

# REGIS Training for Researchers

Sessions have been designed so that they can be attended sequentially (Monday-Friday) or as standalone sessions. 10 cycles will be held from May to September with all sessions, except for the REGIS General Overview, running for 30 minutes. Further cycles will be scheduled and dates updated on the [REGIS website](#)

## Day 1 Monday

10 <sup>th</sup> May 2021, 10:00am-11:30am	<b>Webinar 1: 1 1/2hr - REGIS General Overview</b> The General Overview will lightly touch on each of the areas discussed in the 30min sessions. <ul style="list-style-type: none"> <li>Gain a better understanding of how to navigate the external portal of REGIS</li> <li>Gain a better understanding of how applications (submission to approval/authorisation) flow through REGIS</li> <li>Gain better understanding of how post approval activities (amendments, safety reporting, progress reports) flow through REGIS</li> </ul>
17 <sup>th</sup> May 2021, 10:00am-11:30am	
24 <sup>th</sup> May 2021, 10:00am-11:30am	
31 <sup>st</sup> May 2021, 11:00am-12:30pm	
7 <sup>th</sup> June 2021, 11:00am-12:30pm	
28 <sup>th</sup> June 2021, 11:00am-12:30pm	
5 <sup>th</sup> July 2021, 1:00pm-2:30pm	
12 <sup>th</sup> July 2021, 1:00pm-2:30pm	
23 <sup>rd</sup> August 2021, 1:00pm-2:30pm	
30 <sup>th</sup> August 2021, 1:00pm-2:30pm	

## Day 2 Tuesday

11 <sup>th</sup> May 2021, 10:00am-10:30am	<b>Webinar 2: 30min - Project Registration</b> <ul style="list-style-type: none"> <li>When Ethics is managed by a NSW/ACT HREC (in REGIS)</li> <li>When Ethics is managed by another NMA HREC (outside of REGIS)</li> <li>Understanding information flow from Project Registration to ETH and/or STE</li> <li>How to upload documents or change documents</li> <li>Why correctly identifying Coordinating Principal Investigator (CPI), Principal Investigator (PI) is important</li> <li>Who can complete and submit Project Registration</li> </ul>
18 <sup>th</sup> May 2021, 10:00am-10:30am	
25 <sup>th</sup> May 2021, 10:00am-10:30am	
1 <sup>st</sup> June 2021, 11:00am-11:30am	
8 <sup>th</sup> June 2021, 11:00am-11:30am	
29 <sup>th</sup> June 2021, 11:00am-11:30am	
6 <sup>th</sup> July 2021, 1:00pm-1:30pm	
13 <sup>th</sup> July 2021, 1:00pm-1:30pm	
24 <sup>th</sup> August 2021, 1:00pm-1:30pm	
31 <sup>st</sup> August 2021, 1:00pm-1:30pm	<b>Webinar 3: 30min - Creating and Submitting a HREA (ETH) for a NSW/ACT Health HREC (ethics in REGIS)</b> In this session we will step through the most important areas for a smooth application submission including; <ul style="list-style-type: none"> <li>Understanding Project Team details</li> <li>Who can submit and who will get correspondence</li> <li>What to do if project team details change between Project Registration and HREA submission</li> <li>Understanding Document Management</li> <li>Understand information flow from Project Registration and to NSW SSAs</li> </ul> <p><i>This is a system session and will not go through what should be put in each question for the HREC to address.</i></p>
11 <sup>th</sup> May 2021, 10:45am-11:15am	
18 <sup>th</sup> May 2021, 10:45am-11:15am	
25 <sup>th</sup> May 2021, 10:45am-11:15am	
1 <sup>st</sup> June 2021, 11:45am-12:15pm	
8 <sup>th</sup> June 2021, 11:45am-12:15pm	
29 <sup>th</sup> June 2021, 11:45am-12:15pm	
6 <sup>th</sup> July 2021, 1:45pm-2:15pm	
13 <sup>th</sup> July 2021, 1:45pm-2:15pm	
24 <sup>th</sup> August 2021, 1:45pm-2:15pm	
31 <sup>st</sup> August 2021, 1:45pm-2:15pm	<b>Webinar 4: 30min - Creating and submitting an SSA (STE) when Ethics is managed by a NSW/ACT HREC (ethics in REGIS) and when Ethics in managed by another jurisdictions</b>
11 <sup>th</sup> May 2021, 11:30am-12:00pm	

18 <sup>th</sup> May 2021, 11:30am-12:00pm	<p><b>NMA HREC (QLD, VIC, SA, WA)</b></p> <p>In this session we will step through the most important areas for a smooth application submission to a NSW RGO including;</p> <ul style="list-style-type: none"> <li>• Understanding information flow from Project Registration and ETH (when ethics is in REGIS)</li> <li>• Who can submit and who will get correspondence</li> <li>• What to do if PI details change between Project Registration (PR) and STE submission</li> <li>• Understanding document management</li> <li>• Understand the Head of Department (HOD) selection and what to do if you can't locate a HOD</li> <li>• When the system progresses an application to the Research Office and when the applicant needs to action</li> </ul> <p><i>This is a system session and will not address what should be put in each question for the RGO to review.</i></p>
25 <sup>th</sup> May 2021, 11:30am-12:00pm	
1 <sup>st</sup> June 2021, 12:30pm-1:00pm	
8 <sup>th</sup> June 2021, 12:30pm-1:00pm	
29 <sup>th</sup> June 2021, 12:30pm-1:00pm	
6 <sup>th</sup> July 2021, 2:30pm-3:00pm	
13 <sup>th</sup> July 2021, 2:30pm-3:00pm	
24 <sup>th</sup> August 2021, 2:30pm-3:00pm	
31 <sup>st</sup> August 2021, 2:30pm-3:00pm	

#### Day 3 Wednesday

12 <sup>th</sup> May 2021, 10:00am-10:30am	<p><b>Webinar 5: 30min - Resubmitting an Ineligible application and when HOD not supported</b></p> <ul style="list-style-type: none"> <li>• Understanding how you will be notified/system generated notifications</li> <li>• Step through what do to if your application is made Ineligible after initial submission</li> <li>• How to check which HOD have or have not made a decision regarding the support of your study at site</li> <li>• What to do when your application is HOD not supported</li> </ul>
19 <sup>th</sup> May 2021, 10:00am-10:30am	
26 <sup>th</sup> May 2021, 10:00am-10:30am	
2 <sup>nd</sup> June 2021, 11:00am-11:30am	
9 <sup>th</sup> June 2021, 11:00am-11:30am	
30 <sup>th</sup> June 2021, 11:00am-11:30am	
7 <sup>th</sup> July 2021, 1:00pm-1:30pm	
14 <sup>th</sup> July 2021, 1:00pm-1:30pm	
25 <sup>th</sup> August 2021, 1:00pm-1:30pm	
1 <sup>st</sup> September 2021, 1:00pm-1:30pm	<p><b>Webinar 6: 30min - Responding to a request to information to an initial application</b></p> <p>Step through the two types of request for information for an application:</p> <ul style="list-style-type: none"> <li>• Decision Pending (updating the application form or related documents) <ul style="list-style-type: none"> <li>○ Document management - system versioning and tracked changes</li> </ul> </li> <li>• Approved/Authorised Pending (locating the completing the More Information Required form)</li> <li>• When approved/authorised how to locate the approved documents</li> </ul>
12 <sup>th</sup> May 2021, 10:45am-11:15am	
19 <sup>th</sup> May 2021, 10:45am-11:15am	
26 <sup>th</sup> May 2021, 10:45am-11:15am	
2 <sup>nd</sup> June 2021, 11:45am-12:15pm	
9 <sup>th</sup> June 2021, 11:45am-12:15pm	
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7 <sup>th</sup> July 2021, 1:45pm-2:15pm	
14 <sup>th</sup> July 2021, 1:45pm-2:15pm	
25 <sup>th</sup> August 2021, 1:45pm-2:15pm	
1 <sup>st</sup> September 2021, 1:45pm-2:15pm	

#### Day 4 Thursday

13 <sup>th</sup> May 2021, 10:00am-10:30am	<p><b>Webinar 7: 30min - Creating and submitting Ethics forms/documents (Amendments and Safety Reporting) and responding to a request for information</b></p> <ul style="list-style-type: none"> <li>• Process for locating, creating, submitting, responding to a request for information and locating approved documents in external portal (Amendment and Safety Reporting)</li> <li>• How to locate the amendment form</li> </ul>
20 <sup>th</sup> May 2021, 10:00am-10:30am	
27 <sup>th</sup> May 2021, 10:00am-10:30am	
3 <sup>rd</sup> June 2021, 11:00am-11:30am	
10 <sup>th</sup> June 2021, 11:00am-11:30am	

1 <sup>st</sup> July 2021, 11:00am-11:30am 8 <sup>th</sup> July 2021, 1:00pm-1:30pm 15 <sup>th</sup> July 2021, 1:00pm-1:30pm 26 <sup>th</sup> August 2021, 1:00pm-1:30pm 2 <sup>nd</sup> September 2021, 1:00pm-1:30pm	<ul style="list-style-type: none"> <li>• Understanding the types of amendment</li> <li>• Who can access/edit/submit the amendment form</li> <li>• Document management <ul style="list-style-type: none"> <li>○ when a document already exists in the system and a new version is being submitted</li> <li>○ when a new document (not yet reviewed) is being submitted</li> </ul> </li> <li>• What to do when/if more information is requested</li> <li>• What happens on approval - How documents are auto shared to RGOs and how REGIS is streamlining submissions of safety reports to NSW RGOs</li> <li>• Locate approved documents in external portal</li> </ul>
13 <sup>th</sup> May 2021, 10:45am-11:15am 20 <sup>th</sup> May 2021, 10:45am-11:15am 27 <sup>th</sup> May 2021, 10:45am-11:15am 3 <sup>rd</sup> June 2021, 11:45am-12:15am 10 <sup>th</sup> June 2021, 11:45am-12:15am 1 <sup>st</sup> July 2021, 11:45am-12:15am 8 <sup>th</sup> July 2021, 1:45pm-2:15pm 15 <sup>th</sup> July 2021, 1:45pm-2:15pm 26 <sup>th</sup> August 2021, 1:45pm-2:15pm 2 <sup>nd</sup> September 2021, 1:45pm-2:15pm	<p><b>Webinar 8: 30min - Submitting a progress report to a NSW/ACT HREC (and a short overview of external HREC progress reports submitted in REGIS. This will be discussed further in webinar 13)</b></p> <ul style="list-style-type: none"> <li>• System generated notifications</li> <li>• Locating the progress report</li> <li>• Who can access/edit/submit</li> <li>• Understanding the NSW progress report (single form for HREC and all NSW sites)</li> <li>• Understanding project status - annual report/final report</li> <li>• What to do when/if more information is required</li> <li>• Document management - how to locate approved documents</li> <li>• Touch on what happens on HREC approval - REGIS streamlining submission to NSW RGOs.</li> <li>• Locate approved documents in external portal</li> </ul>

Day 5 Friday

14 <sup>th</sup> May 2021, 10:00am-10:30am 21 <sup>st</sup> May 2021, 10:00am-10:30am 28 <sup>th</sup> May 2021, 10:00am-10:30am 4 <sup>th</sup> June 2021, 11:00am-11:30am 11 <sup>th</sup> June 2021, 11:00am-11:30am 2 <sup>nd</sup> July 2021, 11:00am-11:30am 9 <sup>th</sup> July 2021, 1:00pm-1:30pm 16 <sup>th</sup> July 2021, 1:00pm-1:30pm 27 <sup>th</sup> August 2021, 1:00pm-1:30pm 3 <sup>rd</sup> September 2021, 1:00pm-1:30pm	<p><b>Webinar 9: 30min - Overview of Governance post-approval activities in REGIS</b></p> <p>This session is the same information shared in the General Overview webinar, but will focus only on Governance Post Approval.</p> <ul style="list-style-type: none"> <li>• How items flow when Ethics managed by a NSW/ACT HREC (ethics in REGIS) and when Ethics is managed by another NMA HREC (ethics outside REGIS)</li> <li>• Understand system automation and streamlining</li> <li>• Locate approved documents in external portal</li> </ul>
14 <sup>th</sup> May 2021, 10:45am-11:15am 21 <sup>st</sup> May 2021, 10:45am-11:15am 28 <sup>th</sup> May 2021, 10:45am-11:15am 4 <sup>th</sup> June 2021, 11:45am-12:15pm 11 <sup>th</sup> June 2021, 11:45am-12:15pm 2 <sup>nd</sup> July 2021, 11:45am-12:15pm 9 <sup>th</sup> July 2021, 1:45pm-2:15pm 16 <sup>th</sup> July 2021, 1:45pm-2:15pm 27 <sup>th</sup> August 2021, 1:45pm-2:15pm 3 <sup>rd</sup> September 2021, 1:45pm-2:15pm	<p><b>Webinar 10: 30min - Creating and submitting Governance forms/documents (Site Amendments and Safety Reporting) and responding to a request for information.</b></p> <ul style="list-style-type: none"> <li>• Process for locating, creating, submitting, responding to a request for information and locating approved documents in external portal (Site Amendments and Safety Reporting)</li> <li>• How to locate the site amendment form</li> <li>• Understanding the types of site amendments</li> <li>• Who can access/edit/submit the site amendment form</li> <li>• Document management <ul style="list-style-type: none"> <li>○ when a document already exists in the system and a new version is being submitted</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ when a new document (not yet reviewed) is being submitted</li> <li>• What to do when/if more information is requested</li> <li>• Understanding the system automation and streamlining when ethics exists in REGIS</li> <li>• Locate approved documents in external portal</li> </ul>
14 <sup>th</sup> May 2021, 11:30am-12:00pm	<p><b>Webinar 11: 30 min - Submitting Governance milestones</b> (Certificate of Currency, External HREC Progress/Final Reports and First Patient In)</p> <ul style="list-style-type: none"> <li>• Understanding site milestone types</li> <li>• System generated notifications</li> <li>• Locating the site milestones</li> <li>• Who can access/edit/submit</li> <li>• Understanding the NSW progress report (single form for HREC and all NSW sites)</li> <li>• Understanding project status - annual report/final report</li> <li>• What to do when/if more information is required</li> <li>• Document management - how to located approved documents</li> <li>• Understanding the system automation and streamlining when ethics exists in REGIS</li> <li>• Locate approved documents in external portal</li> </ul>
21 <sup>st</sup> May 2021, 11:30am-12:00pm	
28 <sup>th</sup> May 2021, 11:30am-12:00pm	
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27 <sup>th</sup> August 2021, 2:30pm-3:00pm	
3 <sup>rd</sup> September 2021, 2:30pm-3:00pm	