

RADAR Electronic consent training notes v1

Electronic consent to recruit patients can be used alongside existing methods such as face to face.

The main things to note are: patient email address is required. Patient should be contacted before e-consent is initiated to ensure informed consent and to check patient details. Every completed envelope has a cost implication therefore researcher should be fairly confident the patient wishes to take part.

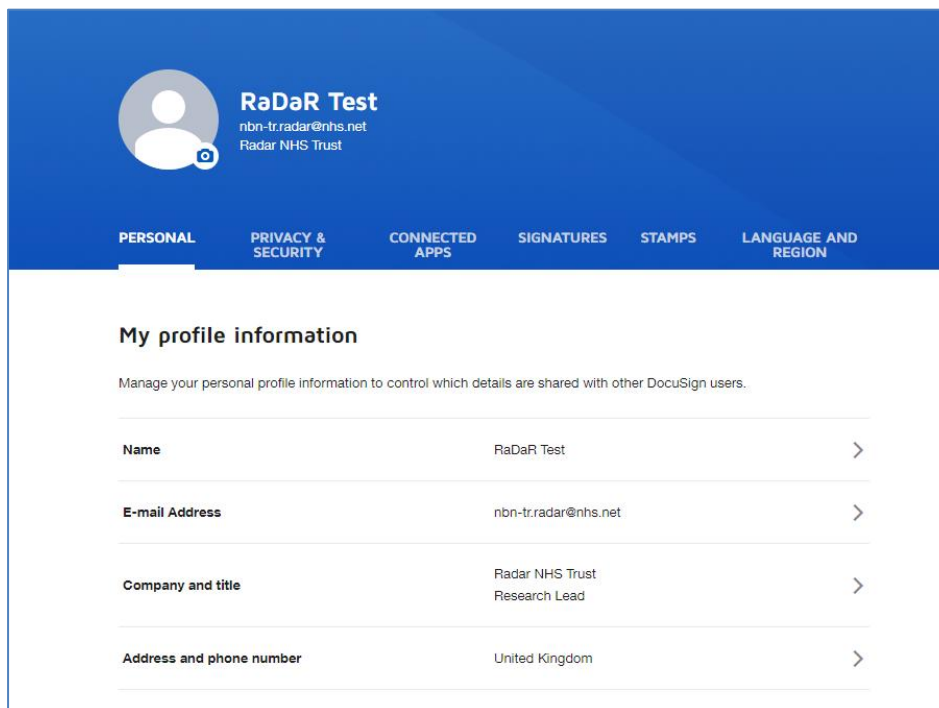
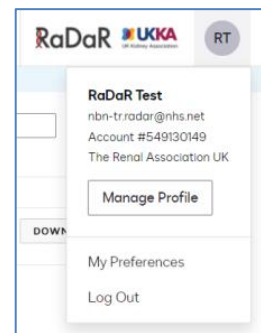
<https://account.docusign.com/#/username>

Site set up

- RADAR team sets up site user accounts with user name and email details provided.
- RADAR team sets up site letter/consent/PIS templates for site using site trust logo and contact details.
- For more sites with more than one user, RADAR team can enable “shared envelopes” for delegated management of envelopes. Upon request.

User set up

- User will be given PIN to activate their account. They will need to create a strong password.
- When user first logs in, they should check and **complete details** on user profile as contact details are displayed on emails to patient. Go to to circle top right of page, then **Manage Profile**. Go to **Personal** and add details. You can also go to **Signatures** to add your standard signature (this can speed up consent form countersignatures).



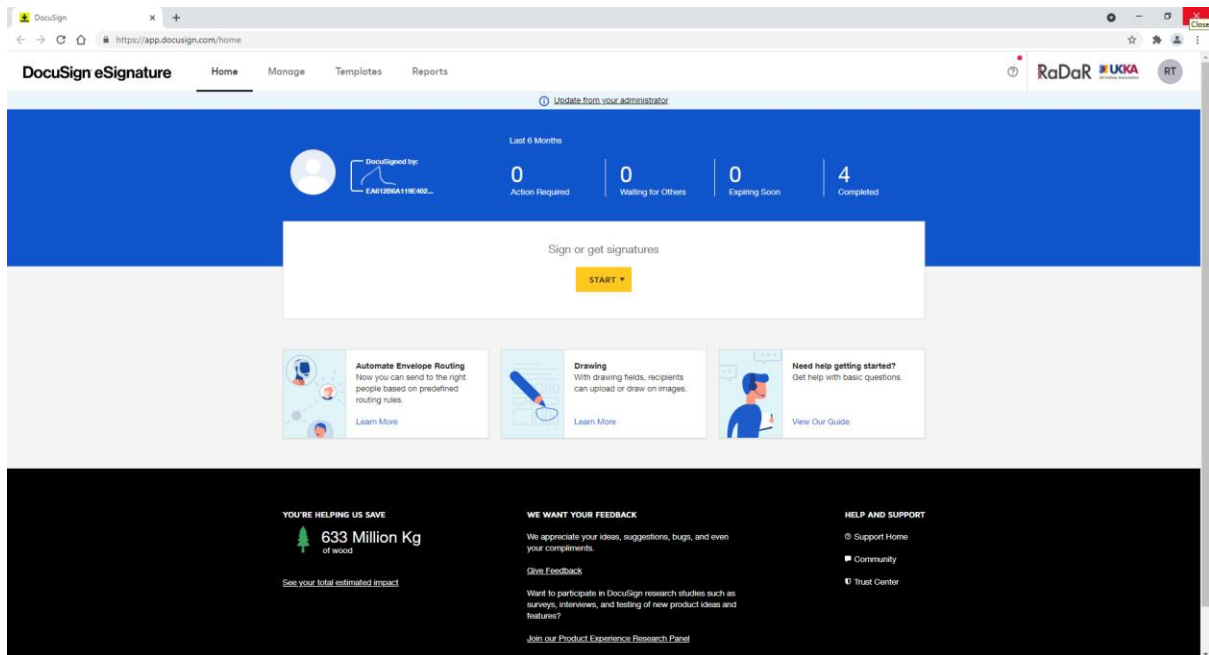
One page summary of e-consent process


1. Researcher makes contact with patient or parent/guardian and explains study.
2. Researcher checks and confirms email address with what is held.
3. Researcher explains that consent form and information will be sent to them by email shortly.
4. Researcher logs into <https://account.docuSign.com/#/username>
5. Researcher selects correct consent template in **Templates** tab, prefills field/s and sends.
6. The consent form completion status can be tracked within DocuSign under **Manage** tab. Various reports are available under **Reports** tab
7. The email sent to patient has a "Review Document" button. Patient can read the information and sign the consent form when they are ready (14 day expiry). When reviewing documents, the yellow "Start" button will take them straight to where they need to sign. They can draw or upload a signature.
8. Researcher countersigns the consent form (within DocuSign if they are sender).
9. A notification email will be sent to the patient after the researcher signs form. Patient can then click link in email to download or print completed form.
10. Completed consents can be organised into custom folders with **Manage** page.
11. You can print completed consent form or save as PDF into folder on your network drive.
12. The researcher is free to recruit patient to RADAR once consent form is completed correctly.

Comprehensive instructions on e-consent process

Book electronic consent

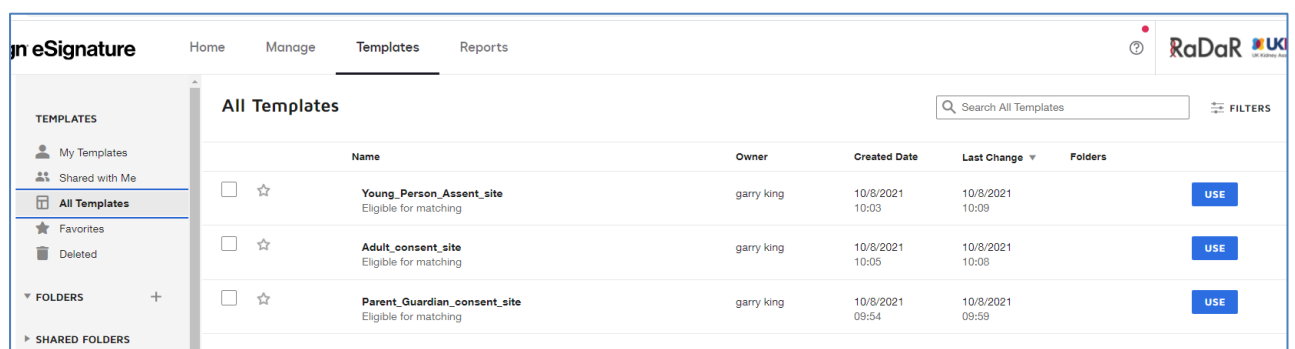
Site user logs into DocuSign (<https://account.docusign.com/#/username>), you will arrive at DocuSign landing page.



Please note, in the following steps, whenever you select options to a new page you can always navigate backwards with arrow  at top left in blue banner or yellow **NEXT** button to proceed to next stage.

Initiate e-consent

1. Go to **Templates** tab (templates are pre-designed packages of documents)
2. Click **All Templates** on left-hand side
3. **Use** correct consent package e.g. "Adult_consent_site_name" (click blue **USE** button)



Add Recipient details

The next page allows you to see what is being sent and to whom

The screenshot shows a web interface for adding documents and recipients to an envelope. The top section, 'Add Documents to the Envelope', displays three document thumbnails: 'Parent Guardian Consent Le...', 'Parent Guardian Information...', and 'Parent Guardian Consent Fo...'. Below this is the 'Add Recipients to the Envelope' section, which includes a checkbox for 'Set signing order' and two recipient forms. The first form is for a 'Patient' with fields for 'Name *' and 'Email *'. The second form is for a 'Researcher' with fields for 'Name *' and 'Email *'. At the bottom, there is a 'Message to All Recipients' section with a subject line and a character count.

Add Documents to the Envelope – you can ignore this because all required documents have been added. You can view the documents here if you like by clicking view when hovering over them. You can delete letter/PIS from envelope here if you wish e.g. when patient already has been sent one.

Add Recipients to the Envelope

1. **Add patient name and email.** If you have chosen parent/guardian template then add the name and email of parent/guardian (you will be given chance to add child/ward's name in consent form later).
2. **Add researcher name and email.** Typically this is the sender/user that is logged in. You can choose from a dropdown list of previous researcher names/emails at site or use user address book to save you typing details.

This is a close-up of the 'Add Recipients to the Envelope' form. It shows the 'Patient' and 'Researcher' sections. The 'Patient' section has a 'Name *' field with a dropdown menu and an 'Email *' field. The 'Researcher' section has a 'Name *' field with a dropdown menu and an 'Email *' field. The form is set to 'Set signing order'.

Message to All Recipients

1. The subject and email message has default text. Please leave the email subject as it is (this shows a merge field which will show patient name (or Parent/Guardian) to make it easier to reference in emails). You can add further instructions to email message if you wish.
2. Click **Next** when you wish to proceed

Message to All Recipients

Email Subject *

Characters remaining: 36

Email Message

Characters remaining: 9886

Pre-fill fields on Consent Form

Here you are given opportunity to add pre-fill information to form before it gets sent. Any site contact details will be shown here alongside trust logo.

Consent to RaDaR by [[Patient_UserName]] on behalf of child/ward

RECIPIENT PREVIEW SEND

Garrytest

Search Fields

Standard Fields

- Signature
- Initial
- Date Signed
- Name
- Email
- Company
- Title
- Text
- Checkbox
- Dropdown
- Radio
- Payment Item
- Drawing
- Formula
- Attachment
- Note
- Approve

Documents

Parent Guardian Cons...
Pages: 1

Parent Guardian Infor...
Parent Guardian Cons...

BACK SEND

On the consent form itself, the recruitment site name should already be defaulted to your site name. You should **copy/paste the patient NHS number** (perhaps from your clinical system) into the correct field. The **Parent/Guardian form** also has **child/ward name to enter here**.

National Registry of Rare Kidney Diseases (RaDaR)

Parent/Guardian Consent Form (children up to 18 years of age)

For parents of children up to the age of 18 and legal guardians of adults with limited capacity

Recruiting Site: Hospital

Child/Ward Name: Text

NHS /CHI /HSC Number: Text

***If you click send before you enter the pre-fill fields then you will get a warning.**

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Recruiting Site: Hospital
Child/Ward Name: Text
NHS /CHI /HSC Number: Text

In signing up to RaDaR, I agree to the following:

- I have read the information sheet and have had an opportunity to ask questions about RaDaR.
- I understand that my child/ward's participation in RaDaR is voluntary and that we can withdraw at any time without giving a reason. I also understand that this agreement will lapse when my child reaches 18 years of age when they can choose to consent on their own behalf, subject to capacity.
- I understand that relevant sections of my child/ward's medical record may be looked at by individuals from RaDaR and regulatory authorities and NHS Trusts where it is relevant to taking part in research. I give permission for these individuals to have access to such records.
- I agree that my child/ward's past, present and future clinical data can be used for ongoing and future research into kidney disease and related conditions.. I understand that my child/ward's data will be

BACK SEND

When you are ready click the **yellow send button!**

The application will indicate that it has been sent.

Tracking e-consent status

Go to **Manage** tab. The **Sent** folder will show status of envelopes sent. If you haven't navigated anywhere else, you can click F5 to refresh the screen. The status updates automatically once form is signed by the patient. Once patient signs, if the researcher who needs to countersign is the sender logged in then they can sign straightaway in application else they will be sent an email to do this.

in eSignature Home Manage Templates Reports

NEW ▾

Shared Envelopes

ENVELOPES

- Inbox
- Sent**
- Drafts
- Deleted

Sent Search Sent

Filtered by: Date (Last 6 Months) | Edit

Subject	Status
<input type="checkbox"/> <input type="radio"/> Consent to RaDaR by Garrytest on behalf of child/ward To: Garrytest, Garry Researcher	<div style="width: 100%;"><div style="width: 100%;"></div></div> 0/2 done Waiting for Others

Looking for more? | Edit your filters

Clicking the envelope shows more info on the status.

ign eSignature Home **Manage** Templates Reports

Consent to RaDaR by Garrytest on behalf of child/ward ⓘ

Envelope ID
Last change on 10/8/2021 | 12:11
Sent on 10/8/2021 | 12:11

🕒 **Waiting for Others**

RESEND MOVE CORRECT MORE ▾

Recipients

	CURRENT	
2	Garrytest garry.king@nhs.net	Needs to Sign
3	Garry Researcher nbn-tr.radar@nhs.net	Needs to Sign

Message
Please review the information and sign the consent form for RaDaR, Registry for Rare Kidney Diseases. Many thanks

Email/docs sent to patient

Logos/pictures may not appear due to email limitations. Patient should click **“Review Documents”**

The image shows the content of an email sent to a patient. At the top, there are logos for RaDaR (Registry for Rare Kidney Diseases) and UKKA (UK Kidney Association). Below the logos is a blue rectangular box with a white circular icon containing a document and a pen. The text inside the box reads: "RaDaR Test sent you a document to review and sign." Below this text is a yellow button with the text "REVIEW DOCUMENTS". At the bottom of the email, there is a section for "RaDaR Test" with the email address "nbn-tr.radar@nhs.net". Below this is a paragraph: "Please review the information and sign the consent form for RaDaR, Registry for Rare Kidney Diseases." followed by "Many thanks". At the very bottom, it says "Powered by DocuSign".

Patient Reviews Documents

The web browser will open up a page. The message appears “This site uses cookies, some of which are required for the operation of the site”. **Click OK blue button at top right.**

To initiate review, Tick “**I agree to use electronic records and signatures**”

Click **Continue**

Read documents (letter, patient information sheet) and scroll down to the consent form.

Note: clicking **START** or **FINISH** will take you to straight to end of document for signature.

This screenshot shows the 'Request for Signature' page for RaDaR. At the top, there is a cookie consent banner with an 'OK' button. Below it, the page title is 'Request for Signature' and the sender is 'RaDaR Test, The Renal Association UK'. A message asks the user to review information and sign the consent form. A blue bar contains a checked checkbox for 'I agree to use electronic records and signatures' and a yellow 'CONTINUE' button. The main content area displays the 'National Registry of Rare Kidney Diseases (RaDaR) Parent/Guardian Consent Letter' with a 'Dear Parent/Guardian,' salutation and introductory text. A form field for 'name' is visible with sub-labels 'email' and 'Tel'.

Please note, there are **More Options** top right of page if patient wishes to Finish Later, Decline or sign on paper.

This screenshot shows the 'More Options' dropdown menu. The menu is open, showing a list of actions: 'Finish Later' (highlighted), 'Sign on Paper', 'Decline', 'Help & Support', 'About DocuSign', 'View History', 'View Certificate (PDF)', 'View Electronic Record and Signature Disclosure', and 'Session information'.

Once documents are read, patient can click on the **Sign** box in order to provide signature.

The screenshot shows a consent form titled 'National Registry of Rare Kidney Diseases Parent/Guardian Consent Form Version 9 13.08.2020'. It contains several bullet points of consent terms. Below the terms, there are fields for 'Your name' (Garrytest), 'Date' (10/8/2021 | 12:22 PM BST), 'Your e-mail address' (Garry.king@nhs.net), and 'Your signature'. A yellow arrow points to a 'SIGN' button. Below the signature field, there is a 'Required - Sign Here' label and a 'Sign' button with a downward arrow. The form also includes a 'Thank you for your help.' message, a 'For office use only' section with fields for 'Researcher's name' (Garry Researcher) and 'Date', and a 'Consent obtained in person/by post /electronically (delete as applicable)' checkbox. At the bottom, there is a 'FINISH' button.

You are given 3 options, select a default signature, draw or upload.

Draw is typically selected.

The Upload option enables you to get a signature you may have saved on your device.

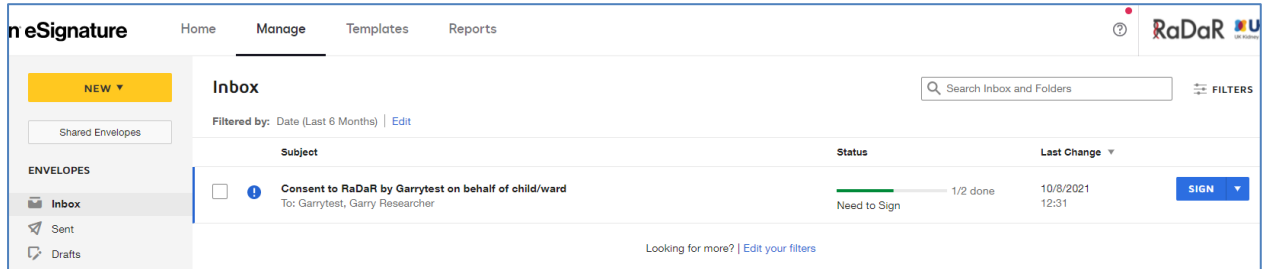
The 'Adopt Your Signature' dialog box prompts the user to confirm their name, initials, and signature. It has fields for 'Full Name*' (Garrytest) and 'Initials*' (G). Below these fields, there are three options: 'OR SELECT A SIGNATURE', 'DRAW' (which is selected), and 'UPLOAD'. Under the 'DRAW' option, there is a 'DRAW YOUR SIGNATURE' section with a 'Clear' link and a signature canvas showing a handwritten signature. At the bottom, there are two buttons: 'ADOPT AND SIGN' and 'CANCEL'. A small disclaimer at the bottom states: 'By selecting Adopt and Sign, I agree that the signature and initials will be the electronic representation of my signature and initials for all purposes when I (or my agent) use them on documents, including legally binding contracts – just the same as a pen-and-paper signature or initial.'

After signature, click **Adopt and Sign** button, then **Finish** button. You may get a pop up message that “you are done signing”. Click **done**.

The form will be sent to research for countersignature. The patient will be sent link to completed documents after countersignature. They can save or print completed documents.

Researcher signature and completed documents

The manage tab inbox shows all documents waiting to be signed by researcher. Researcher can sign in the application by using signature saved in user profile. Specified researchers who don't have DocuSign account can sign via an email (similar to patient).



Your signature.....
Thank you for your help.
For office use only

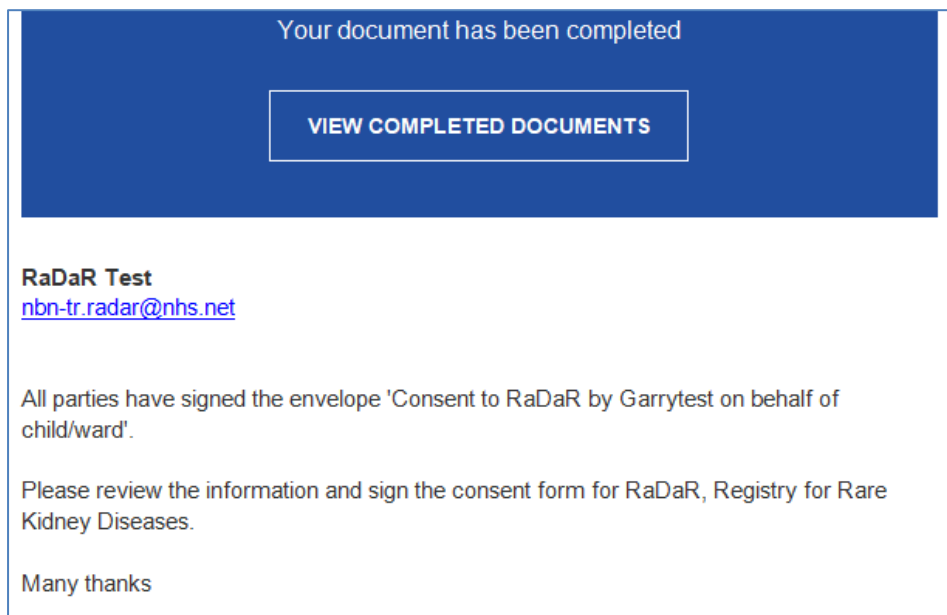
Researcher's name Gar
Date..... 10/8/2021 | 12:34 PM

Researcher's signature
Consent obtained in person/by post /electronically (delete as applicable)

National Registry of Rare Kidney Diseases Parent/Guardian Consent Form Version 9 13.08.2020

The form includes a yellow box with the text 'Required - Sign Here' and a 'Sign' button with a downward arrow. The 'Date' field is pre-filled with '10/8/2021 | 12:34 PM'.

Once researcher signs, patient will get an email with a link to the completed documents.

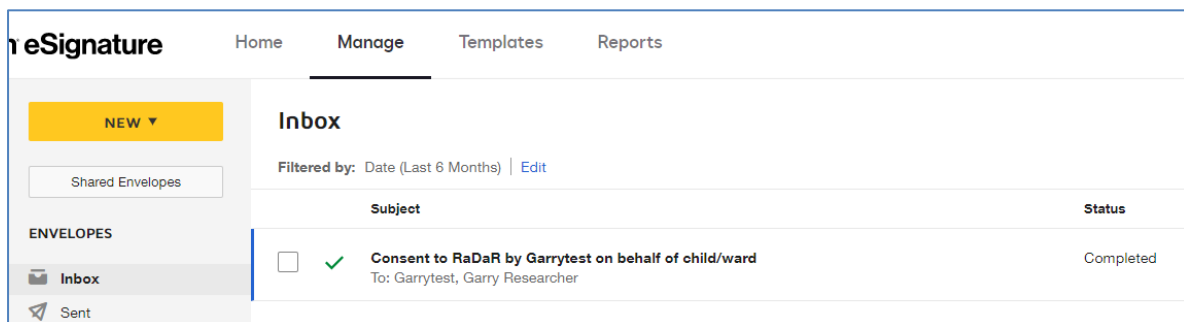


Researcher can see all completed envelopes in the inbox of the **Manage** tab.

Researcher can recruit all patients with completed consents to RADAR!

Note: completed envelopes can be moved to created folders to tidy up the space.

You can **print or save the consent form** as a PDF on your local network folder from your records. At the relevant completed document row, use the dropdown next to download button and select "Print". You then have the option to print, if available, or to "Save as PDF". If you save as PDF then select custom to choose the last page number where the consent form is. Give the form an appropriate filename such as patient name or NHS number then save.



Other Features

The **Reports** tab enables the user to run reports to see the status of sent envelopes and provide lists.

In the **Manage** tab there is a "Shared Envelopes" button. Use this to see the envelope status lists of other users at your site in case of delegation. Radar team can set up shared envelopes for users at site upon request.

