



QUICK REFERENCE GUIDE

REGIS

COVID-19 Fields

FOR RESEARCH OFFICES

COVID-19 New Applications

Entering COVID-19 data for a New Application

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.

This information will need to be manually entered into REGIS.

It is recommended that the data is entered as part of a successful eligibility either before or after the eligible email is sent.

Step 1

Locate the output form with the New Application COVID questions.

ETH: Project registration form
STE: STE/SSA form

Data entry is only required where the response is "Yes"

Project Registration Output example

COVID Research	
Research Office: If the response is "Yes" please enter the study type into the COVID menu option in the Application (pre-approval folder).	
Is this application directly related to COVID-19 Research *	Yes
This study is a :	New COVID-19 study - other category

Site Application Output example

COVID-19	
Research Office: If the response is "Yes" please enter the study type into the COVID menu option in the Application (pre-approval folder).	
Is this application directly related to COVID-19 Research *	Yes
This is a :	New COVID Diagnostic Test

Step 2

Click on the Management tile in the left-hand menu and then select COVID-19.

Step 3

Click edit on the right-hand menu.



Step 4

Select "+ Add" to enter the COVID-19 details entered as appears on the output form. New applications only require the 'NEW COVID Study Type' details to be entered.

Step 5

Click "Ok" at the bottom of the page to save.

Note: You should only have one line of data captured in the Application answering only the New COVID Study Type.

Pausing a review due to COVID-19

Where a PHO has indicated they will be pausing any non-COVID-19 related reviews the RO can indicate this by using the Pause (COVID) status in the application.

Search 'COVID' and four options will appear.

Select the appropriate status.

No other data entry is required.

COVID-19 Post Approval

Processing Post Approval Forms Outside of REGIS

All Research Offices are required to collect the COVID data. All forms in REGIS have been updated with the required information to allow researchers to provide the response. The use of REGIS forms is the preferred method. Research Offices that are currently accepting external submission of amendments, safety reports and final report will need to consider how they will collect this data.

Entering COVID-19 data for Post Approval

COVID-19

Found 4 items

Order	New COVID Study Type	REGIS Form ID
1		015774
2		015778
3		015775
4		015777

Every Amendment, Significant Safety Issue (SSI) and Final Report will ask if the action is due to COVID. Where the answer is Yes a COVID-19 data entry row should be completed e.g. two SSI's and two amendments submitted that

include COVID-19 data need an entry each

Amendments

During the amendment submission researchers will be asked '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.

Step 1

Locate the output form with the COVID-19 questions.

Note: Data entry is only required where the response is "Yes"

Amendment Form Output example

COVID-19	
Research Office: If the response is "Yes" please enter the following details into the COVID-19 menu option in the Project (post-approval folder).	
Form id, date form first submitted, response to each of the below questions	
Is this amendment to add a SARS-CoV-2 test?	Yes
Is this amendment to add a new COVID-19 related element ('other' category)?	No
Is this amendment to respond to wider COVID-19 situation?	Yes
Is the study being suspension due to COVID-19?	No
Is the study being termination due to COVID-19?	No

Step 2

Identifier: Copy the unique identifier as this needs to be entered into the COVID-19 section.

Identifier
014884

Step 3

Click on the Management tile in the left-hand menu and select COVID-19.

Management

- Timeline
- Classifications
- Clinical Trial - First Patient Enro...
- Comments
- Contacts
- COVID-19

Step 4

Select '+ Add' to enter the COVID-19 details entered on the Amendment form, under 'COVID-19'.

Required details to be entered are from "REGIS Form ID" to "If CPI terminated – reason".

REGIS Form ID	
Date initial submission	dd/mm/yyyy
Study amendment to add a SARS-CoV-2 - COVID test	<input type="checkbox"/> No
Study amendment to add a new COVID-19 related element - other category	<input type="checkbox"/> No
Study amendment to respond to wider COVID-19 situation	<input type="checkbox"/> No
Study suspension due to COVID-19 situation	<input type="checkbox"/> No
Study termination due to COVID-19 situation	<input type="checkbox"/> No
Terminated Decision	
If CPI terminated - reason	

Tip: Remember you need to select 'Edit' to add data.

If "Study termination due to COVID-19 situation" then "Termination Decision" and "If CPI terminated – reason" is required.

Step 7



Click 'Ok' at the bottom of the page to save.

Step 8

Study Suspension or Study Termination will require the Research Office to manually update the status.

Click the status in the top right-hand corner to access the drop-down menu.

Search "COVID" and two options will appear.

Select the status as indicated on the amendment form.

Approved

COVID

Active

Suspended (COVID)

Terminated (COVID)

Make this change in the Project AND Application

Tip: If you cannot access the drop-down menu then you will need to select "Edit"

Step 9

Remember to Share the amendment form with related entities so NSW sites are able to also collect this information.

In Related Document select "Visible in related entity"



Visible in related entity

For status definitions see [Post approval Status](#) For technical assistance, contact REGIS HELP DESK

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COVID-19 Post Approval

Significant Safety Issue (SSI)

During the SSI submission researchers will be asked if "This safety event is directly related to a COVID-19 situation?". If the response is answered 'Yes' then the Research Office will need to manually enter these details as well as the 'Form type' when processing the SSI

- ❖ Urgent safety measure
- ❖ Temporary halt of a trial for safety reasons
- ❖ Early termination of a trial for safety reasons

Step 1

Locate the output form with the COVID-19 questions.

Data entry is only required where the response is "Yes" to process.

COVID-19	
<small>Research Office: If the response is "Yes" please enter the following details into the COVID-19 menu option in the Project (post approval folder). Form id, date form first submitted, SSI due to COVID, USM due to COVID. If the study is being temporarily halted (suspended) or terminated the related questions should be answered and the status of the project and application should be manually changed.</small>	
This safety event is directly related to a COVID-19 situation?	Yes
<small>If this safety report is due to COVID AND the study is being temporarily halted or terminated the status of the study should be changed to "suspended (COVID)" or "terminated (COVID)"</small>	

Step 2

Identifier: Copy the unique identifier as this needs to be entered into the COVID-19 section.

Identifier
014884

Step 3

Click on the Management tile in the left-hand menu and then select COVID-19.

Management

- Timeline
- Classifications
- Clinical Trial - First Patient Enro...
- Comments
- Contacts
- COVID-19

Step 4

Click 'Edit' on the right-hand menu.

Step 5

Select '+ Add' to enter the COVID-19 details entered on the SSI Notification form, under 'COVID-19'.

When review the form you will need to identify and manually enter the below questions

+ Add
Bulk update

NOT REQUIRED FOR SSI NOTIFICATIONS
New COVID Study type

REGIS Form ID
Date initial submission dd/mm/yyyy

Study amendment to add a SARS-CoV-2 COVID test No
Study amendment to add a new COVID-19 related element to other category No
Study amendment to respond to wider COVID-19 situation No
Study suspension due to COVID-19 situation No
Study termination due to COVID-19 situation No
Terminated Decision
If CPI terminated - reason
Serious Breach - Protocol Violation due to COVID-19 situation No
SSI due to COVID-19 situation No
USM due to COVID-19 situation No

Ok Cancel

Step 6

Click 'Ok' at the bottom of the page to save.

Step 7

If the researcher has indicated "Temporary Halt of a Trial for Safety Reasons" or "Early Termination of a Trial for Safety Reasons" then you will need to manually update the status.

Click the status in the top right-hand corner to access the drop-down menu.

Search 'COVID' and two options will appear.

Select the status as indicated on the amendment form.

Approved
COVID
Active
Suspended (COVID)
Terminated (COVID)

Make this change in the Project AND Application.

Tip: If you cannot access the drop-down menu then you will need to select 'Edit'

For status definitions see [Post approval Status](#)

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COVID-19 Post Approval

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 response is 'Yes' then the Research Office will need to manually enter these details when processing the Final Report.

Step 1

Locate the output form with the COVID-19 questions.

Data entry is only required where the response is "Yes"

COVID-19	
Research Office: If the response is "Yes" please enter the following details into the COVID-19 menu option in the Project (post-approval folder). Form id, date form first submitted, study terminated question, termination decision, IF CPI termination reason. The project and application should be manually changed. "Terminated (COVID)"	
Is the study being Terminated/Abandoned due to COVID-19?	Yes
Research Office: Please enter the following details into the COVID-19 menu option in the Project (post-approval folder). Form id, date form first submitted, study terminated question, termination decision, IF CPI termination reason. The project and application should be manually changed. "Terminated (COVID)"	
Who made the decision to terminate the trial?	CPI Decision
Please select the decision to terminate (select all that apply):	Participant Safety Considerations

Step 2

Click on the Management tile in the left-hand menu and select COVID-19.

Management

- Timeline
- Classifications
- Clinical Trial - First Patient Enro...
- Comments
- Contacts
- COVID-19

Step 3

Click edit on the right-hand menu.

Step 4

Select '+ Add' to enter the COVID-19 details entered on the SSI Notification form, under 'COVID-19'.

Study suspension due to COVID-19 situation	<input type="checkbox"/> No
Study termination due to COVID-19 situation	<input type="checkbox"/> No
Terminated Decision	
If CPI terminated - reason	

Step 5

Click 'Ok' at the bottom of the page to save.

Step 6

If the Researcher has indicated the study has been "Terminated/Abandoned due to COVID-19" then you will manually update the status.

Click the status in the top right-hand corner to access the drop-down menu.

Search 'COVID' and two options will appear.

Select the status as indicated on the amendment form.

Approved

Active
 Suspended (COVID)
 Terminated (COVID)

Make this change in the Project **AND** Application.

For status definitions see [Post approval Status](#)

Governance Post Approval Data Entry

NSW HREC

Shared NSW HREC amendment forms will appear in the STE project in Related Documents.

Project

2019/STE
 Tags Greater than

Related documents

If you can't see the form please contact the Research Office managing the ethics and ask them to share the document.

Data entry steps are exactly the same as described above.

If a status change is required please follow the steps described above.

NMA/Other Jurisdiction HRECs

Where an amendment, safety notification, final report or other post approval document is received the Research Office will take a "best attempt" to capture the COVID-19 data.

If a status change is required please follow the steps described above.

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COVID-19 Data Definitions

New Application Study Types

- ❖ **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.

Post Approval

- ❖ **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.

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Pre-Approval Status

- ❖ **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

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.

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