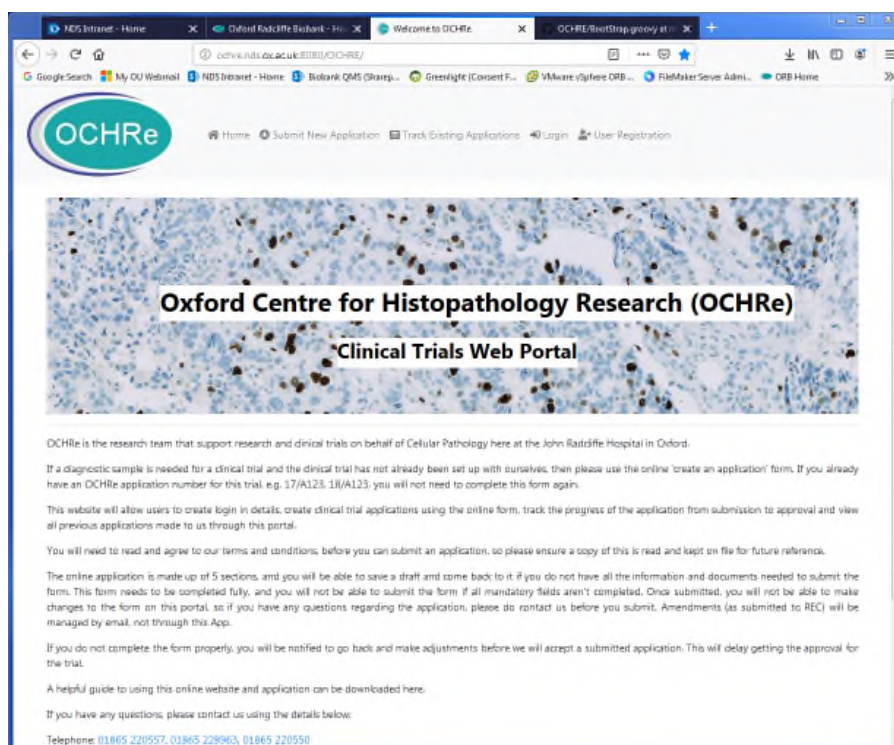


Quick Start Guide - OCHRe Clinical Trials Web Portal

Introduction



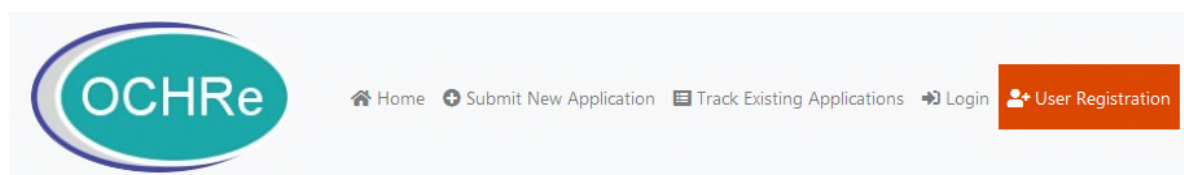
The OCHRe Clinical Trials Web Portal is a browser based tool to allow researchers to create and submit on-line applications for access to NHS diagnostic samples for research or clinical trials. Applicants first create a personal log-in on the user registration page, which then allows them to start to create, prepare and eventually to submit for Tissue Access Committee approval requests for access to diagnostic samples for study purposes. Registered users have access only to those applications they themselves have created.

The application comprises five sections, Applicant Details, Funding Details, Approval Details, Project Details and Sample Details, all of which must be properly completed, including the uploading of all requested supporting documentation, before the request can be submitted. However the user can save and quit the application at the end of any stage of data entry, pending later attachment of the requested documentation if necessary, and return to continue later.

Applicants can also access their existing OCHRe applications to view progress through the approval process, or to review past submissions made through this portal.

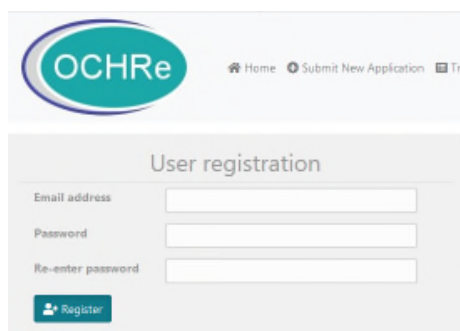
User registration

To create a user account, click the **User Registration** menu item on the portal home page.



This displays a user registration form which asks for a user email address and password, which must be entered in both the **Password** and the **Re-enter password** fields, with which to create the account.

Quick Start Guide - OCHRe Clinical Trials Web Portal

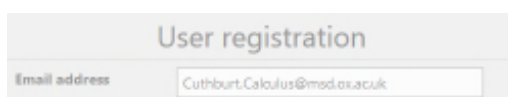
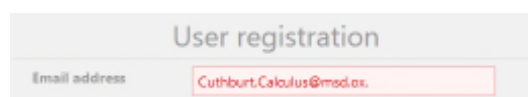
The screenshot shows the OCHRe logo at the top left. To its right are navigation links: Home, Submit New Application, and Track Existing Applications. Below the logo is a 'User registration' form with three input fields: 'Email address', 'Password', and 'Re-enter password'. A blue 'Register' button with a user icon is at the bottom left of the form.

Having entered the account details, click the Register button  to create the account.

If the account is created successfully, the application login form displays.

User Constraints

The user name must conform to the standard pattern of an email address – valid formats will display grey, invalid formats in red.

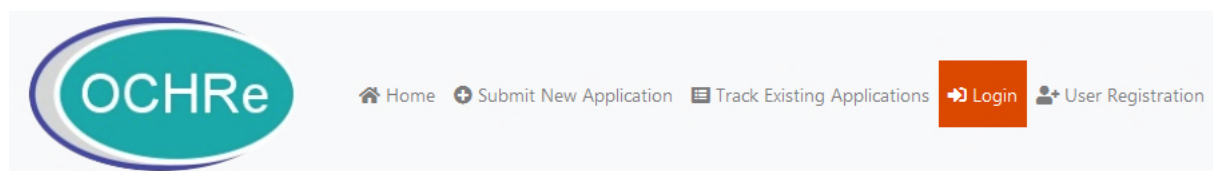
This screenshot shows the 'Email address' field in the 'User registration' form. The text 'Cuthbert.Calculus@med.ox.ac.uk' is entered and displayed in a grey font, indicating it is a valid format.This screenshot shows the 'Email address' field in the 'User registration' form. The text 'Cuthbert.Calculus@med.ox.' is entered and displayed in red, indicating it is an invalid format.

The chosen password must also be entered in the Re-enter password text box, exactly matching the password given above. If the Register button is clicked when the two passwords do not match, an error message displays.

Please enter matching password

Login

To log in to an existing user account, click the login men item on the portal home page.

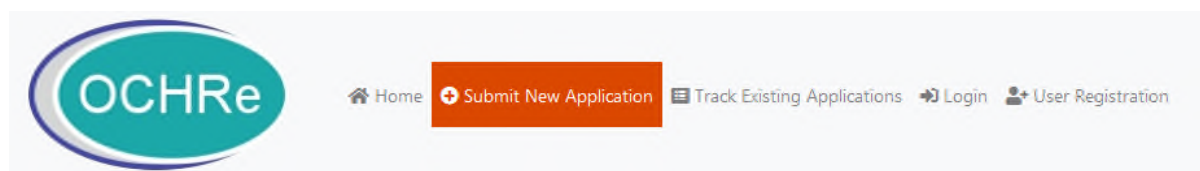
The screenshot shows the OCHRe logo and navigation links: Home, Submit New Application, Track Existing Applications, Login, and User Registration. The 'Login' button is highlighted with a red border.

This displays a user login form in which to enter the user account email address and password.

Having entered the account credentials, click the Login button. 

If the login is successful, the user's applications home page displays.

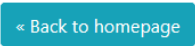
Submit New Application

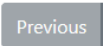
The screenshot shows the OCHRe logo and navigation links: Home, Submit New Application, Track Existing Applications, Login, and User Registration. The 'Submit New Application' button is highlighted with a red border.

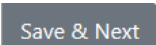
Quick Start Guide - OCHRe Clinical Trials Web Portal

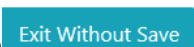
Clicking the Submit New Application menu item displays, for the currently logged-in user, **Section 1: Applicant Details** of the **UCHRe Application** form. The link is accessible from the OCHRe WebPortal external home page, but if no user is currently logged-in, the login page will first display.

Navigation buttons

The **Back to homepage** button  closes the current application without saving any changes and displays the user's Applications homepage.

The **Previous** button  navigates from the currently displayed section of the form to the preceding section. This button is disabled if the currently displayed section of the form is section 1.

The **Save & Next** button  saves data as entered in the currently displayed section of the OCHRe application form and displays the next section ready for data entry or edit.

The **Exit Without Save** button  closes the current OCHRe application without saving any changes and reverts to the user's home screen.

Quick Start Guide - OCHRe Clinical Trials Web Portal

Section 1: Applicant Details

Application 1

[« Back to homepage](#)

Section 1
Applicant details

Section 2
Funding details

Section 3
Approval details

Section 4
Project details

Section 5
Samples, service and data

Section 1 Applicant details

Lead applicant (e.g. Clinical Trial PI)

Title *
Professor

Name *
Cuthbert Calculus

Work Address *
2109b Juniper
Boulevard
Haddockston

Telephone Number *
01865 22550

Email Address *
Cuthbert.Calculus@m

Trial Contact (e.g. Clinical Trial Administrator/Manager)

Title *
Dr

Name *
Tom Thompson

Work Address *
Big Blue Box
Oxford Science Park
Oxford OX2 9TY

Telephone Number *
01865 220557

Email Address *
tom.tom@ctmu.ox.ac.i

Sample Request Contact (e.g. Research Nurse or Clinical Trial Practitioner)

Title *
Dr

Name *
Tim Thompson

Work Address *
Big Blue Box
Oxford Science Park
Oxford OX2 9TY

Telephone Number *
01865 220557

Email Address *
tim.tom@ctm.ox.ac.uk

Is shipping details different from above? *
☒ Yes ☐ No

Shipping Details

Title *
Dr

Name *
Tom Thompson

Work Address *
Big Blue Box
Oxford Science Park
Oxford OX2 9TY

Telephone Number *
01865 220557

Email Address *
tom.tom@ctmu.ox.ac.i

Previous

Save & Next

Exit Without Save

The **Applicant Details** form requests information on the principle contacts involved in the study. It consists of four panels, **Lead Applicant**, **Trial Contact**, **Sample request Contact** and **Shipping Details**.

The **Shipping Details** panel, however, is hidden unless the **Is shipping details different from above?** -

Is shipping details different from above? *
'Yes' radio button ☒ Yes ☐ No is selected.

Each panel, except for the **Shipping Details** panel if hidden, requires **Title**, **Name**, **Work Address**, **Telephone Number** and **Email address** to be entered.

Actions

Clicking the **Is shipping details different from above?** **'Yes'** radio button displays the **Shipping Details** panel, the **'No'** radio button hides it.

Quick Start Guide - OCHRe Clinical Trials Web Portal

The **Previous** button is displayed but disabled.

The **Back to Homepage**, **Save & Next** and **Exit Without Save** buttons are available and act as described above.

Section 2: Funding Details

Application 1

The screenshot shows the 'Section 2 Funding details' form. At the top, there is a navigation bar with five sections: Section 1 (Applicant details), Section 2 (Funding details), Section 3 (Approval details), Section 4 (Project details), and Section 5 (Samples, service and data). Section 2 is currently active. Below the navigation bar, there is a 'Back to homepage' button. The main form area is titled 'Section 2 Funding details'. It contains a 'Research funder' section with a dropdown menu labeled 'Please select *'. The dropdown menu is open, showing three options: 'Commercial', 'NHS', and 'University'. Below the dropdown, there is a 'Contact person for quotation / funding' section. This section contains several input fields: 'Title *' (with 'Dr' entered), 'Name *' (with 'Tom Thompson' entered), 'Work Address *' (with 'Big Blue Box', 'Oxford Science Park', and 'Oxford OX2 9TY' entered), 'Telephone Number *' (with '01865 220557' entered), and 'Email Address *' (with 'm.tom@ctmu.ox.ac.uk' entered). At the bottom right of the form, there are three buttons: 'Previous', 'Save & Next', and 'Exit Without Save'.

The **Funding Details** section of the form requests information about the source of funding for the study and to whom to address quotations or funding questions.

The research funder type is selected from the options available in a drop-down list box.

The funding contact details requested comprise **Title**, **Name**, **Work Address**, **Telephone Number** and **Email Address** as for other contacts in section 1 of the form as described previously.

Actions

The **Back to Homepage**, **Previous**, **Save & Next** and **Exit Without Save** buttons are available and act as described in the **Navigation** section above.

Quick Start Guide - OCHRe Clinical Trials Web Portal

Section 3: Approval Details

Application 1

[« Back to homepage](#)

Section 1
Applicant details

Section 2
Funding details

Section 3
Approval details

Section 4
Project details

Section 5
Samples, service and data

Section 3 Approval details

Ethical approval details

Please attach a copy of the approval letter *

This is a letter of approval.docx

Have you uploaded all documents?

☐ Yes ☒ Pending

Attach more documents

Reference No * Title *

Please fill in this field.

Approval Date *

Consent forms and PIS's

Please attach all copies of consent forms and corresponding PIS's. *

No file selected.

Have you uploaded all documents?

☐ Yes ☐ Pending

Attach more documents

R&D approval details

Organisation* PID *

Other Information

Something else to go here, but what?

Registration on portfolio (NIHR, other)

Please select *

Quick Start Guide - OCHRe Clinical Trials Web Portal

Sponsor

Organisation *
Volkerbiopharm BgH

Has an MTA been arranged? (required for samples being requested from Oxford to be sent outside Oxford). This may already be included in CTA.

Please select *
Yes

Please attach a copy of the MTA or CTA *
Browse... This is an example CTA.docx

Have you uploaded all documents?
☐ Yes ☐ Pending

Attach more documents
Add

Previous Save & Next Exit Without Save

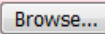
The **Approval Details** section of the form requests information about project approvals and for copies of associated documentation, including approval letters, consent forms, Patient Information Sheets (PISs) and where applicable, for transfer of Oxford samples away from Oxford, Material Transfer Agreements (MTAs).

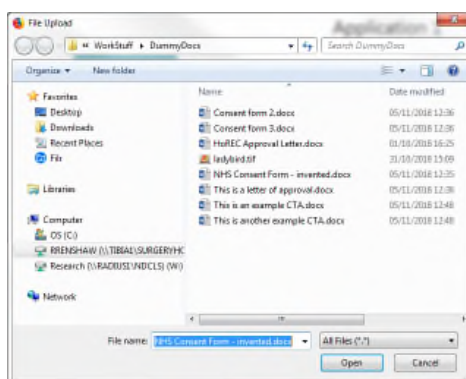
The **R&D Approvals** panel **Organisations** dropdown lists two options, 'OUH' and 'Other'. Selecting the **Other** option sets the **R&D Approvals** panel **Other Information** form field as required.

The **Registration on portfolio** dropdown lists two options, 'Not Registered....' and 'Registered....'. Selecting the 'Registered....' option displays a further field in which to record the name of the portfolio.

The 'Has an MTA been arranged?' dropdown lists three options, 'Yes', 'No needed' and 'Within CTA'. Selecting the 'No needed' option hides the file browse and upload control for the upload of supporting documentation.


Actions

The **Browse** button  No file selected. opens a standard file selection dialog to locate and to attach copies of the requested documents to the application record.



Quick Start Guide - OCHRe Clinical Trials Web Portal

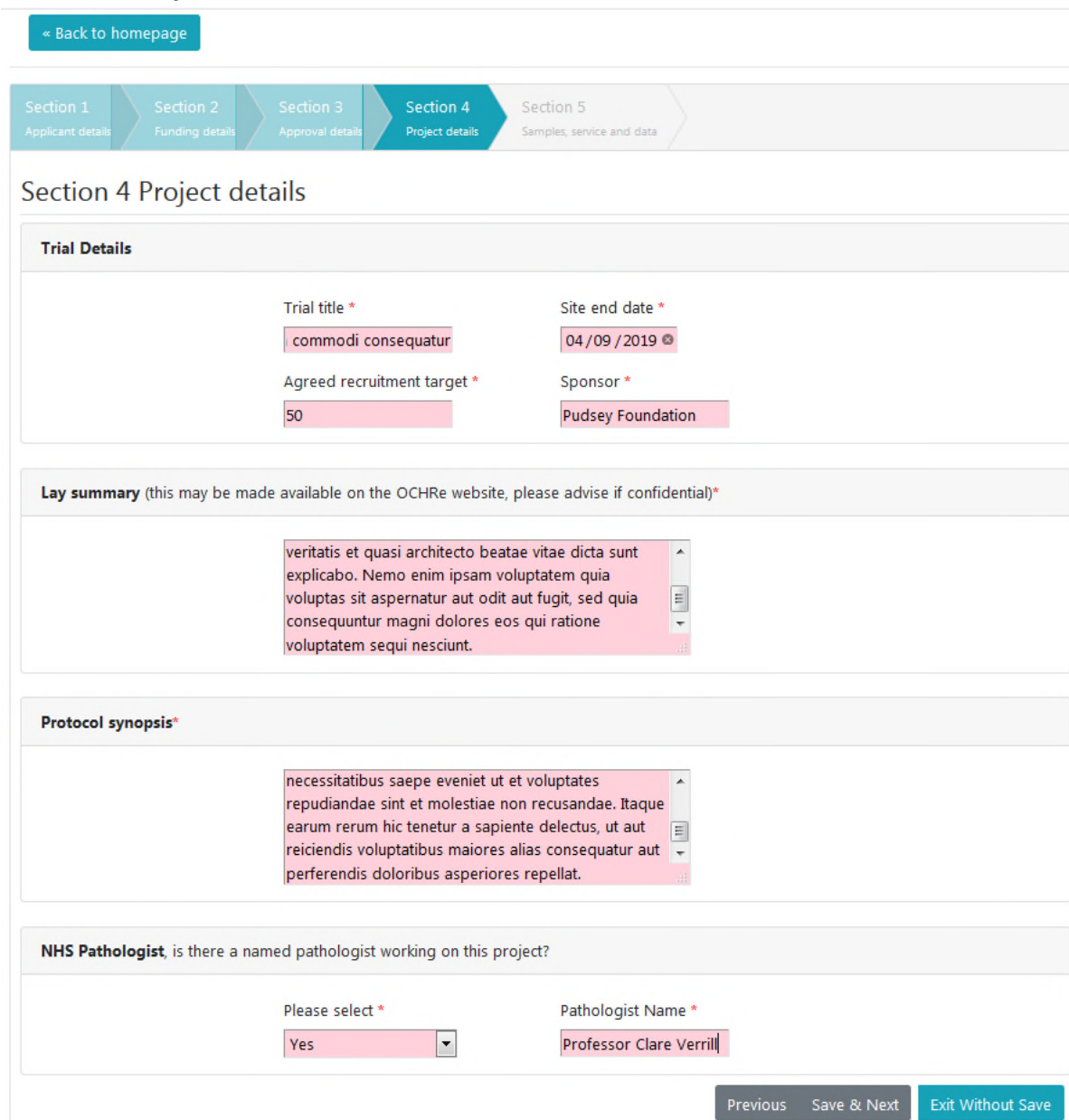
The **Open** button on the **File Upload** dialog closes the dialog and copies the selected filename into the underlying web form data field. The **Cancel** button closes the dialog without making any change.

The **Add** button  creates a new file attachment record to add further supporting documents as required.

The **Remove** button  removes the last attached file record.

The **Back to Homepage**, **Previous**, **Save & Next** and **Exit Without Save** buttons are available and act as described in the **Navigation** section above.

Section 4: Project Details



The screenshot shows the 'Section 4 Project details' form. At the top, there is a navigation bar with five sections: Section 1 (Applicant details), Section 2 (Funding details), Section 3 (Approval details), Section 4 (Project details), and Section 5 (Samples, service and data). Section 4 is currently active. Below the navigation bar, the form is titled 'Section 4 Project details'. It contains several sections: 'Trial Details' with fields for 'Trial title *' (filled with 'commodi consequatur'), 'Site end date *' (filled with '04/09/2019'), 'Agreed recruitment target *' (filled with '50'), and 'Sponsor *' (filled with 'Pudsey Foundation'). Below this is a 'Lay summary' section with a text area containing a Latin placeholder text. Next is a 'Protocol synopsis' section with another text area containing a Latin placeholder text. At the bottom, there is a section for 'NHS Pathologist' with a dropdown menu set to 'Yes' and a 'Pathologist Name *' field filled with 'Professor Clare Verrill'. At the very bottom of the form, there are three buttons: 'Previous', 'Save & Next', and 'Exit Without Save'.

The **Project Details** section of the form requests information about the project, including title, expected end date, recruitment target and study sponsor, along with a lay summary and a synopsis of the methodology to be used.

Quick Start Guide - OCHRe Clinical Trials Web Portal

Selecting the **NHS Pathologist** drop down **Yes** option displays an additional form field in which to record the pathologist's name.

Actions

The **Back to Homepage**, **Previous**, **Save & Next** and **Exit Without Save** buttons are available and act as described in the **Navigation** section above.

Section 5: Samples, Services and Data

Section 1
Applicant details

Section 2
Funding details

Section 3
Approval details

Section 4
Project details

Section 5
Samples, service and data

Section 5 Samples, service and data

Please identify every sample that the study requires (per patient)

Timepoint *

Please select an item in the list.

What is this sample for? *

What is required? *

Please note that you could request multiple samples per timepoint, click on the Add button

Add

How will material be used? (How will you use the materials requested in this application? For trials: include whether it is for screening (eligibility assessment), primary or secondary outcome measures, and/ or exploratory objectives?)*

Data requirements (Specify any accompanying data you require e.g. copy of pathology reports)

Please select *

Is there a clinical trial specific form that we or the pathologist have to complete?

Please attach

Browse...

No file selected.

Terms and Conditions

I agree with the T&C *

Previous

Save & Next

Submit

Exit Without Save

OCHRe Web Portal Quick Start

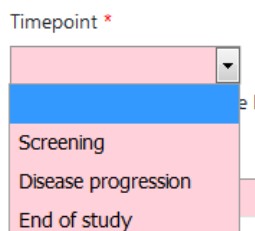
Page 9 of 14

23 Oct 19

Quick Start Guide - OCHRe Clinical Trials Web Portal

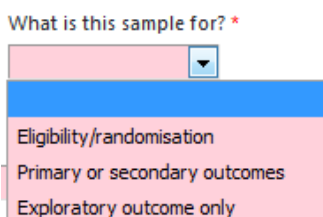
The **Samples, service and data** section of the form requests information about the type, number and processing of the samples being requested.

The **Timepoint** dropdown lists three options, '**Screening**', '**Disease progression**' and '**End of Study**'.



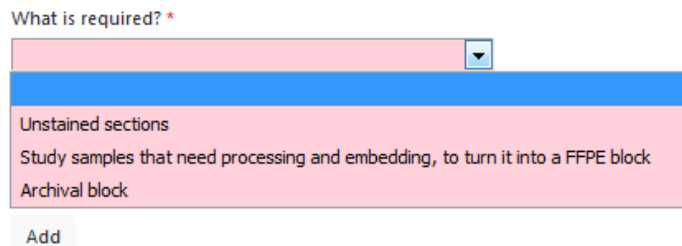
A screenshot of a dropdown menu labeled 'Timepoint *'. The menu is open, showing three options: 'Screening', 'Disease progression', and 'End of study'. The 'Screening' option is highlighted in blue.

The **What is this sample for?** dropdown lists three options, '**Eligibility/Randomisation**', '**Primary or secondary outcomes**' and '**Exploratory outcome only**'.



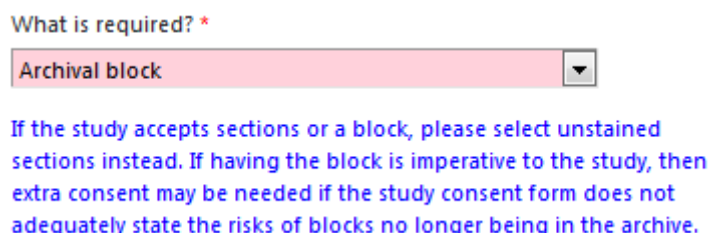
A screenshot of a dropdown menu labeled 'What is this sample for? *'. The menu is open, showing three options: 'Eligibility/randomisation', 'Primary or secondary outcomes', and 'Exploratory outcome only'. The 'Eligibility/randomisation' option is highlighted in blue.

The **What is required?** dropdown lists three options, '**Unstained sections**', '**Study samples that need processing and embedding, to turn it into an FFPE block**' and '**Archival Block**'.



A screenshot of a dropdown menu labeled 'What is required? *'. The menu is open, showing three options: 'Unstained sections', 'Study samples that need processing and embedding, to turn it into a FFPE block', and 'Archival block'. The 'Archival block' option is highlighted in blue. Below the menu is an 'Add' button.

Selecting the **Archival block** option displays a message about a possible requirement for extra consent.



A screenshot showing the 'What is required? *' dropdown menu with 'Archival block' selected. Below the menu, a message is displayed in blue text: 'If the study accepts sections or a block, please select unstained sections instead. If having the block is imperative to the study, then extra consent may be needed if the study consent form does not adequately state the risks of blocks no longer being in the archive.'

Selecting the **Unstained sections** option displays four further form fields in which to enter additional information about the sections required.

Quick Start Guide - OCHRe Clinical Trials Web Portal

Please identify every sample that the study requires (per patient)

Timepoint *	What is this sample for? *
Screening	Primary or secondary
What is required? *	
Unstained sections	
Number of sections *	Thickness of sections *
Enter number of sections	Enter thickness of sections
Type of slide *	Do any need to be stained? *
Any special requirements (labelling or cutting process)	

Please note that you could request multiple samples per timepoint, click on the Add button

Add

The **Type of Slide** dropdown lists two options, '**Charged**' and '**Uncharged**'.

Type of slide *

Charged

Uncharged

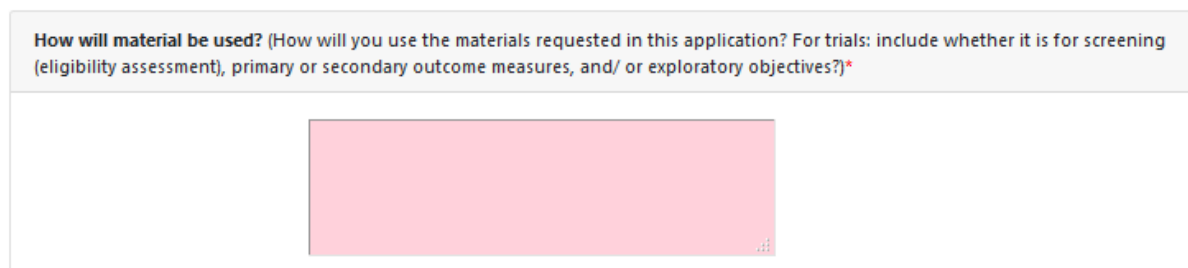
The **Do any need to be stained?** dropdown lists two options, '**Yes**' and '**No**'. Selection the '**Yes**' option displays a further text area in which the details of the staining required must be specified. The **Any Special Requirements?** text area can be used for recording more general requirements as to how the requested material is prepared and/or labelled, applying either to unstained or stained slides.

Type of slide *	Do any need to be stained? *
	Yes
Please select an item in the list.	Yes
Please specify staining *	No
Any special requirements (labelling or cutting process)	

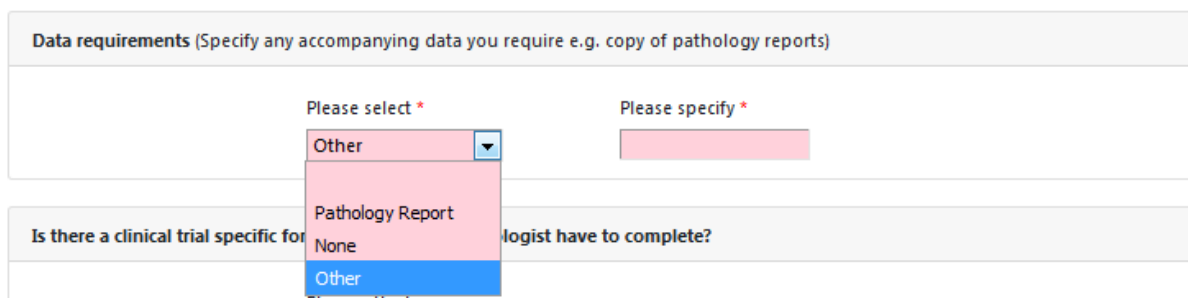
Please note that you could request multiple samples per timepoint, click on the Add button

Add

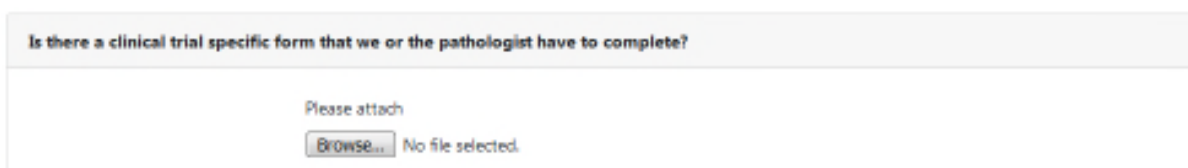
Quick Start Guide - OCHRe Clinical Trials Web Portal



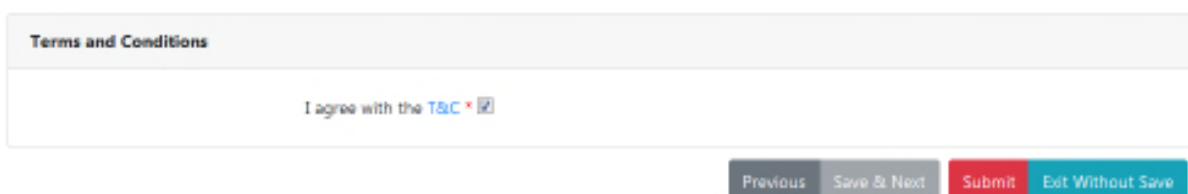
The **How will material be used?** panel provides a multiline text area in which to enter the requested information.



The **Data Requirements** panel requests information about any data requirements associated with the sample request. The **Data Requirements** dropdown lists three options, '**Pathology Report**', '**None**' and '**Other**'. Selecting the '**Other**' option displays a further field in which to provide information on what other data is actually required.



The **Clinical Trial Form** panel of the form provides a button to browse for, and upload, an external file of a trial specific form if required.



The **Terms and Conditions** panel at the foot of the form includes a link to an online copy of Ochre's Terms and Conditions for access to samples and /or data. The applicant **must** tick the T&C checkbox to agree to these before an application can be submitted.

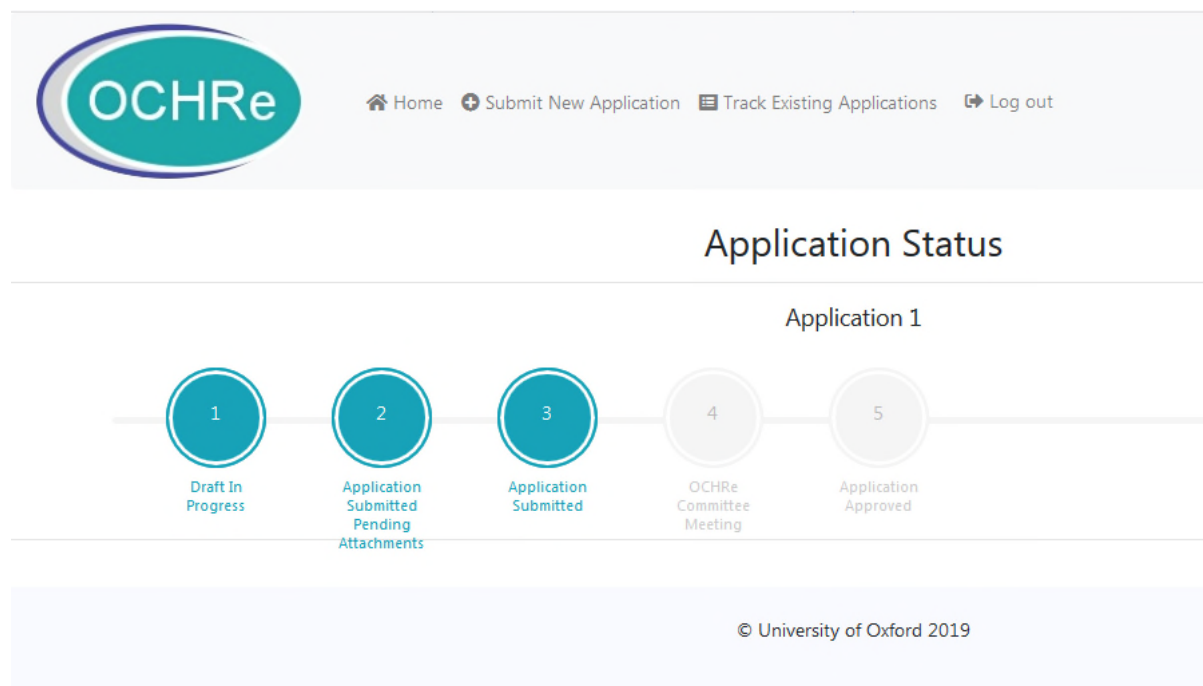
Actions

The **Back to Homepage**, **Previous**, **Save & Next** and **Exit Without Save** buttons are available and act as described in the **Navigation** section above.

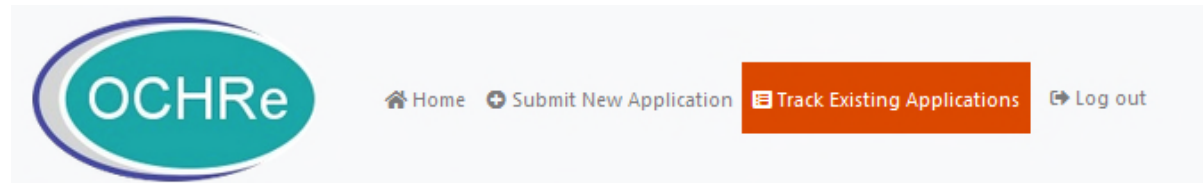
The sample requirements **Add** button displays a new copy of the sample requirements section of the webpage, identical to the initially existing one, to allow multiple requests, for example for different timepoints, different types of sample or different treatments.

Quick Start Guide - OCHRe Clinical Trials Web Portal

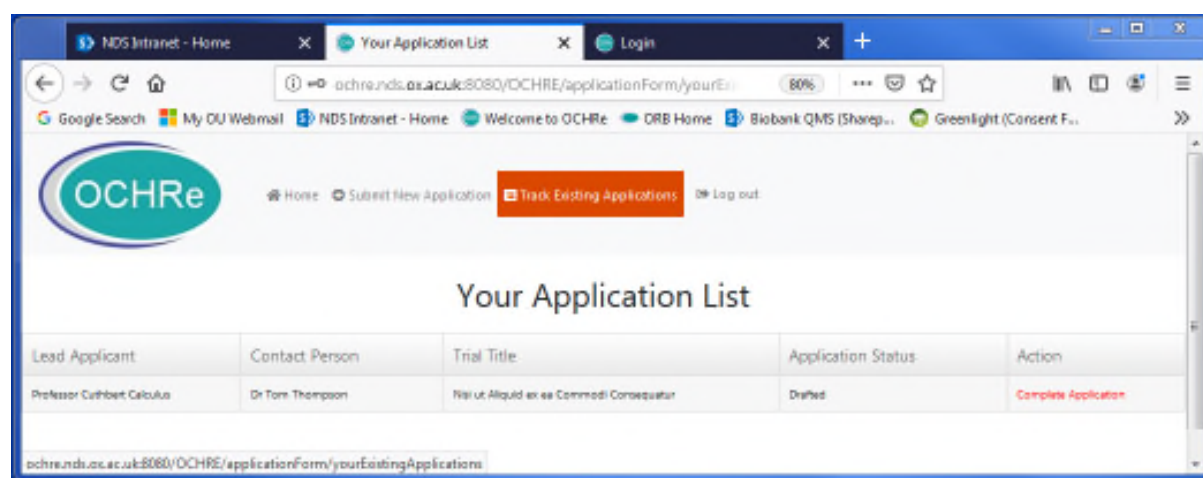
The **Submit** button completes data entry and displays the OCHRe Application Status web page with the completed steps in the application process coloured blue, and those still pending greyed out.



Track Existing Application



Clicking the **Track Existing Applications** menu item displays a web page listing for the currently logged-in user those OCHRe applications created and in progress, or submitted, through the OCHRe Applications Web Portal. The link is accessible from the OCHRe WebPortal external home page, but if no user is currently logged-in, the login page will first display, requiring authentication of the provided username and password before progressing to the **Your Applications List** web page.



Quick Start Guide - OCHRe Clinical Trials Web Portal

The listed applications show details of the lead applicant and contact, along with the status of the application and an action link.

Possible statuses are: **Drafted**, **Submitted**, **Submitted Pending Attachments**, **OCHRe Committee Meeting**, and **Application Approved**.

For applications with '**Drafted**' status, the **Action** column shows a **Complete Action** link.

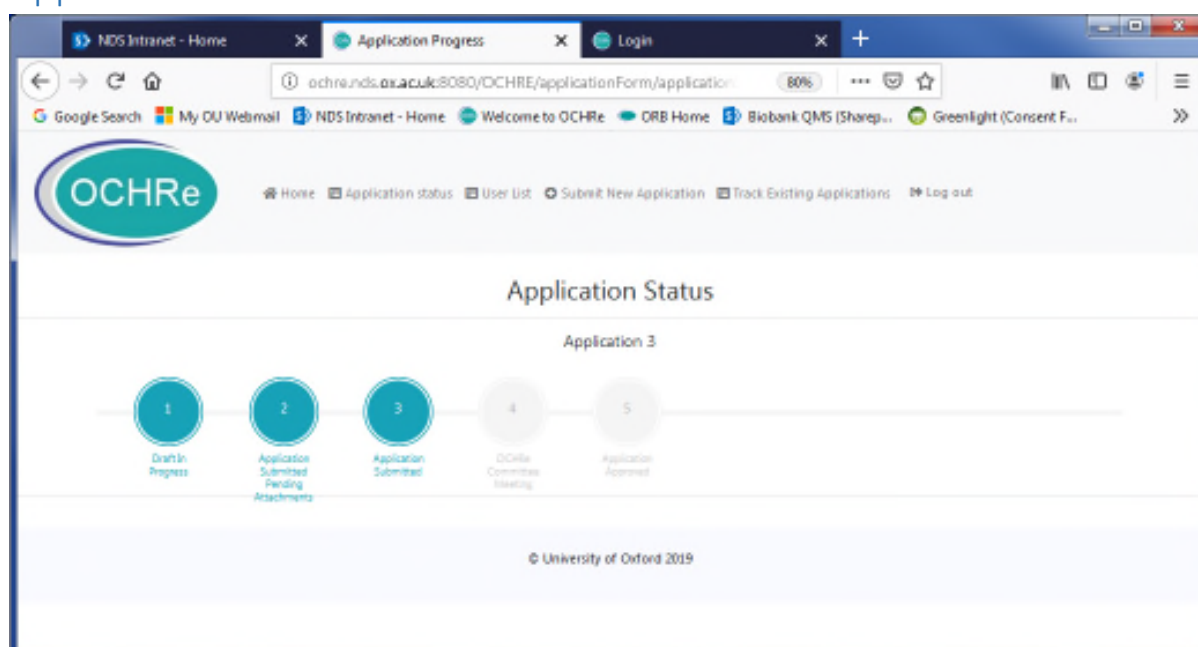
For applications with '**Submitted**' status, the **Action** Column shows a **View Progress** link.

Actions

Clicking the **Complete Action** link opens the Application Form web page for the section following the one most recently saved.

Clicking the **View Progress** link opens the **Application Status** web page showing the completed and still pending steps of the application process.

Application Status



The **Application Status** web page displays a series of steps representing different stages in the OCHRe application process, with those completed coloured blue and those still pending coloured grey.