TCD Sponsorship Request Form

Purpose and Instructions:

The purpose of this form is to request TCD Sponsorship, in principle, for your trial/study when applying for funding. **Clinical Research is research that involves humans (patients or volunteers) their samples or their health data.**

TCD sponsorship includes providing appropriate **insurance cover** for study participants, University staff conducting the trial/study and the University (Institution) itself.

This form should be completed by PI or designee **when applying for funding** for all clinical research trials/studies **where the application requires a named sponsor** (e.g. HRB DIFA).

This form must be completed at one sitting, it cannot be saved mid-way and restarted. You may see/ print a pdf of the sponsorship request form on this website, if you wish to see the form in advance of completing it. When you submit the form click 'send email confirmation', to give you access to view the form later.

If you are not sure how to answer any of the questions below email: clinicaltrialsponsorship@tcd.ie

Some of your responses may need to be sent on to the State Claims Agency and/or University's Insurance underwriters. Please ensure your responses are in lay person's terms and can be understood by persons who have limited clinical or scientific knowledge.

* Required

Principal Investigator (PI) Details

1. Full name *

2. Email address *

3. Department: *

4. Is the PI: *

Please select at most 2 options.

- [ ] TCD Employee
- [ ] HSE Employee
- [ ] Joint TCD/HSE Employee
- [ ] Other

5. If Other, please specify:

(If PI is an employee of the HSE/voluntary hospital only, please clarify her/his affiliation with TCD)

Study Details

6. Study Title *

7. Please provide a brief summary of the proposed study *

(Max 300 words)

8. Please select which study type applies to your planned research *

If you are unsure of the category for your study, please email: clinicaltrialsponsorship@tcd.ie

- ◯ An interventional clinical trial of an investigational medicinal product/ medicine/ (IMP)?
- ◯ An interventional clinical investigation of a medical device or software App?
- ◯ An interventional clinical trial of another intervention e.g., Food, Exercise, Behavioural intervention?
- ◯ An observational study only?

9. Estimated study start date: *

10. Study duration in months: *

The value must be a number

Location of Research

(e.g in academic institution, hospital, CRF-SJH, primary care locations)

11. Will the study be run in conjunction with the Clinical Research Facility at St James's Hospital (CRF-SJH)? *

- ◯ Yes
- ◯ No

12. How many sites will carry out the study?

The value must be a number

13. Please specify the locations of the clinical sites.

Funding Source

14. Are you applying for funding for this study: *

- ◯ Yes
- ◯ No

15. Please specify the funding source for this study. If you are applying to a funding agency, please specify the agency and programme (e.g., HRB DIFA).

Parties involved in the Study and their Role

16. Please clarify who is writing/designing the protocol *
(Max 50 words)

17. Is any other external/third party providing financial, in-kind, or other support for the study? *

- ◯ Yes
- ◯ No

18. If yes, clarify their role (for example providing free products):

Participant Population

19. Who will participate in your study?

- [ ] Healthy volunteer
- [ ] Patient

20. Anticipated number of participants**:**

The value must be a number

21. Will your research involve any of the following populations?

- [ ] Pregnant / nursing women
- [ ] Children under 16
- [ ] HIV
- [ ] Hepatitis
- [ ] CJD

Involvement of TCD Employees in the study

22. Will TCD employees be collecting biological samples (e.g., blood, urine, faeces, saliva, etc.)? *

- ◯ Yes
- ◯ No

23. If yes, please specify what samples, who will collect them and where:
(Max 100 words)

24. Will any diagnostic investigations other than blood/ urine tests be performed as part of the study?

- ◯ Yes
- ◯ No

25. If yes, please specify what, by whom and where:
(Max 100 words)

Additional Details

26. Please specify if there are any other factors that should be highlighted to the Sponsor/ Insurer to allow their risk assessment.
(Max 300 words)

27. Applicant Name:
*