issues of confidentiality |
| Protocol  | Attach if available assuming no issues of confidentiality |
| Proposed funder | Name: |
| Call title: |
| Deadline: |
| URL:  |
| [ ]  Outline/Expression of Interest [ ]  Full [ ]  Resubmission |
| Proposed sponsor  | Name: |
| Has the proposal been discussed? [ ]  Yes [ ]  No  |
| If yes, outcome: |
| Proposed project start date and duration |  |
| CTU services of interest(select all that apply) | [ ]  Full service (all of below) [ ]  Trial design[ ]  Protocol development[ ]  Ethics and regulatory submissions [ ]  Trial management[ ]  Trial Master File maintenance [ ]  Pharmacovigilance [ ]  Monitoring[ ]  Quality assurance[ ]  Database development[ ]  Data management [ ]  Randomisation [ ]  IMP management[ ]  Pharmacy[ ]  Statistics[ ]  Clinical trial report production [ ]  Publication  |
| **Please complete sections below if known** |
| Type  | [ ]  Clinical Trial of Investigational Medicinal Product (CTIMP)\*[ ]  Medical device\*\*[ ]  Surgery[ ]  Qualitative[ ]  Access to existing datasets[ ]  Other specify:  |
| \*IMP | Name: |
| Licensing status:  |
| Supplier: |
| \*\*Device | Name: |
| Licensing status:  |
| Supplier: |
| Phase | [ ]  I [ ]  II [ ]  III [ ]  IV [ ]  Pilot/feasibility  |
| Design | [ ]  Parallel [ ]  Crossover [ ]  Adaptive [ ]  Other specify:  |
| Randomised  | [ ]  Yes [ ]  No  |
| If yes, number of arms: | Ratio: |
|  |  |
| Control arm | [ ]  Placebo [ ]  Standard of care [ ]  Other specify:  |
| Blinding | [ ]  Open label [ ]  Single blind [ ]  Double blind [ ]  Assessor blind  |
| Primary outcome |  |
| Secondary outcome(s) |  |
| Follow-up period |  |
| Location | [ ]  UK [ ]  Multinational (EU only) [ ]  (Multinational (incl. non-EU)  |
| No. of sites |  |
| No. of participants  |  |
| Participants | [ ]  Healthy volunteers [ ]  Type I diabetes [ ]  Type II diabetes [ ]  Other specify: |
| Feasibility/recruitment rate data |  |
| Competing trials | [ ]  Yes [ ]  No  |
| If yes, provide details: ­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­ |
| Statistical design |  |
| Genetics | [ ]  Yes [ ]  No  |
| Biomarkers | [ ]  Yes [ ]  No |
| Health Economics | [ ]  Yes [ ]  No |
| Quality of Life or Patient Reported Outcome Measures | [ ]  Yes [ ]  No |
| Qualitative | [ ]  Yes [ ]  No |
| PPI plans |  |
| Other collaborators |  |
| Other information |  |
| **Please return to dtu@dtu.ox.ac.uk** |
|  |
| **For office use only** |
| Date of receipt (dd/mmm/yyyy): |
| Receipt acknowledged by (print name): |
| Content Management System Reference Number:  |
| Date of DTU Management Committee review (dd/mmm/yyyy): |
| Outcome of review: |
| Feedback: |
| Date outcome/feedback returned: |
| Feedback returned by (print name):  |