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Remote consent for systemic anti-cancer therapy in patients with cancer during Covid-19 pandemic

UCLH Guideline
Local (Cancer Services)

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Review By Date	July 2020
Responsible Director	Professor Geoff Bellingham- Medical Director Surgery and Cancer Board
Monitoring Committee	Divisional Governance Committee Cancer services
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If reading a printed copy always check that it is the most recent approved version which can be found on the department's Clinical Guidelines page on MyUCLH.

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1.0 Summary

1.1 Requirements: Cancer patients are at high risk during the Covid-19 pandemic and are advised to isolate by NHS England; many will also need to continue with treatment of their cancer. In order to minimise their risk by limiting face to face contact at the hospital, measures are being put in place to be able to offer ongoing treatment using remote consent.

1.2 Key points: Remote consent will follow a structured process using nationally available consent forms.

1.3 Action by staff: Consultants and Specialist Registrars will follow a simple structured procedure with documentation of patients' informed consent.

2.0 Equality Impact Statement

The author of this guideline has undertaken an Equality Impact Assessment (EIA) and has concluded that there is no negative impact on any of the protected equalities groups. The completed EIA form is available from the Quality and Safety Department.

3.0 Introduction

This guideline has been drawn up to enable the remote agreement (consent) of patients with cancer/ neoplasms to undergo anti-cancer treatment and their associated medications. This is an emergency guideline produced in response to the COVID-19 pandemic to enable patients to commence treatment with required medications either without, or limiting, face to face contact at the hospital.

4.0 Objectives

4.1 To enable prescribing clinicians to obtain consent to commence urgent or alternative treatment, for patients either without the requirement for them to attend the hospital in person, or lessen their attendance; both to reduce the patients' risk of contracting COVID-19 (recognising that most patients with cancer will be particularly vulnerable to COVID-19-related complications) and to protect other patients attending the Cancer Centre..

4.2 To lay down the process by which consent to commence treatment is obtained remotely by the prescribing clinician.

5.0 Scope

5.1 This document applies to clinicians prescribing Systemic Anti Cancer treatment (SACT) in the Cancer Services division.

5.2 This document relates to the process of obtaining consent to treatment remotely, it does not address the administration or monitoring of the medication concerned.

5.3 This guidance may not be suitable for use with those patients who are unable to be communicated with electronically. An alternative plan using postal communication may be agreed with the patient during COVID-19 bearing in mind the timeliness of SACT.

6.0 Definitions

Cancer- a disease caused by an uncontrolled division of abnormal cells in a part of the body or a malignant growth or tumour resulting from an uncontrolled division of cells. Also known as a malignant neoplasm.

"*Coronavirus disease 2019* (COVID-19) is a potentially severe acute respiratory infection caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The clinical presentation is that of a respiratory infection with a symptom severity ranging from a mild common cold-like illness, to a severe viral pneumonia leading to acute respiratory distress syndrome that is potentially fatal."[1]

COVID-19 is highly contagious and persons with underlying health conditions such as cancer have been advised to stay at home and practice 'social distancing' by the NHS[2].

7.0 Duties & Responsibilities

7.1 Prescribing clinicians (Consultants and Specialist Registrars trained in the administration of systemic anti-cancer therapy) are responsible for obtaining consent to treatment by discussing the benefits, risks, alternatives and option of no treatment with the patient so that they have sufficient information to allow them to make a decision.

7.2 In normal practice this discussion takes place in the outpatient clinic. Due to the COVID-19 outbreak and the vulnerability of patients with cancers/ malignant neoplasms, this document provides guidance for clinicians on obtaining consent remotely and documentation of the consent.

8.0 Development & Evidence Base

Due to the COVID-19 outbreak in late 2019 and the vulnerability of patients with cancer, this document provides guidance for clinicians on obtaining consent remotely, documentation of the consent and the dispensing of medications by post if required. The format for discussions regarding consent are based on the Cancer Research UK Consent forms for SACT (systemic anti-cancer therapy).[4/5]

9.0 Consultation

9.1 Dr Kirit Ardeshna - Clinical Haematologist and Divisional Clinical Director for Cancer Services

9.2 Dr Kirsty Thomson – Consultant Haematologist and Clinical Lead Haematology

9.3 Dr Rebecca Roylance – Consultant Medical Oncologist and Clinical Lead Oncology

9.4 Prof Jonathan Ledermann – Professor in Medical Oncology

9.5 Dr Jon Lambert - Consultant Haematologist

9.6 Dr Naomi Fersht – Consultant Clinical Oncology – Clinical Lead for Radiotherapy

9.7 Dr Martin Forster – Consultant Medical Oncologist – Clinical Lead for Chemotherapy

9.8 Simon Cheesman – Lead Pharmicist

9.9 Alexa Jarvis – Clinical Guidelines Co-ordinator, Quality and Safety Department

9.10 Sophie Barbour (HEMPSONS) s.barbour@hempsons.co.uk

9.11 Matthew Hall – Head of Information Governance and Data Protection Officer

9.12 Chrissie O'Leary – Deputy Divisional Manager Cancer Services

10.0 Guidance (Flowchart available at appendix B)

- Determine that the patient requires urgent treatment for their cancer which cannot be delayed until after the COVID-19 outbreak resolves. There may also be patients who need to consent to oral therapy as a less toxic, safer option to their current regimen.
- During the initial consultation with the patient, discuss and document the recommendation that the patient should start treatment; including rationale for chosen therapy, potential benefits and risks of therapy, and the benefits/ risks of delaying treatment versus starting urgently.
- Advise patient that travel to the clinic is unadvisable and medications may be posted where appropriate.
- Obtain and document patient's agreement to remote consent. In addition, enquire if patient is satisfied to use email to share treatment information with UCLH. **Check that the email address is correct on Epic.** Advise patient that a data confirmation form (see appendix C) will be sent out, alongside their consent form, to confirm this. Alert patient that this **data will <u>not</u> be password protected** to allow patients to return using multiple types of devices, including mobile phones and tablets. Document this in the Epic NOTES tab, along with the rest of the conversation.
- Ask clinical team PA to print off the appropriate consent form (Cancer Research UK Consent Form for Systemic Anti- Cancer Therapy, (there are generic SACT and immunotherapy ones where a treatment specific one is not available.[4/5]). Clinician to partially complete form including patient details, intended benefits of treatment, side-effects/risks of treatment, and then sign/date form as normal. Write on the form it will be sent to patient for discussion/signature by phone at a future date. The section for the patient's signature should be left blank. Use the clinical team PAs to support this process as needed including sending forms using the generic tumour group email addresses.
- For Lenalidomide, Pomalidomide, Thalidonide and Vismodegib complete the same process for the treatment incitation forms. [6]
- If the patient is happy to proceed, and in agreement to scan or photograph the signed forms and email them back to UCLH, check address and contact details (including email address) on Epic are correct. Agree date for telephone discussion of consent to treatment with the patient.
- Clinical team PA should send initial email asking patient to provide full name, DOB and first line of address to confirm email is correct. Arrange for detailed written information about the anti-cancer treatment (examples in appendix A), the partially completed consent form, and the data confirmation form to be sent to patient by the PA. Add the accurate

return email address eg. Tumour specific email addresses that PAs manage or to PA in 250 Euston Road. (by email, if they have access to a printer to print the forms to sign, or 1st class post).

- Telephone the patient at the pre-agreed time. Carry out the 3-point identity check to ensure you are talking to the correct patient:

  Full name + Date of birth + First line of address

- Confirm patient has received and read the information about the anti-cancer treatment, the partially completed consent form and the data confirmation form. Confirm that the patient has understood and is able to consent to the process. If there is any doubt about either the patient's identity or their capacity to consent then the clinician will not proceed.
- The format for the discussion should be structured around the Cancer Research UK Consent forms for SACT (systemic anti-cancer therapy) which are available for the majority of regimens for many cancer types. If not available use the generic CRUK form[4/5] and structure discussion around the patient information you supplied.
- Summarise the most important points, ensuring the patient has understood these. In order to confirm that the patient understands, ask patient the following questions (responses expected in very simple, layman's terms):
  - The reason for their treatment?
  - The benefits of the treatment?
  - The risks associated with the treatment?
  - How to take any medication that they are prescribed?
- Answer any questions the patient may have. Document the discussion, responses to the above set-out questions, including any patient's questions and your responses back to them, in the NOTES tab of the patient's Epic clinical record.
- Document patient's verbal consent and ask patient to sign and date both the consent form and the data confirmation form, if content to do so; then to scan/ photograph both forms for emailing back to the designated UCLH staff. Ensure patient is aware exactly which UCLH email address to email it to.
- Once the consent form and data confirmation form (both signed by the patient) are received at UCLH the administration team (PAs or chemo. admin. team) will scan the documents onto the MEDIA tab in Epic
- Make a note in the NOTES tab that consent and data confirmation have been received.

11.0 Review, Monitoring & Compliance

This is an emergency guideline drawn up in response to the COVID-19 pandemic. It will be reviewed by the Cancer Services divisional governance meeting in 3 months (July 2020) if the meeting is able to go ahead; meanwhile it has had stakeholder consultation and agreement. The trust incident reporting system will be checked for any incidents relating to the use of the guideline as part of the review.

What in the guideline is going to be monitored?	Monitoring method	Who will lead the monitoring?	How often?	Where will it be reported?
What do you need to monitor? Use of the guideline - to reduce, thus protect, patients visiting the trust	**How are you going to monitor?** Datix review for incidents in relation to use of the remote consent process Patient feedback	**Who is responsible for the monitoring?** Divisional Clinical Director, Cancer Services	**How often will monitoring activity be carried out?** 3 monthly initially	**Which Board or committee or other group/ forum will receive the monitoring outcomes/ reports?** Cancer services governance group

12.0 References

1. https://bestpractice.bmj.com/topics/en-gb/3000168
2. https://www.nhs.uk/conditions/coronavirus-covid-19/advice-for-people-at-high-risk/

13.0 Appendices

Appendix A

Patient information leaflets available here :
https://www.cancerresearchuk.org/sites/default/files/cancer-stats/mpn_hydroxycarbamide_v1/mpn_hydroxycarbamide_v1.pdf

3. https://www.cancerresearchuk.org/health-professional/treatment-and-other-post-diagnosis-issues/consent-forms-for-sact-systemic-anti-cancer-therapy#sact_conset9
4. Generic SACT
5. Generic Immunotherapy
6. Treatment incitation forms

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Appendix B

Flow chart for guidance on remote consenting for SACT in the Cancer Services division during the COVID-19 pandemic

Does patient require **urgent treatment** for their cancer which cannot be delayed until after the COVID-19 outbreak resolves?

- No → Delay therapy
- Yes

Initial consultation with the patient:
Discuss and document the recommendation that the patient should start treatment;

- including **rationale** for chosen therapy,
- potential **benefits**
- **risks** of therapy,
- and the benefits/ risks **of delaying treatment** versus **starting urgently.**

Advise patient that unnecessary travel to the clinic is inadvisable during the COVID-19 pandemic and medications may be posted where appropriate.

Obtain and **document** patient's agreement to **remote consent**. In addition:

- Enquire if patient is satisfied to use email to share treatment information with UCLH.
- Advise patient that a data confirmation form will be sent out, alongside their consent form, to confirm this. **Check the email address on Epic is correct.** Alert patient that this **data will <u>not</u> be password protected** to allow patients to return using multiple types of devices, including mobile phones and tablets.
- Document this in the Epic NOTES tab, along with the rest of the conversation.

Patient is happy to proceed, and in agreement to scan or photograph the signed forms and email them back to UCLH?

- **Check** their address and contact details (including email address) on Epic are correct.
- Agree the **date** for telephone discussion of consent to treatment.

- Ask the clinical team PA to print off the appropriate consent form (CRUK Consent Form for SACT).
- Clinician to partially complete including patient details, intended benefits of treatment, side-effects/risks of treatment, and then sign/date form as normal.
- Write on the form it will be sent to patient for discussion/signature by phone at a future date.
- The section for the patient's signature should be left blank.

Clinical PA to check the email address is correct. Send the PIL about the anti-cancer treatment, the consent form(s), and the data confirmation form to patient (by email, if they have access to a printer to print the forms to sign, or 1st class post).

- Clinician calls the patient at the pre-agreed time.
- Carry out the **3-point identity** check to ensure you are talking to the correct patient: **Full name + Date of birth + First line of address**

Confirm patient has received and read the information about the anti-cancer treatment, the consent form and the data confirmation form. Confirm that the patient has understood and **is able to consent** to the process. If there is any doubt about either the patient's identity or their capacity to consent then the clinician will not proceed.

The **format** for the discussion should be structured around the CRUK Consent forms for SACT.

- **Answer** any questions the patient may have.
- **Document** the discussion, responses to the above set-out questions, including any patient's questions and your responses to back to them, in the NOTES tab of the patient's Epic clinical record.

Summarise the most important points, ensuring the patient has understood these.
In order to confirm what the patient understands, ask patient the following questions

- The reason for their treatment?
- The benefits of the treatment?
- The risks associated with the treatment?
- How to take any medication that they are prescribed?

Document patient's verbal consent and ask patient to **sign and date** both the consent form(s) and the data confirmation form, if content to do so; then **to scan/ photograph** forms for emailing back to the designated UCLH staff. Ensure patient is aware exactly which UCLH email address to email it to.

The clinician records in the NOTES tab that consent has been received.

Appendix C

Patient identification Label
(minimum of Patient Name, Date of Birth, Hospital No., NHS No.)

Consent to receive email communications via your personal email account

This form has been developed to ensure patients are aware that all correspondence received by University College London Hospitals NHS Foundation trust is dealt with in accordance with the Data Protection Act 2018, but this level of confidentiality cannot be guaranteed once correspondence has left the hospital in the form of an email.

Please note personal email accounts held by the general public are not secure and so could be open to breaches in their personal information. University College London Hospitals NHS Foundation cannot accept any responsibility for emails that do not reach the intended recipient.

Email communication is only for routine enquiries and will be answered in due course.

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I……. *(print name)* **would like to allow the use of my personal email account to receive communications from University College London Hospitals NHS Foundation for the purposes of remote consent to treatment with Systemic Anti-Cancer treatment. I have read and understood the above information and am aware of the potential risk to my personal information. I confirm that my email address is:**

…… *(enter email address)*

Please note only emails received from the email address above will be responded to. If you wish to change your email address at any time, please request a new form to update your details accordingly.

Signed……

Date……

If you reply with the form attached, we will accept your email as an electronic signature of consent.
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