Guidance for the implementation of Cancer Research UK SACT consent forms electronically (e-consent)

Developed by the e-consent working group on behalf of the Systemic Anti-Cancer Therapy (SACT) National Steering Group

Supporting

CANCER RESEARCH UK

NHS
Guy's and St Thomas'
NHS Foundation Trust

Foreword

This guidance document is written by the e-consent working group which is part of the national regimen specific CRUK SACT consent form project. It is intended for the NHS SACT providers to introduce and facilitate the implementation of the consent forms electronically.

Due to the complexity of the IT infrastructure and varied electronic patient record and SACT prescribing systems across the NHS, the project team cannot provide one single national solution. The e-consent working group has therefore outlined several solutions by working with potential providers who are able to deliver e-consent. Each NHS organisation may then decide which particular solution will be best suited to their systems and financial constraints.

This guidance is intended to help NHS organisations to configure and maintain e-consent solutions, including adoption of CRUK e-consent forms, by defining a framework specified by the e-consent working group.

Disclaimer: users are responsible for ensuring their own compliance with all applicable laws and regulations associated with IT governance.

Contents

Abbreviations

SACT	Systemic Anti-Cancer Therapy
CRUK	Cancer Research UK
NSG	National Steering Group
GSFT	Guy's and St Thomas' Foundation Trust
PAS	Patient Administration System
EPR	Electronic Patient Record
TOR	Terms of Reference
UK SACT Board	UK Systemic Anti-Cancer Therapy Board

2.0 Introduction

2.1 Cancer Research UK Systemic Anti-Cancer Therapy (SACT) consent forms: current status

Since 2016, the national regimen specific CRUK SACT consent forms have been available to all SACT providers in the UK via the Cancer Research UK website (**cruk.org/sact**). CRUK awarded a grant to Guy's and St Thomas' Foundation Trust (GSTFT) to fund a pharmacist to develop and publish a national library of SACT regimen-specific consent forms. The UK SACT Board recommends the use of these SACT forms. Guidance on consent for SACT to support the process is available on the CRUK website. Whilst the UK SACT Board is the overarching governing body for the project, the SACT NSG (National Steering Group) oversees the progress, uptake, and strategic development of the project at a national level.

Two separate national surveys were carried out in 2017 and 2018. Feedback from both the surveys was very positive regarding the use and content of the forms. CRUK provides a monthly analysis of the website and shows that downloads of the consent forms has increased year on year since 2017.

As the project continues to evolve and there is increasing uptake of electronic prescribing systems, there are growing requests from NHS trusts for electronic consent forms. Some organisations are not adopting the CRUK forms as they are not electronically available. Current practice is to download and print the forms from the CRUK website.

Remote consent has been of particular importance during the COVID-19 pandemic, reducing the frequency of patients travelling to and attending hospital. As a result, guidance on remote consent was also generated which is available on the CRUK website.

The need for an electronic solution both within the hospital setting and remotely is thus clearly required.

2.2 Purpose of the guidance

The purpose of this guidance is to:

- Describe the requirement to adopt the CRUK SACT consent forms electronically and recommend potential solutions
- Outline a framework of requirements agreed by the e-consent working group
- Introduce potential providers who are able to deliver e-consent within the agreed framework
- Outline the governance requirements for use of CRUK SACT consent forms specified by the CRUK legal team

2.3 Benefits of e-consent

The availability of electronic consent forms will help to improve the efficiency of the consent process by eliminating wasteful steps of printing and scanning consent forms, reducing paper waste and removing the need for additional administrative support. It will greatly benefit patient experience, particularly in scenarios where a patient portal and remote consent functionality are available.

2.4 Role of the e-consent working group

Electronic consent and implementation of electronic SACT regimen-specific consent forms is becoming an increasing priority. This will significantly help to supplement the changes in practice in the health care system across the UK as we move towards more digitalised consultations.

Introducing a new technology, such as e-consent, undoubtedly comes with various challenges and intricacies. It was therefore agreed at the SACT NSG in March 2020 to set up a working group dedicated to developing the e-consent process with appropriate membership which would facilitate this work stream. The Terms of reference (ToR) (**Appendix 1**) and programme of work were confirmed by the e-consent working group. An options appraisal for electronic consent and comparison of paper-based and electronic pathways of consent was undertaken. Members of the e-consent working group are from various professions (clinicians, patient representatives, IT representatives, and representatives from CRUK). Some members are part of the NSG and others are external with experience of implementing e-consent within their own organisations.

There is variation across the UK in the patient administration systems (PAS) and SACT prescribing systems used. This, together with variable IT infrastructure makes it difficult to provide one compatible national solution. Therefore, it was deemed more appropriate to provide multiple options which may be compatible with specific systems. In this way each trust can identify the best solution for their trust.

The working group formulated a set of questions on which to base the framework. The working group then collaborated with potential e-consent providers. Prior to formal presentations the providers were sent the set questions to answer. Two of the 4 providers completed this and is shown in **Appendix 3**. Each provider then presented their e-consent solution. The outcomes are summarised in **Appendix 4**.

The CRUK SACT forms have been included as part of the solution as they are comprehensive, peer reviewed and readily available on the CRUK website.

3.0 Considerations for e-consent

It is not possible for the working group to comment on the IT governance or logistics of interface for individual organisations or dictate what would be suitable from a technical or financial perspective.

The working group developed the following key points to be considered when introducing electronic consent. This is not an exhaustive list:

- How the product will be integrated into the local PAS to allow patient data and demographics to be linked (eg web based, cloud based, local server)
- Access security and governance (compatibility with fire walls, virus checkers, internet security, password security)
- Version control and management of the regimen-specific consent forms
  - CRUK SACT forms are reviewed every 3 years and ad hoc changes are made to reflect feedback or safety alerts
  - The most updated forms are available on the CRUK website
  - Publication of the forms is communicated by direct emails by the CRUK project lead pharmacist to the lead SACT clinicians (or equivalent) of NHS organisations in the UK who are SACT providers and members of the professional groups represented on the UK SACT Board
- **It is the responsibility of each organisation to ensure the most up to date forms from the website are reflected or feeding into the electronic system avoiding the risk of out of date forms being used**
- Consider if additional resources are required for maintenance of the forms and subsequent financial implications as a result
- Functionality to allow change of decision to be recorded and redundant forms to be archived
- Functionality for confirmation or re-confirmation of consent
- Provide an audit history for each form (eg record of changes made, text added)
- Option to add specific risks and information
- Inclusion of multimedia components if needed
- Functionality to email information to patient
- Option for remote consent with remote signature
- Storage of completed forms within the system database only or EPR or both
- Cost (pre, during and post launch)

4.0 Overview of the framework

The purpose of the framework is to support and guide the trusts in the decision-making of which e-consent solution to explore or adopt. It is anticipated that clinicians, with their IT teams, will look at the above questions and then with the information provided in Appendix 3 and Appendix 4 to determine the type of e-consent that is appropriate for their trust or network. Many of e-consent providers will be very flexible in terms of the specification they can provide, and that they are all at various stages of development. In addition, the list of providers is not exclusive. Since the workshop where the above providers show-cased their work, we have been made aware of others.

We consider this guidance to be an iterative process, and may represent a first step for some organisations who are considering e-consent.

5.0 Guidance for use of CRUK consent forms electronically

Digital consent solutions offer multiple advantages to clinical practice, especially with the availability of sophisticated modules allowing customisation to user needs. However, there is a risk of vital information from the consent forms being removed or edited. As a result, there are various factors that need to be carefully considered when developing and using electronic consent forms.

The production of the CRUK SACT consent forms involve a rigorous and peer reviewed process before being published on the CRUK website. Therefore, we would strongly recommend that the forms are used in their entirety without change. However, we acknowledge that the layout and some of the wording may change for technical or clinical reasons.

5.1 Use of the consent forms without amendments

The CRUK logo and consent form footer can be included in electronic consent forms where the content of the forms is used unamended in its entirety **[1]**. The format, font and/or colours can be changed if necessary, but the text and CRUK logo should be unamended. Please ensure that the logo is incorporated in compliance with the CRUK brand guidelines in **Appendix 5.** The footer at the bottom of each page of the consent form includes the names of those who have prepared, checked and approved the forms, as well as the details of version and date.

In this instance, please include the following disclaimer:

The content of this form was developed by Cancer Research UK and Guy's and St Thomas' NHS Foundation Trust. Cancer Research UK and Guy's and St Thomas' NHS Foundation Trust will not accept any responsibility for any claim whether for damages or otherwise, or any other liability arising out of or in connection with the form or its use.

5.2 When amendments are made to the consent form contents

Where providers base their electronic consent forms on the CRUK consent forms but change some of the content for technical or clinical reasons, the CRUK logo and consent form footer should not be used.

The following disclaimer should be included within the e-consent system in a way that makes it clearly visible to both clinician and patient.

Parts of this form are based on content developed by Cancer Research UK and Guy's and St. Thomas' NHS Foundation Trust. Some of that content may have been selected and/or modified by the electronic system provider, hospital trust or clinician depending on the patient's individual circumstances. It is the responsibility of each individual organisation to ensure that relevant legal requirements and appropriate governance and safety clearance procedures within their own clinical services have been followed prior to implementation of electronic consent. Cancer Research UK and Guy's and St. Thomas' NHS Foundation Trust will not accept any responsibility for any claim whether for damages or otherwise, or any other liability arising out of or in connection with the form or its use.

For our records, it would be useful for us to know if you have used the CRUK SACT consent forms either in their entirety or as a basis for your e-consent forms. Therefore, we ask that you notify the Project Lead Pharmacist if this is the case.

[1] The format, font and/or colours can be changed if necessary, but the text and CRUK logo should be unamended.

6.0 Financial considerations

In view of the different models that have been developed and their unique relationship to a specific organisation, it is not possible to comment on the financial and resource implications of adopting and developing e-consent. This will need to be agreed by each provider and organisation or network.

7.0 Governance

Once a solution is agreed by the organisation, there should be local governance policies in place to ensure the ongoing robustness of the system.

8.0 Appendices

8.1 Appendix 1: Terms of Reference (ToR) for the e-consent working group

Background

The UK SACT Board issued guidance for consent for SACT in May 2016 and recommends the use of SACT regimen-specific consent forms in the UK. Cancer Research UK (CRUK) has been providing support for this project since 2016, by means of a grant to fund a pharmacist to develop and publish a national library of SACT regimen-specific consent forms and by hosting the forms on the Cancer Research UK website. The CRUK Information Lead pharmacist post is hosted at Guy's and St. Thomas' NHS Foundation Trust. All solid tumour regimen-specific consent forms (with the exception of sarcoma) have been published and progress towards the haemato-oncology regimen-specific consent forms are underway. In collaboration with the paediatric working group, generic and ALL paediatric consent forms have been developed. The SACT NSG oversees the progress, uptake, and strategic development of the project at a national level and across the devolved nations.

Feedback from two separate national surveys (2017 and 2018) has demonstrated positive comments regarding the use and contents of the forms. The monthly downloads of the consent forms has also increased year on year since 2017. As the project continues to evolve, there has been growing feedback and comments from many trusts about the availability of the forms electronically. Some boards are not adopting the forms as they are not electronically available.

Implementing the SACT regimen specific consent forms electronically is increasingly becoming a priority. This will significantly also help to supplement the changes in practice across the health care system at a national level as we move towards more digital consultations. Introducing a new technology such as e-consent will come with various challenges and complexity. It was therefore agreed at the SACT NSG (March 2020) to set up a working group dedicated to developing the e-consent process with appropriate membership which will greatly facilitate this work stream.

This document outlines the terms of reference and the framework by which the working group aims to achieve set tasks and will continue to be reviewed as this work stream develops.

Purpose

The main purpose of the national SACT e-consent steering group is to provide overall steer for the project and future developments. Please note the tasks below will continually be reviewed and updated in accordance with the members of the group.

Strategic tasks will include:

- Coordinating the ongoing development of e-consent process in line with remote consent.
- Agree and develop a generic e-consent framework which can be used to support the different systems available in the Trusts across the UK
- Outline multiple solutions for the NHS Trusts to choose from
  - Different providers to present their e-consent package to the group (This will include information on use of multiple devices and signature options)
  - As a group list the advantages and disadvantages of each package
  - Produce a framework document outlining the options available on e-consent. Each Trust to choose suitable options
  - Finance and IT governance (including interface) to be decided locally (independent of the e-consent working group)
- Strict adherence to information governance policy
  - Management of version control (forms reviewed every 3 years or ad hoc changes)
  - Ideally use of the CRUK SACT consent forms should be unchanged. If changes are to be made, the Project Lead Pharmacist to be contacted in the first instance.
- Develop a strategy for future developments
  - Task and finish group
  - Reconvene following feedback
  - Incorporate with the NSG in the future once objectives achieved.

Operation

The lead clinician for the national SACT regimen-specific consent form project (member of the UK Chemotherapy Board) and Project Lead Pharmacist (Oncology Pharmacist – CRUK Information Lead) will coordinate meetings. An appropriate chair to be elected for the meeting. The pharmacist will provide administrative support for the meetings.

8.0 Appendices

Membership

The working group will draw its membership from the national steering group members with clinicians with a specific interest in e-consent or with previous experience in the field. Additional members include local IT personnel and patient representatives. So far we have the following members:

- **Janine Mansi** – Lead clinician for the national SACT regimen-specific consent form project and member of the UK SACT Board
- **Lucy Cox and Alia Nizam** – Project Lead Pharmacists (Oncology Pharmacists – CRUK Information Leads)
- **Helen Thompson** (CRUK, Patient Information and Involvement)
- **Georgina Spencer** (CRUK, Patient Information Nurse Specialist)
- **Vikas Jogia** (CIS System Manager/Pharmacist at GSTT)
- **Martin Forster** (Consultant Medical Oncologist)
- **Mariam Aziz** (Quality and Service Improvement Manager)
- **Anne Armstrong** (NSG representative for breast)
- **Farah Rehman** (Consultant Medical Oncologist)
- **Ernest Redwood-Sawyerr** (Digital transformation manager from RMH)
- **Mary Maclean** (National Clinical Lead – Cancer Medicines)
- **John Murphy** (Consultant Haematologist)
- **Peter Forsyth** (Consultant Haematologist)

Co-opted members

Patient representative(s) from NSG.

Frequency of meetings

The e-consent working group takes place virtually and meets as required.

The agenda will be prepared in advance of the meeting by the project lead pharmacist and minutes disseminated following the meeting.

Reporting

The group will report to the National Steering Group and UK SACT Board.

8.0 Appendices

8.2 Appendix 2: Comparison of paper versus electronic consent pathways

8.2.1 Schematic of paper and electronic consent pathways

Schematic patient pathway with paper SACT consent forms

- SACT consent form printed & given to patient alongside information (information sheet, alert card, CNS details)
- Appointment with HCP to discuss SACT
- Patient demographics to be documented on the SACT form

  (Form may need to re-printed if misplaced)
- Patient signs consent form with HCP
- Signed SACT photocopied and copy given to patient
- Admin support team to scan the signed SACT forms on patient record

  (Risk of delays to scanning or misplacement)
- Signed master copy

  Scanned/filed in patient record

Schematic patient pathway with electronic SACT consent forms

- SACT consent form printed and given to patient alongside information (information sheet, alert card, CNS details)
- Appointment with HCP to discuss SACT
- SACT consent form downloaded with demographics pre-populated

  (No printing required)
- Patient e-signs consent forms with HCP
- SACT consent form e-signed saved on system

  (Signed form printed or emailed for patient)

8.2.2 Options appraisal of paper versus electronic consent pathways

Option appraisal for patient pathway	Option 1: Do nothing	Option 2: Potential e-consent SACT pathway without an electronic tablet and unavailability of patient portal	Option 3: e-consent SACT pathway with an electronic tablet and/or patient portal
Description	• Information sheets, alert card, SACT consent forms (given if face to face, directed to website or posted) prior to the consent process • Patient name and hospital number to be written on the form • Patient signs the SACT form with the clinician • Copy of the signed consent form given to the patient • Master copy scanned to the electronic system or patient medical record	• Information sheets, alert card, SACT consent forms (given if face to face, directed to website or posted) prior to the consent process • Clinician downloads the SACT consent form on the electronic system with demographics pre-populated or manually entered • Patient to view the SACT form with the clinician on a desktop • Once consent process completed, patient to sign electronically on the desk top. • Signed SACT form saved on the system • Signed SACT form printed and given to patient	• Information sheets, alert card, SACT consent forms (directed to website or emailed).or sent via patient portal • Clinician downloads the SACT consent form on the electronic system with demographics pre-populated or manually transferred • Patient to view the SACT form via a tablet while the clinician goes through it • Once consent process completed, patient signs consent form on the tablet electronically. • Copy of the signed consent form sent to the patient via the portal or can be printed if patient prefers
Advantages/benefits	• No cost implication. Continue current practice • Easy access to the CRUK website and easily printed • No training required • Other than availability of printer and internet access, does not rely on IT infrastructure	• Consent form pre-populated with patient demographics • Easy access through the system and no need to print or find a printed copy. • Signed form saved on the electronic patient record instantly • No risk of misplacement of forms • No risk of scanning forms into incorrect patient records • No delays in treatment (no delay in scanning) • Admin support not required	• Consent form pre-populated with patient demographics • Easy access for the clinician through the system and no need to print or find a printed copy. • Suitable for a remote consent setting • Signed form saved on the electronic patient record instantly • No risk of misplacement of forms • No risk of scanning forms into incorrect patient records • No delays in treatment (no delay in scanning) • Admin support not required

Risks/disadvantages	• Increase paper and use of printer • Hand write patient demographics on the form • Misplacement of forms, errors in scanning and delays to scanning on the system potentially leading to delay in treatment. • Admin support required for scanning signed consent forms • Admin support required to print the SACT consent forms in bulk • Patient may misplace the signed consent	• Cannot be done if the patient is consented remotely • Development of a software/ change in IT infrastructure to enable interface with the CRUK SACT forms and electronic signatures • Cost implication? Assess key people required and steps in the process to enable for the above to happen (CRUK technical team, external company, an NHS IT expert • Prior to the consent process patient still needs a copy of the consent form (unless happy to be signposted via the website)	• Development of a software/change in IT infrastructure to enable interface with the CRUK SACT forms and electronic signatures • IT infrastructure to allow connection with tablets and development of patient portal • Cost implication? Assess key people required and steps in the process to enable for the above to happen (CRUK technical team, external company, an NHS IT expert) • Require good wifi access for tablets • Added cost implication for tablets purchase and maintenance • Prior to the consent process patient still needs a copy of the consent form (unless happy to be signposted via the website)
Timeline	To be discussed	To be discussed	To be discussed
Cost implications	Nil	Moderate? To be assessed	Moderate to high? To be assessed
Recommendations	To be discussed	To be discussed	To be discussed

8.3 Appendix 3: Questions and answers submitted by e-consent providers

Questions	Voice Technologies	IQ Health
Use of forms		
How do you envisage the current SACT forms to be used in your e-consent system? Eg would the current PDFs be lifted without changes?	FormStream forms are stored within the system database in a HTML format; At the simplest level, we would be able to take the existing PDFs and create the forms to operate and look as close as possible to the existing PDF forms, however, we often find that improvements in the operation of the form can be made when they are developed into a dynamic web-based format.	Our proposed solution is to enable the existing CRUK SACT consent forms to be uploaded into the proposed system. These forms will be tagged against a regimen code. This means that the consent forms and the content do not need to be changed in anyway. This approach will make the management of content much simpler.
Would the pdfs be amended to accommodate your e-consent system? If amended, would the forms also lose the CRUK logo?	As above, the forms would need to be translated into a HTML format to be able to operate within FormStream but we can create the forms in such a way that they are as close to the original PDF's as possible and there would be no loss of logo with this. Our existing customers often incorporate their logos onto their forms and so we are experienced in developing these into the forms.	The forms would display the CRUK logo and render as they do now.
How would you ensure that e-consent forms are updated in line with the CRUK SACT forms on the website? (Revalidation takes place every 3 years but there may be also ad hoc changes)	The FormStream system and forms are all developed and supported by our in-house teams and we can therefore support any review and update schedule required. We have a close working relationship with all our customers and so, if any updates are required, a customer would typically contact us with the updated requirements and we would work to develop and update the forms across all affected sites.	A process would be required to allow an authorised user to upload an updated version of the consent form within the e-Consent system. The e-Consent system will provide a version control system to ensure that only the latest version of a form is ever available for use for a hospital from the central library of consent forms.
Would you need assistance/support from the CRUK design team (who currently load the forms on the CRUK website) to enable e-consent?	The level of support required would largely depend on whether there is a need to further develop the functionality of the forms whilst they are being transferred into the HTML format as, if there is, we would need input and guidance on this. However, if the only requirement is to replicate the existing forms then we would need very littwle input. As a minimum requirement we would, however, typically ask a customer to review and approve the forms before they move into a live environment and so we would ask for support with this process.	The proposed solution would involve a collaboration between CRUK and iQ HealthTech such that CRUK would be a content provider and iQ HealthTech would manage the upload of consent forms into the system. Alternatively, this upload process could also be managed by CRUK via the system user interface

If assistance/support is required from the CRUK design team, would this be ongoing or one off support?	We would not expect any assistance or support required to be on an on-going basis, however, we would request support from a review and approval point of view whenever forms are to be updated.	There should be little or no support required from the CRUK design team as our proposed solution will be able to use the forms as they have been designed. CRUK would provide the content eg the PDF consent forms.
Will the product have ability to translate into other languages?	Whilst forms can be developed in another language if the translation is provided, there is no in-built feature within FormStream to translate the forms in real-time.	The system would be designed such that the language within the patient part of the application could be localised. The content would be provided by CRUK eg the SACT consent forms, the system will be designed in such a way to have a language variant for each form as available options for the patient. CRUK would provide the forms in whichever languages they are required. Where multiple language variants of the consent forms are available the patient could select the language most appropriate to them. This aspect will need to go through some user testing to determine the most appropriate way of achieving this.
Accessibility and integration of the forms with Trust IT system		
How would this be implemented across a network of hospitals/ trusts? How easy is it to make these forms available to a varied network of hospitals? Will this be dependent on the individual; IT system used by the hospital? Is this a separate conversation for you and the individual hospital?	At present, most NHS Boards or Trusts who utilise our FormStream product have their own local installation of the software hosted on local servers, however, there are some instances where the system is shared 'cross-border' via the use of NHS Wide Area Networks. In the immediate future we would envisage that this setup would continue and that installations and forms would be managed at a Board/ Trust level, however, there are plans to move to a Cloud based offering in the longer term.	The proposed solution would be hosted externally to any hospitals within purpose built, secure datacentres that meet NHS Digital information security policy. The system would be accessible via the internet as per NHS Digitals Internet First policy. The system could run standalone without any systems integration, but options for integration would streamline the workflow for the hospital trusts. For integrations with existing hospitals EPR and ePrescribing systems its envisaged that a secure VPN connection would be made between the hospital trust and the eConsent system. This ensures any traffic sent between the hospital and the eConsent system is appropriately encrypted in transit. It is also envisaged that the proposed system would enable a signed document to be "pushed out" of the eConsent system to another system such as an EPR, via an HL7 message. This provides the ability for a hospital to make the consent form more widely available to other stakeholders who may not need access to the eConsent system. It would be a separate conversation with each of the hospital trusts to configure the networking and integrations to the various systems.

Can patient data/demographics be pulled from patient electronic records? (Will this be dependent on the IT system)?	Patient demographics can be pulled from local Patient Administration systems for display and use on the forms and we support the majority of the commonly used systems throughout the UK. This is the primary reason why installations of FormStream are typically managed and hosted locally within each Board/Trust as this ensures the system has access to the PAS systems which are often also hosted locally.	This will depend on the IT systems at the Trust and the desire to integrate to streamline the workflow. Integration will use our integration engine software which is HL7 compliant. This will ensure compatibility with any recognised hospital EPR system used in the UK for pulling demographic records into the eConsent system. The proposed solution will also be able to consume integration messages to allow data to be pushed into the eConsent system from an ePrescribing system. This will require the appropriate HL7 trigger points and messages to be constructed to support such an integration. The Mosaiq and Aria systems offer a lot of configuration options in terms of integration. We have successfully integrated our iQemo system with Mosaiq for transferring demographics, documents and scheduling so this kind of integration would be possible with some configuration required from the Trust's IT team. We envisage supporting three workflows. A partially integrated system where patient data can be pulled from an EPR from the eConsent system when searching for the patient. The consent record is created manually by the user eg selecting the appropriate treatment regimen linked to the appropriate consent form. 1. A completely standalone system where all patient data is entered manually by the Trust users and the consent record is manually created by selecting the appropriate treatment regimen. 2. A partially integrated system where patient data can be pulled from an EPR from the eConsent system when searching for the patient. The consent record is created manually by the user eg selecting the appropriate treatment regimen linked to the appropriate consent form. 3. A fully integrated system where the patient and regimen data are pushed from the chemotherapy e-prescribing solution at the Trust which automatically creates the consent record for the doctor and patient to sign. The proposed system will provide an HL7 integration to enable the signed PDF consent forms to be pushed out to another system eg an EPR.

Where will be the library of forms be held to enable the interface?	The form library is held within the system Microsoft SQL database. Again, this is typically locally hosted within each Board or Trust.	Our proposed solution involves a central national library of consent forms,that can be tagged to a regimen/procedure. Access to maintain this central library would be restricted to authorised users. The library will be able to be managed centrally and available to all subscribing Trusts. This will be held within the document store within the system and available on the internet.
Does it run with all types of firewalls, virus checkers, internet security etc to avoid access issues?	The main technical requirements for FormStream are that it is run using a HTML5 compliant browser such as Internet Explorer 11+ or Google Chrome.	The proposed solution is web based which will mean that the application will be device agnostic and firewalls and virus checkers will not block access. No client software will need to be installed on any hospital trust or patient devices. A virus checker will be used by the system to automatically scan any documents that are uploaded before they are stored in the eConsent system.
With respect to security are there any IG requirements? Password security? Cookies used?	Access to FormStream is achieved through one of two means. Access can be granted via Active Directory integration in which case a user can use their Windows username and password to log in. With Active Directory integration, password policy and security is governed by local IT policy. An alternative means of access can be granted using authentication against the Winscribe dictation system which is in use in many Boards and Trusts throughout the UK. In this instance password policy and security is governed by the Winscribe dictation system.	Agreements will need to be held between iQ HealthTech and each Trust that uses the eConsent system as iQ HealthTech would become a data processor on behalf of each of the Trusts. These are standard agreements that we already have in place with Trusts that use our iQemo system. These agreements could be repurposed for the eConsent system. The lawful purpose of processing the data would be slightly different eg for the purpose of managing consent to treatment as opposed to managing chemotherapy prescribing. We build security into all our applications by design so standard NHS digital compliant password rules will be adhered to including the option for multi-factor authentication. Some cookies may be used for the application usage eg to persist logins. There is no requirement for using tracking cookies or suchlike.
Is there functional capability to integrate the CRUK consent forms along with bespoke in-house Trust library form content into a common format – as well as images and hyperlinks?	The FormStream system is currently being used by our customers for a range of eForm workflows and needs and so bespoke in-house Trust forms can be developed and added to the system as required and will sit alongside the form SACT process.	This could be considered in the application design, we are designing the platform to enable different types of consent to be included in a consent form library so that this system can be used for non-SACT procedures eg surgical procedures, radiotherapy etc.

How does your system provide for ongoing editorial access for bespoke in house forms added to your platform, and will there be ongoing protection of this intellectual property?	All FormStream forms are currently developed by our in-house team of developers and so ongoing updates and edits of forms are typically managed directly between our customers and teams. However, if any Trust or Board has in-house development capabilities, it would be possible for them to develop and manage their own forms for use within the system.	For a bespoke Trust library it is envisaged that the content would be curated outside of the eConsent system and then uploaded and tagged to the appropriate procedure. The intellectual property of any content created would remain with the creator. iQ HealthTech will not own any Intellectual Property surrounding the content eg the consent forms. The proposed solution is a vehicle for managing and surfacing the content (consent forms) to the respective users (clinicians and patients) for digital signing.
Does your system allow for ability for change of decision to be recorded and form archived (with reasons for refusal)?	FormStream forms can be developed to allow for data entry of any relevant information and can be continually updated and saved throughout the entire process. Once the process is complete, users can choose to finalize and complete a form in which case it is visible in the system but in a read-only format.	This could be incorporated into the application design as a key requirement.
Can you allow a reconfirm function on the forms on the day of SACT, after which the form should be locked and be non-editable?	As above, forms can be developed to allow entry of any relevant data and an automatic finalisation of the form can be triggered if certain data items are ticked on the form for example.	This could be incorporated into the application design as a key requirement.
Does your system provide an audit history for each form, ie when was it first shared with the patient, when were items of info added, and when was it signed off?	Our system provides an audit trail which includes the following information: date/time stamp of when a form is first created and by who, date/time stamp of when a job is saved and by who, date/time stamp of when a job is verified (signed off) and by who. Additionally, date/time stamps can be added to certain sections of a form to show when they were added or first filled out.	This will be incorporated into the application design as a key requirement, as a clinical system all user actions (logins, record views, signatures etc) will be captured by an audit trail incorporating username, date/timestamp, IP address, action type, action detail, previous and new value(s).
Does your system provide the facility to add in specific risks and information for any given patient (after Montgomery)	As FormStream forms are developed specifically for use within the system, sections can be added to each form which allow for the recording of information such as risks associated with the given patient.	This could be incorporated into the application design as a key requirement.

Does your system have the ability to incorporate images, diagrams and other educational material.	FormStream includes a number of features which allow jpeg images to be uploaded into the forms. Support for creating basic line diagrams is also included.	The proposed system will allow any content to be uploaded to support the consent forms ideally in a PDF format as this will be easily readable on many devices without needing any proprietary software to be installed.
Accessibility for patients; Remote or non-remote		
What range of devices can patients access forms from? Mobile (Apple/ Android), tablet, Mac OS or Windows?	FormStream can be accessed from any device with a supported browser and so can be accessed from a range of devices. However, as installations of FormStream are typically hosted within an individual Board or Trust, the forms will typically be accessed using existing infrastructure within the Board or Trust.	The web based system will be platform agnostic. The web application will be designed to be responsive so that it can automatically re-size to fit different device screen sizes and resolutions. We propose that an app would run on both Android and iOS for patients and for those patients who don't want to/can't use an app there would be a web application that they can log into.
Is there functionality to email information? (Then securely unlocked)	Completed and signed off forms can be emailed to pre-configured email addresses as a PDF attachment however there is no additional layer of security to this other than that provided by email systems.	We propose that no actual content would be emailed, however secure links to content would be sent enabling the end user (patient or clinician) to be able to click a link, authenticate and then view the information.
Is there a functionality to attach videos or other forms (eg CRUK/Macmillan leaflet/pdf)?	Images can be embedded within the completed forms, however, there is no functionality to attach a video or PDF.	This is functionality that will be on the development road map. It may not be incorporated into the first iteration of the system. Our vision is to link multiple supportive documents/files to a consent form to support the patient with their informed consent decision.
Will there be easy ability to produce hard copy if needed, and also to generate a locked non-editable version for storage in Trust EPR?	As the forms are accessible in a browser and hard copy can be generated at any point via the in-built browser print functionality. We also provide a range of interfaces to the commonly used EPR systems for the purpose of filing the signed off forms against the patients electronic record.	The consent forms will be able to be exported as signed PDF documents that are "locked" after they are signed in a similar way to how DocuSign works. These will be able to be printed if required. The proposed eConsent system will provide an HL7 document interface to enable signed consent forms to be pushed out of the eConsent system to another system such as and EPR for storage and for visibility to the wider Trust staff. This will require an interface configuration at local Trust level.

Is there a facility for more than one clinician to input risk information into the form before the patient's final sign off?	FormStream form security is governed at a form level, therefore, any clinician with access to a specific form template can contribute to any existing forms at any stage in the process. This allows for true collaborative multi-disciplinary working on forms within the system.	This could be incorporated into the application design as a key requirement.
Is there an option for remote signing? How would the remote signing take place?	Unfortunately, there is no current option for remote signing as the software is typically hosted and accessed from within the confines of the Board or Trust network. In person signing is supported via USB signature pad devices which integrate directly with the FormStream system.	Yes. Remote signing would be managed in a similar fashion to how a DocuSign electronic signature would work. The patient would be sent an email indicating that they have a consent form to review and sign. They would click the link to login to the system and be presented with the consent form that requires signing along with any supporting documents. Signing would be completed by entering their name to generate the electronic signature. The record would be captured and stored in the system. The signed document would be made immediately available to the treating hospital. The patient would be able to review a copy of their consent form(s) and any supporting files.
How will patients have access to the forms once they have signed?	With our existing SACT implementation in NHS Highland, patients are provided with a hard copy of the form after they have signed.	It is proposed that patients will be able to access all their records at anytime within the system either by logging into the web application or their app on their mobile device.
Once signed, is it saved in the system by default? (as above)	Completed FormStream forms are stored within the system database indefinitely but can be archived and purged as necessary.	This would be the designed approach.
Have disability access standards been incorporated? Eg font type, colours, layout?	As FormStream forms are custom developments font type, colours and layout to support the required access standards can be incorporated.	This will be incorporated into the final designs and tested with users.

Cost and finance		
What are the costs associated and how do you see this funded?	We can support this project being funded at a national or individual Trust level. Costs can be defined on a national level for the main workflow. Individual Trusts costs can be defined to implement and integrate with local IT systems.	It is proposed that the eConsent system is funded by the Trusts and other treatment providers (eg private hospitals) who would use the system. The proposed model would be a subscription that would incorporate user licenses, web hosting, document storage, data backup and technical support. We are not proposing a cost for CRUK, we envisage CRUK would be a content partner. Would there be any content licensing considerations from CRUK eg using the consent forms in the private sector? Would there be any content licensing considerations from CRUK eg using the consent forms in the private sector?
Will this cost include ongoing IT support launch of product?	Ongoing support and maintenance can be specified as part of the wider specification. We offer full support services which can also include form revisions and updates. Costs include training of system end users.	Yes.
Will the cost vary dependent on the individual IT system?	Yes, the cost will vary depending on the individual Trusts demographic feed or national feed.	Optional additional costs would be built into proposals if hospital trusts want to streamline the workflow via system integrations. These would be costed separately and would depend on the system being integrated and the complexity of the interface eg whether bespoke integrations would be required.

8.4 Appendix 4: Presentations by providers

8.4.1 Voice Technologies (FormStream)

Voice Technologies organisation is based in Glasgow and has an office in Sheffield. Range of products available and in use eg digital dictation, speech recognition and e-form solution via FormStream.

FormStream replaces paper forms and is in use in a number of settings eg MDT forms, pre-op assessment forms and many others. See **voicetechnologies.co.uk/products/formstream/nhs-e-form-library** and Appendix 2 for more details.

Current use of e-consent forms

SACT consent process actively being used in NHS Highland using a standard patient consent form. Currently no live implementation in England.

In 2021, Voice Technologies has been commissioned by NHS Highland to fully develop a single e-form for use within FormStream that will include all regimens available on the CRUK website. This operates by allowing a user to select a specific regimen on the form and the remainder of the form is then auto-populated with the regimen specific information. The form also includes the 'in-person' electronic signing of the form (as demonstrated). Now Voice Technologies are working towards potential solutions for remote sign in.

IT interface

FormStream is a web based solution. Requires local installation of the software hosted on local servers, therefore can be accessed anywhere within the network. Demographics can be pulled from the local PAS. Currently no cloud solution.

Use of the forms

The forms can be customised to suit client needs. FormStream can replicate the existing PDF versions of the CRUK forms and create them as close to the original as possible with no loss of logo or information. The forms will be in HTML format to be able to operate within FormStream.

- Potential for additional functionalities to be added. eg calculations, jpeg images.
- Option for locking available to prevent editing of the forms.
- USB signature pad plugged into PC to allow real time signatures and multiple signatures if required.
- Hard copy of signed forms printed.
- Patient only has access to paper copy of the form. Not available for patients electronically.
- Healthcare professionals can access electronically within the network.
- Team to work closely with client for information on update of the forms.

Storage of the forms

Blank forms are stored within the FormStream database. Forms are developed using HTML/CSS/Javascript.

Forms once completed and verified following consent are stored within FormStream database indefinitely. VT uses a number of distribution options available which allows to push the completed forms into other systems. Not typically pushed back into the PAS (as more of a source of demographics) but they are pushed back into EPR, to the patients GP and via email if required.

For some Trusts in England that use other services of VT, FS can use the following systems to distribute completed forms to the GPs. Some examples of the systems are Sunquest ICE, EDT, MIG, LPRES, MESH.

Advantages

- Forms can be customised; No change in content
- E-consent in use in the Highlands. CRUK ones in the pipeline to be used in the Highlands
- Completed and signed off forms can be pushed back to EPR, stored in FS database and emailed to pre-configured email addresses as a PDF attachment (to other systems as well)
- No ongoing assistance or support required. Only needs to be informed when forms are updated so FormStream can update
- Health care professionals can have access to the forms electronically within the network

Disadvantages

- No remote access by patient or electronic access (working progress)
- Form cannot be emailed to patients (only receives hard copy)
- Cloud based solution on working progress; no timescale as of yet
- Cost implications for installation on server (conversation between Trusts and company)
- May need additional resources to review and approve forms before transferring to live environment (see questions and answers section page 13)

Contacts

For more detailed information, please contact:

Martyn Ross (Business Development Director).
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DDI: 0141 737 1586.
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Colin Wood (Technical Director)
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8.4.2 Patients Know Best (PKB)

Patients Know Best (PKB) is a social enterprise and technology platform that is designed to bring together patient data from health and social care providers and the patient's own data into one secure personal health. For more information see **patientsknowbest.com**.

PKB currently working with multiple ICS/STPs and Health Boards across the UK, contracted for 20% of English lives and currently hosting over 8 million records (accurate March 2021). One of PKB's most notable deployments is in North West London via Cancer Information Exchange, where access to patient records by patients and professionals at large scale is managed. For more information please see **careinformationexchange-nwl.nhs.uk/how-it-works**.

Current use of e-consent forms

For the purpose of the demonstration the PKB team created a template of a CRUK consent. The template is easy to use as it is or the local unit can tailor it. Many fields, free text and tick boxes can be added and configured. For further information see: **https://deploy.patientsknowbest.com/clinical/Specialities/Cancer/consent-careplans**

IT interface

PKB can be accessed via the web browser or where locally enabled via the NHS App for patients. Requires the provider and the patient to be registered on PKB. PKB can also be integrated with the Trust EPR via the trust integration engines to automatically send data to the patients' records. In addition, for example, PKB can be accessed via source systems (professional systems) via single sign on eg Cerner (EPR system for Imperial).

Use of the forms

A library of consent forms (blank forms) can easily be uploaded to the PKB database with no changes to the contents. This can be done by the PKB team or PKB can show a designated user how to add the forms to the database. An example of a CRUK form was added for the purpose of the demonstration. The forms if needed can be enhanced by adding videos, additional documents or links out to the external resources etc.

When forms are updated, old version of the forms can easily be retired from the data base and new forms added.

The form can be viewed in a single record. Eg Professionals can update information on the form and patients can view in real time. Carers receives notification as well. This does not require for the patient and provider to be present in the same location. Therefore allowing remote consent feasible.

Forms can be accessed via the web browser on any device (for both patients and professionals).

Storage of the forms

Blank forms are stored within the PKB database.

Completed forms are immediately stored in the PKB database (can be accessible anytime via the web browser).

If required to be available to the 3rd party systems like EPR, forms can be pulled back into EPR by programming interface.

If patient is re-consented, this will be automatically updated in the web browser as well.

Advantages

- Patient, carers and professionals can access PKB portal anytime and from any device
- Blanks forms can easily uploaded on PKB without change in contents. This can be done by PKB or the trusts. Forms can be customised
- Can be consented remotely and face to face.
- Can be accessed via web browser any time
- PKB in use in NWL STP
- Trusts can use the consent form functionality only and not the other functionalities that PKB has to offer if they wish to
- There are no cost implications, whether uploaded by PKB or trust. Charges are included in the software licences. Templates can be uploaded before the organisation goes live and updated at any time

Contacts

For more detailed information, please contact:

Dr Mohammed Al-Ubaydli (CEO and Founder)
Email: **mohammad@patientsknowbest.com**

Sally Rennison (Vice President of Sales)
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Phone: +44 (0)7786 388 544

8.4.3 Concentric Health

Concentric Health is a health technology start-up based in Wales. It provides a digital consent application supporting shared decision making. Includes remote consent functionality can be used alongside or following a consultation.

Concentric is currently in use at Imperial College Healthcare NHS Trust (Imperial), Chelsea and Westminster Hospital NHS Foundation Trust (C&W), Swansea Bay University Health Board, and Royal Cornwall Hospitals NHS Trust, with integration into electronic health records at most sites. Used across the clinical specialties, including surgical specialties, radiology, oncology and pharmacy. For more information please see **concentric.health/**.

Current use of e-consent forms

Evidence-based templates supported by lay descriptions, video, and Macmillan resources, with the flexibility to personalise the information to the individual patient. Includes options for additional consents (eg medical imaging, tissue for research). Oncology consent being done on Concentric at Imperial and C&W. Collaborative agreement in place with the Royal College of Radiologists with regards to current national radiotherapy consent project.

IT interface

Workflow is best with integration with Trust electronic health records (EHR) for demographics and storing of consent form PDFs. Integrated with Cerner-based systems at Imperial and C&W, and other EHR's elsewhere.

Use of the forms

CRUK form PDFs are not replicated without change in Concentric. Rather the entirety of the clinical content from the CRUK forms is mapped into Concentric's web application structure, supported by additional lay descriptions and resources, with the flexibility of personalising the information. Faithful representation of the CRUK content (that is, covering all the content and relevant context as the CRUK template, but not necessarily using the same design and formatting) is verified internally by GMC-registered Concentric Health clinicians. Local editing of templates, for example with the addition of local post-treatment care information or modification of templates can be done if wished. Patients have access to their consent information and legal consent PDF within the Concentric application, and depending on local setup these may also be available to view via the Trust's patient portal - for example those provided by Patient Knows Best or Induction Zesty.

Storage of the forms

Consent information is securely stored on Concentric Health's UK-based cloud servers with a full audit trail, as well as on Trust document stores. More information regarding information governance is available here: **https://bit.ly/38UuxcG**

Advantages

- Remote consent functionality which can be used alongside or following video/voice consultations
- Trusts have flexibility to add/ edit contents.
- Additional consent modules (eg tissue for research) can be added
- Oncology consent already in use at Imperial and C&W
- Widely used in other specialities (radiology, ophthalmology, surgical specialties etc)

Disadvantages

- CRUK forms are not replicated without change so there is a risk that they are not a faithful representation
- Requires second verification locally

Contacts

For more detailed information, please contact:

Email: **hello@concentric.health**
Phone: +44 (0)7885 984495

8.4.4 iQ Health Tech

A UK based company with a common goal to develop technology to improve patient outcomes. IQ health is the provider for iQemo, electronic chemotherapy prescribing system. Currently 14 trusts across the country uses iQemo (16 by March 2021). The e-consent process is not use and still in the design phase. However, this will be independent of which chemotherapy prescribing system is being used.

See **Appendix 3** for more details.

Current use of e-consent forms

None. Currently in the design and development phase. Expected to be available in January 2022.

IT interface

Proposed solution to be hosted externally or as standalone. More details on integration and interfaced explained in **Appendix 2**.

Use of the forms

CRUK forms to be used in its entirety with no change in content or loss of CRUK logo. Collaboration between iQ Health Tech and CRUK will ensure an authorised user to upload forms ensuring control of version management.

Remote consent option incorporated in the design.

Storage of the forms

The proposed solution involves a central national library of consent forms that can be tagged to a regimen/procedure. Access to maintain this central library would be restricted to authorised users. The library will be able to be managed centrally and available to all subscribing Trusts. This will be held within the document store within the system and available on the internet.

Patients will be able to access records anytime within the system (via web application or app on their mobile device).

Advantages

- Theoretically built in such a way to ensure integration with multiple systems (not just with systems using iQEMO). Standalone option available
- Easy to implement for trusts using iQEMO prescribing
- Solution allows remote consent
- As in design phase, opportunity to influence product

Disadvantages

- Product not completed
- Expected to be available in January 2022
- Options for remote consent but not face to face?

Contacts

For more detailed information, please contact:

Doug Baker (Director, Business Development)
Email: **doug.baker@iQHealthTech.com**
Mobile: +44 (0)7917 410923
Phone: 01202 489554

8.4.5 Epic

Epic is an electronic patient record (EPR) system which brings together all patient information reducing the need for paper record. Epic is in use at UCLH, Great Ormond Street and Cambridge University Hospitals. Many other hospitals across the country are seeking to adopt Epic.

Mariam Aziz, quality and service improvement manager at UCLH, a member of the working group shared the e-consent solution as part of Epic.

In the time since the first version of this guideline, Guy's and St Thomas' (GSTT) NHS Foundation Trust have gone live with the Epic prescribing system.

Current use of e-consent forms

UCLH: Not fully implemented. In working progress.

GSTT: The use of electronic consent has been implemented.

IT interface

The E-consent runs in a system called OnBase (additional purchase) which integrates with Epic. Hosptials/Trust would have to have EPIC as their main system.

Use of the forms

CRUK forms are not used in entirety. Side-effects for regimens are pre-populated in agreement with the relevant clinical team, some of which are from the CRUK forms. The layout of the forms is flexible and can be easily changed.

No remote consent option available. Consent is done face to face and signature carried out electronically using an iPad. The module also facilitates upload of a scanned consent form.

Forms cannot be emailed to patients. Requires to be printed. However, there is a possibility of sharing the form on another app called 'MyCare' where patients have access to their healthcare records.

Storage of the forms

All stored within Epic.

Advantages

- No IT interface /integration issues as OnBase is part of Epic

Disadvantages

- Only specific to trusts using Epic
- No remote consent option
- Consent form cannot be emailed to patient
- Side-effects for regimens are pre-populated in agreement with the clinical team
- Only consent forms available for treatment protocols built into Epic

8.4.6 Magentus (previously Wellbeing Software)

In 2023, the project team met with a consultant from Clatterbridge Cancer Centre for a demonstration of Wellbeing, the electronic consent system used at their trust. The CRUK and local regimen-specific consent forms are built into the system and then validated by clinicians locally. The system facilitates a two-stage consent process. The clinician signs the consent form at the time of consent, and then the patient reads the consent form in their own time, before signing the form in a specific pre-treatment clinic.

8.5 Appendix 5: Cancer Research UK logo guidance

The following pages include guidance on the use of the Cancer Research UK logo.

The main points

Please use the primary version:

CANCER RESEARCH UK

This should be full colour with a minimum size of 20mm in height.

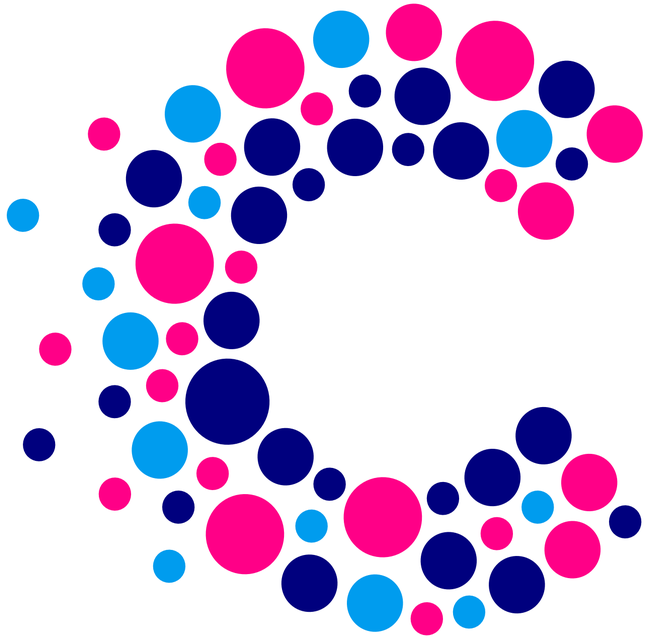
You can download it by either:

- clicking **here** to download
- or by copying and pasting the URL address: **cruk_logo-light-background-primary-rgb-small.png (400×193) (cancerresearchuk.org)**

Logo

Our logo tells the story of our creative concept. Each circle represents a significant moment in beating cancer, all coming together to form our symbol.

Our logo has been designed to have maximum stand out in print and on digital platforms. It's been optimised for small scale use and should be easy to see, wherever we put it.



CANCER
RESEARCH
UK

Logo

Our logo suite

All versions of our logo feature a symbol and wordmark, fixed as a single unit. These come in two configurations; stacked and horizontal.

Primary version

Our stacked logo is our primary choice, as it's the most recognisable version.

Secondary version

We only use our horizontal logo in specific circumstances where beneficial, such as wider formats with generous spacing. We can use this in communications where the logotype can act as the start of a story we're telling or where text follows on from our name.

Colourways

We've created a suite of logos to give us best stand out on different backgrounds.

We use our inverted colour logo on navy backgrounds. We use our white logo on navy, cyan or magenta backgrounds.

Both logos can also be used over imagery but only if there is enough contrast and clear space.

Primary version

Secondary version

Colourways

Logo

Sizing

We've set minimum sizes for print and digital applications, along with a benchmark minimum size rule across the board. Remember, these are minimum sizes. You can make the logo bigger if it suits your design and keeps within the logo's clear space rule.

Within print, make sure the logo doesn't go any smaller than the following recommendations.

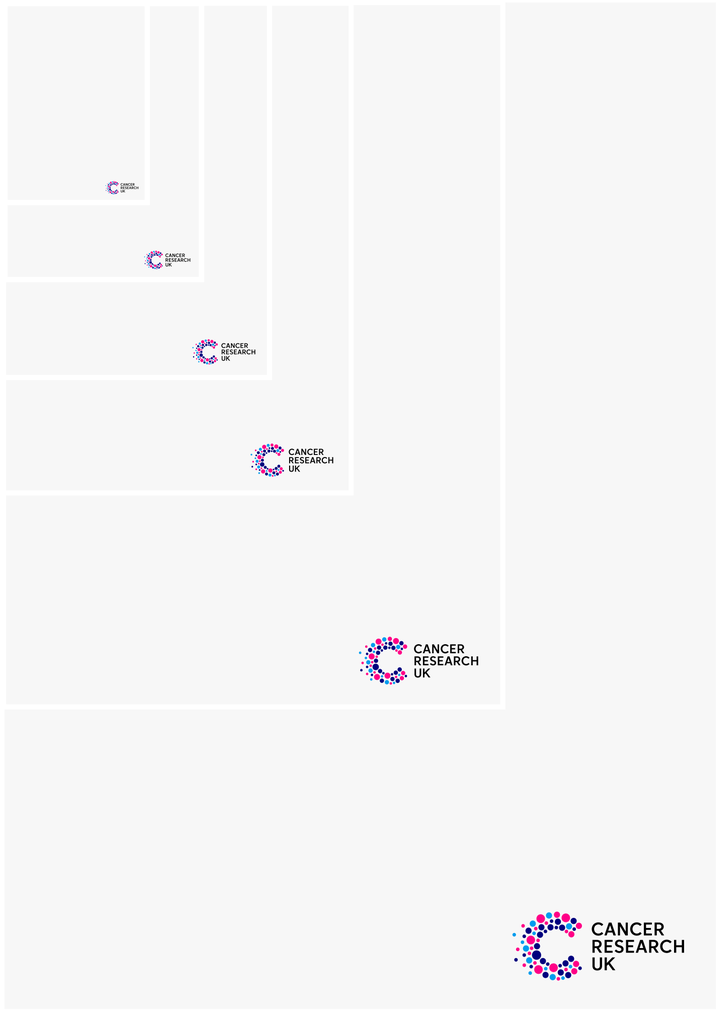
Minimum A sizes
A6: 10mm high
A5: 15mm high
A4: 20mm high
A3: 28mm high
A2: 40mm high
A1: 57mm high

Minimum size
– Master logo
We can use our main logo when sized 10mm/37px and above. When there is a more unconventional use case where our logo is needed under this size, we switch to our small use logo.

– Small use logo
If there is a need to use our logo under the minimum size, please contact our design team:

brand@cancer.org.uk
TheStudio@cancer.org.uk

A sizes



Minimum sizes

Master logo

Height
For Print 10mm
For Digital 37px

Logo

Clear space

Our logo is protected by an exclusion zone to keep it legible.

Clear space

Logo

What not to do

Our logo represents us, our story and why we exist. We give it the respect it deserves. Never recreate, alter or misuse it in any way.

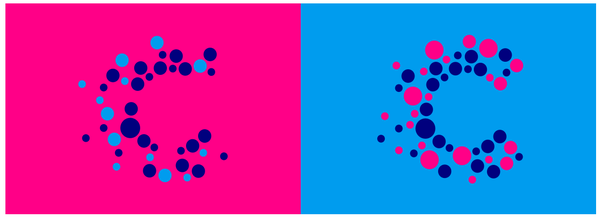
Don’t recolour the logo in any way.

Don’t rotate or angle the logo in any way.

Don’t separate the elements and alter the proportions.

Don’t skew or distort the logo in any way.

Don’t add any effects to the logo.



Don’t use the logos on solid magenta or cyan backgrounds.

Don’t place any of our logos over imagery where the contrast is not high enough to meet accessibility requirements.