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## OpenSAFELY Project Application Form

**This form should be completed by the Project Lead.**

The Project Lead must be an OpenSAFELY Full User, is responsible for the co-ordination of the project team, and will be the primary point of contact with the OpenSAFELY team.

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### GENERAL INFORMATION

**What is your name? \***

First Name

Last Name

**Are you an OpenSAFELY Full User? If you have not yet applied to be an Approved OpenSAFELY User, please apply by following the link below. \***

Yes

No, but I have submitted an application

No. I understand my Project Application cannot be progressed until I have completed a User Application

[Please click here to access the Full User Application Form.](#)

**Are you a Ph.D. student? \***

Yes

No

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## PHD STUDENT SUPERVISOR

Projects led by a Ph.D. student require explicit support from a supervisor. We will contact your supervisor to confirm their support for your project and to check that a Data Sharing Framework Contract (DSFC) with NHS England is in place with the employer of your supervisor. Your application will not be reviewed by NHS England until this has been confirmed.

**What is your supervisor's name? \***

First Name

Last Name

**What is your supervisor's email address? This must be the email provided to them by your organisation, not a personal email address. \***

example@example.com

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## YOUR PROJECT TEAM

Please tell us about the other members of your project team.

*If you are unsure about the distinction between a Full User and a Collaborator, please see the glossary linked at the top of this page.*

Please make sure you include:

- Their full name
  - Their organisation
- You **will** be able to amend/expand your project team in the future.

**Please list all other OpenSAFELY Full Users working on this project. \***

**Please list any OpenSAFELY Collaborators working on this project. \***

**Are all listed members of your project team Approved OpenSAFELY Users? If they have not yet applied to become Approved OpenSAFELY Users, please refer them to the link below. \***

Yes

No, but they have submitted applications

No. I understand my Project Application cannot be progressed until they have completed User Applications

[Please click here to access the User Application Form.](#)

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## PROJECT TYPE AND ETHICS REVIEW

OpenSAFELY projects that meet the Health Research Authority's (HRA) definition of "research" require support from a recognised Research Ethics Committee. The HRA provide [guidance and a self-assessment tool](#) to help categorise projects correctly.

**What type of project do you want to do? \***

- Research
- Service Evaluation
- Audit
- Other

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## RESEARCH PROJECTS

Research project applications cannot be approved by NHS England until evidence of review by a Research Ethics Committee (REC) has been provided.

**Has your project proposal been reviewed by a Research Ethics Committee (REC)? \***

Yes - please send a copy of this review to [applications@opensafely.org](mailto:applications@opensafely.org)

No - please be aware that you will need to provide a copy of this review to NHS England before your application can be formally approved.

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## NON-RESEARCH PROJECTS

Non-research project types do not ordinarily require review by a REC.

If NHS England consider that your project meets the HRA definition of a research project, and this is different to the project type you have selected, we will contact you and request that you arrange an ethics

review.

**How did you determine that your project does not meet the HRA definition of research? \***

Using the HRA guidance and/or self-assessment tool

Through consultation with a REC

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## YOUR PROJECT

This is a chance to explain your project in detail. Please provide as much information as you are able to. Your project description should describe clearly the research you intend to conduct in OpenSAFELY. Please include the following details (max 500 words):

- The question(s) your project is intended to answer
- Data sources intended for use in this project
- Cohorts for analysis
- Time period of analysis
- Analytic or statistical methods intended to be used
- Expected outputs

Please read the [NHS guidance](#) if you need support writing about how you will reach your benefits.

**What is your project title? \***

**Please describe your project. \***

Your description should include the question(s) your project is intended to answer and your proposed methodology. Please see guidance above. Max 500 words.

**What are the expected measurable benefits from your project? Please tick all that apply. \***

Understanding risks to health, trends in diseases and such risks, and controlling and preventing the spread of diseases and such risks

Identifying and understanding information about patients or potential patients with, or at risk of disease

Understanding information about patient access to health services as a direct or indirect result of illness, and the availability and capacity of those services

Health services research on changes in clinical activity and population health and impact, as well as consequences of this

Informing the development and tracking the implementation of new diagnostics and treatments

Other

**How will your project deliver these benefits? \***

When constructing your text, you may wish to consult the NHS England guidance linked above. Max 250 words.

**What Public and Patient Involvement and Engagement has been undertaken? If any, are there any key PPIE activities which directly informed the aims and scope of this project? \***

Max 250 words

## Lay summary. \*

Please provide a lay summary of your project that is written in plain language, does not include any acronyms, and is easily understandable. Your lay summary will be made public on the OpenSAFELY website if your project is approved. Max 300 words.

## NATIONAL DATA OPT OUT (NDOO)

By default, Type 1 Opt Outs for flow outside of GP practices are applied; by default, the National Data Opt Out (NDOO) for research and planning is not applied. If you think NDOO should be applied to your analysis, please indicate this in the question below.

See [opt out of sharing your health records](#) for details of Type 1 Opt Out and the National Data Opt Outs.

### Should the National Data Opt-Out be applied to your project? \*

Yes

No

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## PROJECT SPONSOR

By default, the sponsor is the employer (organisation) of the Project Lead.

*If you are unsure about the role of a Project Sponsor, please see the glossary linked at the top of this page.*

**Which organisation is sponsoring this project? \***

The employer of the Project Lead

Other

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## PROJECT FUNDER

NHS England have introduced a cost-recovery charge for access to OpenSAFELY of £25,000 per project. You do not need to pay this at the point of application, but you must raise a Purchase Order with your organisation before running code against real patient data for your project.

Regular funders of research projects in OpenSAFELY are aware of this new charge. If you have a funding agreement which does not include this sum, NHS England advise that you should approach your funders for the additional amount, but can submit your application in advance of doing this.

If your project is currently not funded then, due to the short timescales in this round of applications, you are encouraged to apply for access, state that you do not yet have funding in place, and seek funding in parallel.

**Do you have funding in place for your project? \***

Yes - For project team and NHSE Access Charge

Yes - For project team only

No - Project funding is not yet in place

**Which organisation will fund your project, or are you applying for funding from? \***

The employer of the Project Lead

NHS England

NIHR

MRC

Other

## CHECKS AND DECLARATION

Before you submit your application, you must check the box to confirm the statement below:  
**I confirm that the information within this application is true and complete. I understand that any omission or misrepresentation within the application may lead to its rejection, or cancellation of any resulting agreement.**

**Please check this box to confirm the above statement is true. \***

Yes