REGIS

COVID-19 Fields

QUICK REFERENCE GUIDE

FOR APPLICANTS

COVID-19 Data Collection - Applicant Guidance

New Applications

All new applications are asked if "*the application directly related to COVID-19 Research?*" Where the response is "Yes" a further question will be asked to describe the type of research.

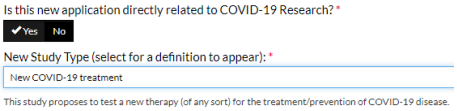
For new applications where Ethics is in REGIS this will be in Project Registration, part B.

For all site applications this in the STE/SSA form Part A.

COVID-19 New Study Definitions

- **New COVID-19 treatment:** this study proposes to test a new therapy (of any sort) for the treatment/prevention of COVID-19 disease.
- **New COVID-19 diagnostic:** this study proposes to test a new method of diagnosing COVID-19 and requires participants.
- **New COVID-19 study ('other' category):** this study proposes to study the COVID-19 disease and/or its related societal situation but does not propose to study a treatment for the COVID-19 disease itself. This may include studies looking at the population of people with/without COVID-19; how COVID-19 behaves in the population/environment; infection control practices directly related to COVID-19; health services research in response to COVID-19; or the effectiveness of population health practices in preventing the spread of COVID-19. This should be used as an 'other' category for any new study that primarily concerns COVID-19 but does not propose to test a therapy to treat the disease.

Project Registration and Site Application Form



The study type definition will appear once the type is selected.

Pausing or withdrawing an application due to COVID-19

- **Pause (COVID)**
  Where RO have been directed to not progress non COVID-19 related reviews. This review is paused and will be completed at a later date.

- **Withdrawn (COVID)**
  The study is being reviewed but the applicant is withdrawing the application as a direct result of COVID-19

The applicant should email the Research Office managing the application and ask that the application be Paused or Withdrawn due to COVID-19.

Post Approval

Every Amendment, Significant Safety Issue (SSI) and Final Report will ask if the action is due to COVID.

Amendments

The Notification of an amendment to a research study asks *'Does this amendment have any relation to COVID-19?'* If this question is answered 'Yes' then more questions will be generated and the Research Office will need to manually enter these details when processing the amendment.

- **Study amendment to add a SARS-CoV-2 test:** this existing study is to be amended to add a test of study participants for the SARS-CoV-2 virus for safety purposes or any other reason.
- **Study amendment to add a new COVID-19 related element ('other' category):** this existing study is to be amended to add a sub-study or other component, such as enabling an epidemiological analysis of COVID-19. This should be used as an 'other' category for an amendment that does not relate to directly testing participants for the SARS-CoV-2 virus.
- **Study amendment to respond to wider COVID-19 situation:** this existing study is to be amended to change an aspect due to government regulation, public health declaration, etc. This may include introduction of, or changes to, study visit schedules, remote monitoring, home delivery of study product to self-isolating participants, etc.
- **Study suspension due to COVID-19 situation:** this amendment proposes temporarily halting an existing study specifically due to the impracticalities of

conducting it while the COVID-19 society restrictions are in place.

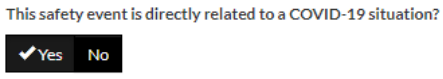
- **Study termination due to COVID-19 situation:** this amendment proposes terminate an existing study specifically due to the impracticalities of conducting it while the COVID-19 society restrictions are in place.

Where the answer to the initial question is Yes additional questions will appear. The additional questions are all mandatory and will need completing.

Where the applicant indicates a suspension or termination due to COVID-19 the Research Office will change the status of the study to match.

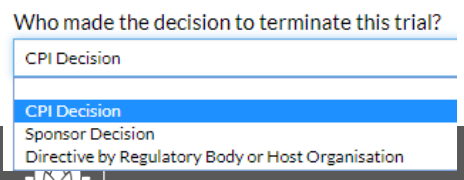
Significant Safety Issue (SSI)

During the SSI submission researchers will be asked a single question is *"This safety event is directly related to a COVID-19 situation?"*

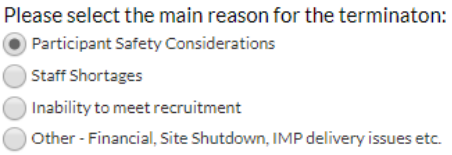


Respond either yes or no and then complete the form per usual.

If the form is for an Early Termination further COVID-19 questions will be asked.



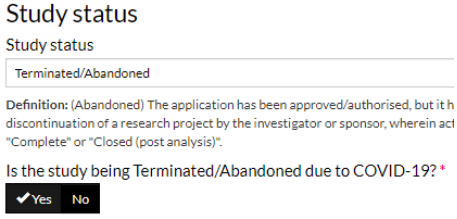
If CPI Decision is selected a final question will be asked



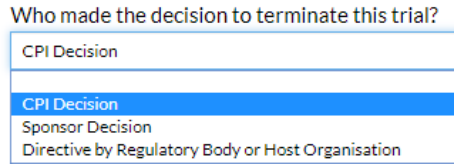
If "Temporary Halt of a Trial for Safety Reasons" or "Early Termination of a Trial for Safety Reasons" is also selected then the Research Office will change the status of the study in REGIS.

Final Report

If a Progress Report is being submitted with a status of Terminated/Abandoned the researchers will be asked "Is the study being Terminated/Abandoned due to COVID-19?"



If the study status is Terminated/Abandoned the final report will be created with these additional COVID-19 questions



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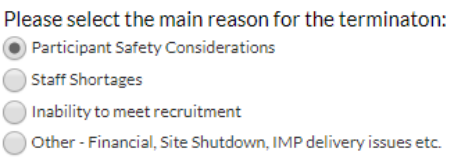

Where a final report is termination due to COVID-19 the Research Office will change the status of the study in REGIS.

Post-Approval Status

- **Suspended (COVID)**
  The study is being temporarily stopped as a direct result of COVID-19
- **Abandoned (COVID)**
  This study has been approved/authorised but has not begun. The study will not begin due to COVID-19.
- **Terminated (COVID)**
  This study is being terminated as a direct result of COVID-19. The study will not reach its anticipated end point.

For technical assistance, contact
REGIS HELP DESK

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