Contents

eProtocol Registration

The first step of creating an application is to apply for a User ID and password. For assistance with your registration please view the 'How to Register' video tutorial on our website.

Verifying new registrations

Bellberry is committed to maintaining and upholding excellence in privacy and security for all those who use our service, including all who register and use the eProtocol system. To further strengthen the security of the registration process, all new applicants will be required to complete the organisational verification of personnel form. This form provides information that allows Bellberry to efficiently and effectively process new applications, while maintaining appropriate security of data.

Authorised representatives

Each organisation must have a dedicated person(s) that assumes responsibility for the authorisation of new personnel registering for eProtocol access from that organisation. The Authorised Representative should be known by staff as they will need to verify the applicant as part of the registration process.

Larger organisations may choose to delegate this role to a departmental level, e.g., a hospital may select the Clinical Trials Manager in each department. For stand-alone clinics, it may be the practice manager or Principal Investigator. The organisation is responsible for determining the person responsible and declaring this person to Bellberry. Bellberry will maintain a list of Authorised Representatives, and each new registration for that organisation will be verified with the nominated representative.

New organisations

New organisations registering with Bellberry will be required to provide additional information, including full address, phone number and ABN. This information is to be included within the relevant sections of the organisational verification of personnel form. Completed Organisational Verification of Personnel forms should be emailed to registrations@bellberry.com.au

Please do not use acronyms in the organisation field on the registration form. The organisation name and address that you enter will appear on all correspondence from Bellberry.

Please ensure that all people that will be involved in the study, i.e. the Principal Investigator, Sub-Investigators and any other nominated contacts are all registered with the same organisation.

Working across multiple organisations

A researcher or nominated contact registering for multiple organisations will be required to register with a different user IDs for each organisation. We suggest using an identifier such as the organisation name and surname or initials.

Nominated Contacts

A study application should have at least one nominated contact listed in addition to the Principal Investigator for administrative and safety purposes. For Investigator-led studies, it is acceptable that the Principal Investigator may also be the Tax Invoice contact in the application.

If authorised by a Principal Investigator, a nominated contact from another organisation, including sponsors, clinical research organisations (CROs), site management organisations (SMOs) etc., may prepare an application on behalf of the Principal Investigator. The nominated contact must be registered with the site at which the study is being conducted. Please note that this may be different to the organisation that the nominated contact is employed by.

User ID

It is suggested that sponsors, CROs and SMOs use their surname, initial and organisation name for the User ID, i.e. 'SmithJ – organisation name'.

Please note that apostrophes cannot be used within a user ID.

Registering in eProtocol

As for all applicants, the Authorised Representative of the organisation (see definition above) must verify the nominated contact by signing the Organisational Verification of Personnel form (OVOP). This form should be completed and emailed to registrations@bellberry.com.au for each separate organisation, prior to registration.

Following completion and submission of the OVOP form, open the eProtocol homepage. Click register > complete registration form > user ID (select a username such as last name, first initial) > organisation name (must be the organisation that the user is to be linked to – e.g. the PI's organisation) > click submit.

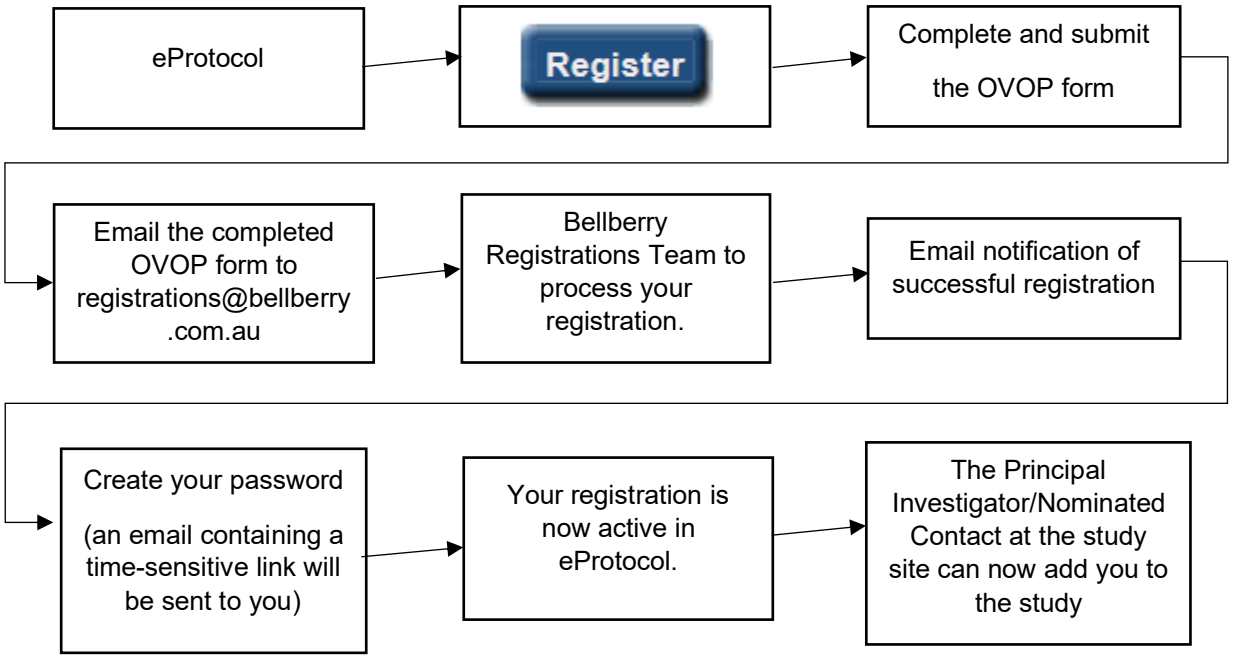
The registration request will be processed by the Bellberry Registrations team and a confirmation email acknowledging receipt of the registration request will be sent to the listed email address.

Once the registration has been processed, the user will receive an automated email from registrations@bellberry.com.au with temporary login details. When the new user accesses eProtocol for the first time, the system will generate a prompt to change the password. This link is time-sensitive and should be accessed as soon as possible.

Passwords are required to be a minimum of 8 characters with a minimum of 3 of the following:

- lowercase
- uppercase
- numbers
- symbols (!, @, #, $, %, ^, &, * etc.,).

eProtocol will generate automatic emails whenever a transaction between the site and the HREC occurs, e.g., when an application is submitted, comments are returned, and so on. All contacts listed on the personnel information page will receive these automated emails.


eProtocol
Register
Complete and submit the OVOP form
Email the completed OVOP form to registrations@bellberry.com.au
Bellberry Registrations Team to process your registration.
Email notification of successful registration
Create your password
(an email containing a time-sensitive link will be sent to you)
Your registration is now active in eProtocol.
The Principal Investigator/Nominated Contact at the study site can now add you to the study

Organisational Verification of Personnel form – First time registration example

This form is used within the eProtocol registration process to verify an individual and their affiliation with the organisation/site in which they wish to register with.

To be completed by the applicant	
Name of applicant:	Dr John Smith
In what capacity do you require access to eProtocol?	×☐ Principal Investigator who will be submitting a study to Bellberry for review
	☐ Sub-Investigator
	☐ Nominated contact (e.g. site staff, CROs)
Name of Principal Investigator (*if different from applicant*):	
Site at which the study is to be conducted (i.e., site where the PI is located):	ABC Medical 1 Research Lane, Adelaide SA 5000
Organisation of applicant (*if different from above*):	
Email address (of applicant):	John@abcmedical.com
Please tick which applies or leave blank if N/A	☐ Sponsor ☐ Clinical Research Organisation (CRO) ☐ Site Management Organisation (SMO)
Are you from a public health organisation or university?	☐ Yes, public health organi ☐ Yes, university × ☐ No

The above details will be used to align this form with your app

John Smith can be listed as an Authorised Rep however will need to nominate a 2nd Authorised Rep as he is not permitted to sign his own OVOP on pg 2. However, he can sign new eProtocol OVOPs in the future for his study personnel. Sites choose who their Authorised Reps are as that person is simply verifying that the applicant belongs to the study site.

Large organisation should have their RGO or Departmental Heads listed as Authorised Reps.

Nomination of Authorised Representative(s)

<u>If no Authorised Representative has previously been nominate</u>

Please note that an Authorised Representative is required to be non … is the responsibility of this individual to verify the above and any future applicar … affiliation with the study site. Please see the definition of authorised representative within B… .

Name:	John Smith	Name:	Sarah Jones
Position:	Director ABC Medical	Position:	Research Nurse ABC Medical
Email:	John@abcmedical.com	Email:	Sarah@abcmedical.com
Phone:	0408 896 870	Phone:	0408 896 871

New Organisations and/or Government Organisations

If the applicant is registering with an organisation that is new to Bellberry conducting research on behalf of/in conjunction with a government organisa below.

This box only needs to be completed once, when the first OVOP for the organisation is submitted.

To be completed by the study site (i.e., the site where the PI is located)	
Organisation address:	1 Research Lane, Adelaide SA 5000
ABN:	123456789
Please confirm whether the name of the organisation as reported by the applicant in the above text box is correct:	
☐ Yes ☐ No, please provide correct name: _____	

Please provide details of the study

Application ID* for existing study or brief study title for a new application: *If there are multiple current Application IDs, please list.	Research study to assess the efficacy of study drug 1234 in healthy volunteers
Please outline approximate timeframe for expected commencement of the study:	3 months' time (1 Apr 2023)
Is this a government departmental study or are you conducting research on behalf of (or in conjunction with) a government organisation?	☐ Yes, please provid × ☐ No, not applic

If the applicant is also an Authorised Rep, they cannot sign this section!

Even though John Smith is an Authorised Rep on pg 1 he cannot sign his own form. He must ask Sarah Jones as the 2nd Authorised Rep to sign to confirm that he is associated with the study site. Study sites can nominate as many Authorised Reps as they would like.

The following must be completed by the Authorised Represent

I, Sarah Jones confirm that the above applicant is an employee/affiliate of ABC Medical and consent to the above applicant being linked to this organisation within eProtocol.

Signature: …… Sarah Jones …… Date: 1 Jan 2023

Please email the completed form to registrations@bellberry.com.au.

Verification of user ID and password will be issued by separate email.

Organisational Verification of Personnel Form – Subsequent registration example

This form is used within the eProtocol registration process to verify an individual and their affiliation with the organisation/site in which they wish to register with.

To be completed by the applicant	
Name of applicant:	Carol Brown
In what capacity do you require access to eProtocol?	☐ Principal Investigator who will be submitting a study to Bellberry for review
	☐ Sub-Investigator
	× ☐ Nominated contact (e.g. site staff, CROs)
Name of Principal Investigator (*if different from applicant*):	Dr John Smith
Site at which the study is to be conducted (i.e., site where the PI is located):	ABC Medical 1 Research Lane, Adelaide SA 5000
Organisation of applicant (*if different from above*):	
Email address (of applicant):	Carol@abcmedical.com
Please tick which applies or leave blank if N/A	☐ Sponsor ☐ Clinical Research Organisation (CRO) ☐ Site Management Organisation (SMO)
Are you from a public health organisation or university?	☐ Yes, public health organisation
	☐ Yes, university
	× ☐ No

The above details will be used to align this form with your application within eProtocol

Nomination of authorised representative(s)

As this is a subsequent OVOP, this section is not required to be completed as the Authorised Representatives have already been declared. One of the declared Authorised representatives is required to sign pg 2 of the OVOP.

If no Authorised Representative has previously been r

Please note that an Authorised Representative is requi
responsibility of this individual to verify the above and any future
study site. Please see the definition of Authorised Representative with

Name:		Name:	
Position:		Position:	
Email:		Email:	
Phone:		Phone:	

New Organisations and/or Government Organisations

If the applicant is registering with an organisation that is new to Bellbe
conducting research on behalf of/in conjunction with a government org
below.

This section only needs to be completed once, when the first OVOP for the study site is submitted. As ABC Medical are already registered this section can remain blank.

To be completed by the study site (i.e., the site where the PI is locate	
Organisation address:	
ABN:	
Please confirm whether the name of the organisation as reported by the applicant in the above text box is correct:	
☐ Yes ☐ No, please provide correct name: _____	

Please provide details of the study

Application ID* for existing study or brief study title for a new application: *If there are multiple current Application IDs, please list.	Application ID from eProtocol to be added here if known or brief study title. If more than 6 multiple study applications are to be declared, please note the words "Multiple Studies"
Please outline approximate time frame for expected commencement of the study:	3 months' time (1 Apr 2023)
Is this a government departmental study or are you conducting research on behalf of (or in conjunction with) a government organisation?	☐ Yes, please provide further information: × ☐ No, not applicable

Carol asks the study sites authorised representatives to sign this section of the OVOP. Authorised Representatives would have been declared the first time the study site was registered in eProtocol.

The following must be completed by the authorised repr

I, Sarah Jones confirm that the above applicant is an employee~~/affiliate~~ of ABC Medical and consent to the above applicant being linked to this organisation within eProtocol.

Signature: ..... Sarah Jones ..... Date: 31 Jan 2023

Please email the completed form to registrations@bellberry.com.au.

Verification of user ID and password will be issued by separate email.

Organisational Verification of Personnel form – CRO or Sponsor registration example

This form is used within the eProtocol registration process to verify an individual and their affiliation with the organisation/site in which they wish to register with.

To be completed by the applicant	
Name of applicant:	Jane Green
In what capacity do you require access to eProtocol?	☐ Principal Investigator who will be submitting a study to Bellberry for review
	☐ Sub-Investigator
	× ☐ Nominated contact (e.g. site staff, CROs)
Name of Principal Investigator (*if different from applicant*):	Dr John Smith
Site at which the study is to be conducted (i.e., site where the PI is located):	ABC Medical 1 Research Lane, Adelaide SA 5000
Organisation of applicant (*if different from above*):	123 CRO Consulting
Email address (of applicant):	Jane@123CRO.com.au
Please tick which applies or leave blank if N/A	☐ Sponsor × ☐ Clinical Research Organisation (CRO) ☐ Site Management Organisation (SMO)
Are you from a public health organisation or university?	☐ Yes, public health organisation
	☐ Yes, university
	× ☐ No

The above details will be used to align this form with your application within eProtocol.

Nomination of authorised representative(s)

If no Authorised Representative has previously been

Please note that an Authorised Representative is re
responsibility of this individual to verify the above and any
study site. Please see the definition of Authorised Representative wi

If the CRO requires access to a study site's application in eProtocol, the applicant will need to confirm with the site who they have listed as the Authorised Representatives or contact Bellberry registrations team for further information.

Name:		Name:	
Position:		Position:	
Email:		Email:	

Phone:		Phone:	

New Organisations and/or Government Organisations

If the applicant is registering with an organisation that is new to Bellberry conducting research on behalf of/in conjunction with a government or below.

This box only needs to be completed once, when the first OVOP for the study site is submitted.

To be completed by the study site (i.e., the site where the PI is located)	
Organisation address:	
ABN:	
Please confirm whether the name of the organisation as reported by the applicant in the above text box is correct:	
☐ Yes ☐ No, please provide correct name: _____	

Please provide details of the study

Application ID* for existing study or brief study title for a new application: *If there are multiple current Application IDs, please list.	Application ID from eProtocol to be added here if known or brief study title. If more than 6 multiple study applications are to be declared, please note the words "Multiple Studies"
Please outline approximate time frame for expected commencement of the study:	3 months' time (1 Apr 2023)
Is this a government departmental study or are you conducting research on behalf of (or in conjunction with) a government organisation?	☐ Yes, × ☐ No, not

As Jane Green is requesting access to the study site's eProtocol application, she will need to ask the Authorised Representative from the study site to complete the authorisation below. This ensures that the study site is aware that a person external to their site is requesting access to their application.

NOTE: If a CRO/Sponsor applicant is working with multiple sites, they require a new User ID per site therefore a new OVOP and online registration is needed. Authorised Representatives are different for each site.

The following must be completed by the authorised repre

I, John Smith confirm that the above applicant is an ~~employee/~~affiliate of ABC Medical and consent to the above applicant being linked to this organisation within eProtocol.

Signature: …… John Smith …… Date: 1 Jan 2023

Please email the completed form to registrations@bellberry.com.au.

Verification of user ID and password will be issued by separate email.

Organisational Verification of Personnel form

This form is used within the eProtocol registration process to verify an individual and their affiliation with the organisation/site in which they wish to register with.

To be completed by the applicant	
Name of applicant:	
In what capacity do you require access to eProtocol?	☐ Principal Investigator who will be submitting a study to Bellberry for review
	☐ Sub-Investigator
	☐ Nominated contact (e.g. site staff, CROs)
Name of Principal Investigator (*if different from applicant*):	
Site at which the study is to be conducted (i.e., site where the PI is located):	
Organisation of applicant (*if different from above*):	
Email address (of applicant):	
Please tick which applies or leave blank if N/A	☐ Sponsor ☐ Clinical Research Organisation (CRO) ☐ Site Management Organisation (SMO)
Are you from a public health organisation or university?	☐ Yes, public health organisation
	☐ Yes, university
	☐ No

The above details will be used to align this form with your application within eProtocol.

Nomination of authorised representative(s)

<u>If no Authorised Representative has previously been nominated for the study site, complete the below.</u>

Please note that an Authorised Representative is required to be nominated by the study site and it is the responsibility of this individual to verify the above and any future applicants and confirm their affiliation with the study site. Please see the definition of Authorised Representative within Bellberry guidance document BA G2 Registrations.

Name:		Name:	
Position:		Position:	
Email:		Email:	

Phone:		Phone:	

New Organisations and/or Government Organisations

If the applicant is registering with an organisation that is new to Bellberry, a government organisation or are conducting research on behalf of/in conjunction with a government organisation, please complete the text box below.

To be completed by the study site (i.e., the site where the PI is located)	
Organisation address:	
ABN:	
Please confirm whether the name of the organisation as reported by the applicant in the above text box is correct:	
☐ Yes ☐ No, please provide correct name: _____	

Please provide details of the study

Application ID* for existing study or brief study title for a new application: *If there are multiple current Application IDs, please list.	
Please outline approximate time frame for expected commencement of the study:	
Is this a government departmental study or are you conducting research on behalf of (or in conjunction with) a government organisation?	☐ Yes, please provide further information:
	☐ No, not applicable.

The following <u>must</u> be completed by the authorised representative:

I, …… confirm that the above applicant is an employee/affiliate of

…… and consent to the above applicant being linked to this organisation within eProtocol.

Signature: …… Date: ….....

Please email the completed form to registrations@bellberry.com.au.

Verification of user ID and password will be issued by separate email.

References

BA F2.1.1 Organisational Verification of Personnel (OVOP)

BA G16 eProtocol Navigation Guide