

PREGNANCY DECLARATION FOR SACT

Scope

National guidance recommends that NHS organisations should establish the pregnancy status of all females between 11 years (who have started their periods) (1) and 55 years before they have certain procedures and treatments, (2).

Entitled Healthcare Professional (HCP) includes the following staff groups: Consultant Oncologists/SPR, chemotherapy nurses.

- HCP is responsible for performing a check on the pregnancy status of all patients receiving treatment. Pregnancy Declaration must be discussed by the entitled Healthcare Professional, HCP, with the patient and the form must be completed.
- HCP is responsible for discussing with the patient the enhanced sensitivity of the developing foetus to anti-cancer drug treatment.
- The entitled healthcare professional must inform patients that a copy of this pregnancy form will be stored with their notes.
- Staff must ensure there is a suitable environment for the patient to have privacy during the discussion.
- If the patient is left alone to complete the form, they first must be given adequate information about the benefits to the patient and the risks to a foetus/un-born child from the anti-cancer treatment and then be given the opportunity, time and suitable environment to ask questions.
- The patient and Healthcare Professional must sign the form and store it in the electronic record system where the consent form and other documents are stored.
- A copy of the pregnancy form will be given to the patient.
- No further action is required unless the patient declares that there is a change in the pregnancy status when they return for their treatment.

During the Discussion:

Note: If the patient does not wish to discuss or disclose their sex at birth or other details of ability to become pregnant or declines to disclose their pregnancy status or complete the form, do not proceed. Send the patient away and contact the patient's Consultant Oncologist.

The HCP must explain the risks to a foetus/un-born child and it is necessary to ask if there is any possibility of pregnancy.

If the patient declares that they were registered at birth as a male, have no variation in their sex characteristics and have no potential to become pregnant:

- No future discussions are required regarding pregnancy.
- The HCP must complete the relevant options in the pregnancy declaration form and ask the patient to sign.
- The HCP must also sign the form to confirm.
- A copy of the form must be given to the patient and also stored electronically with other patient notes.

If the patient declares that they were registered at birth as a female, variation of sex characteristics (VSC), Intersex or DSD:

- The HCP must enquire regarding pregnancy status
- The HCP must give the patient adequate information about the benefits of treatment and the risks to a foetus/un-born child. The patient must then be given the opportunity, time and a suitable environment to ask questions.
- The HCP must warn the patient about the dangers of becoming pregnant during the course of treatment and the risk to a foetus/un-born child.
- The HCP must advise the patient to avoid pregnancy during the treatment. This may require additional advice regarding contraception. In this circumstance please refer the patient to their GP or local pharmacist for advice.
- The HCP must inform the patient that it is their responsibility to inform the HCPs if they are unsure of their pregnancy status or if there is a change with their pregnancy status during treatment.
- The HCP must complete the appropriate boxes in the declaration form and ask the patient to sign the form.
- The HCP must also sign the form to confirm.
- A copy of the form must be given to the patient and also stored electronically with other patient notes.

No further action is required when the patient returns for their treatment unless the patient declares that there is a change in their pregnancy status.

If the HCP identifies the possibility of pregnancy or the pregnancy status is unknown (unknown status would cover, for example, a patient who has irregular periods and is sexually active which may result in pregnancy) the patient must undergo a pregnancy test. The testing process is as follows:

- ➔ Maidstone Hospital: refer patient to Admission Lounge for a cassette type urine pregnancy test. The result must be documented in KOMS under Clinical History.
- ➔ East Kent Hospitals: Will obtain a urine sample from the patient and the HCP takes the sample to Brabourne Ward or the chemotherapy units sluice room for testing. This will take up to five minutes. Paper result will be issued and must be scanned into KOMS under Clinical History.

Note: A pregnancy test is only accurate 7-10 days after conception. Earlier testing or very dilute urine may give a negative result. Alcohol consumption may also interfere with the test result. Therefore, the HCP should inform the patient of these conditions prior to taking the pregnancy test and re-book any appointments with a Consultant Oncologist accordingly. Other causes of raised HCG include trophoblastic disease and certain neoplasms including breast cancer and lung cancer tumours.

- If the result is positive **DO NOT PROCEED WITH TREATMENT**. Inform the patient's Consultant Oncologist / Haematologist / Clinical Specialist and establish how to proceed.
- If the result is negative discuss the following with the patient, and document in the Clinical History in KOMS, in order to establish the accuracy of the result:
 - Last date of menstrual period
 - Date of most recent intercourse
 - Details of most recent alcohol consumption
 - Amount of fluids consumed prior to undertaking test/urine dilution
- If the result is negative and the outcome of the above discussion is that this result is likely to be accurate proceed with treatment.
- If the result is negative and the outcome of the above discussion is that this result is likely to be inaccurate **DO NOT PROCEED WITH TREATMENT**. Inform the patient's Consultant Oncologist / Haematologist / Clinical Specialist and establish how to proceed. Consider retesting after 10 days.

If the HCP identifies possibility of pregnancy but patient does not wish to carry out the pregnancy test:

- ➔ Advise the patient to wait for their menstrual cycle to begin before returning for the procedure.
- ➔ Inform the referring Consultant Oncologist.
- ➔ Complete the pregnancy declaration form on return.
- ➔ Only proceed with treatment following confirmation of approval from Consultant Oncologist.

Patients Returning after a Delay

If the result of the pregnancy declaration process is that the patient must return after a delay, for example, where a second pregnancy test is required or where they opt to wait until their menstrual cycle begins, then on the patient's return a new declaration form must be started.

Treatment of Pregnant Patients in Extenuating Circumstances

Only in exceptional circumstances may patients be treated when pregnant.

The Consultant Oncologist may decide to provide treatment in full consultation with the pregnant patient who has been made fully aware of the risks to the unborn child.

The Pregnancy Declaration must still be filled in and signed by the patient.

Patients Declaration of Pregnancy During Treatment

If the patient declares at a later stage during the course of treatment that there is a possibility that they are pregnant or they confirm they are pregnant:

- **STOP TREATMENT IMMEDIATELY.**
- ➔ Document in the Clinical History in KOMS the reason for stopping treatment.
- ➔ Suggest the patient undertakes a pregnancy test and returns with the result, preferably on the same day - see details of pregnancy testing above.
- ➔ Record result, and any details of discussion, on Clinical History in KOMS and Pregnancy Declaration Form.
- ➔ Inform Consultant Oncologist / Haematologist, Clinical Specialist for further advice and establish how to proceed.
- ➔ Upon return following a gap due to potential pregnancy or delay due to pregnancy testing, complete a new Pregnancy Declaration Form following the above process.

PREGNANCY DECLARATION FORM FOR SYSTEMIC ANTI-CANCER TREATMENT

Patients details	
Full Name:	
R Number:	
Date of birth:	

Your clinician has requested treatment that may damage the development of a baby in the womb. As Healthcare Professionals, it is our professional duty and legal responsibility to discuss the possibility of pregnancy in order to avoid any potential risk to a foetus.

As you are aged between 12 and 55 years old, please answer the following questions:

1. Which sex were you assigned at birth?	Female ☐	Male ☐
If you are aware that you were born with a physical variation in your sex characteristics (VSC), also known by the terms diverse sex development (DSD) or intersex, please let a healthcare professional know. This can be discussed privately if you wish.		

If you have answered Female above and/or have a VSC with the potential of pregnancy, please answer the following question:

2. Are you or might you be pregnant?	Yes ☐	No ☐
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Write your initials in the boxes below to show that you have read and understood the following statements:

I understand that it is important that I do not become pregnant during the course of my treatment. I understand it is my responsibility to inform my doctor / other healthcare professional if I am unsure of my pregnancy status or if it changes during my treatment.	
I am aware that I might still be able to become pregnant even if I am taking testosterone or undergoing other oncological treatment.	

Patient Signature		Date:	
Print Patient's Name			
Healthcare Professional's signature		Date:	
Healthcare Professional's Name			

Making enquiries about pregnancy is a legal requirement. With your permission, a copy of this document will be stored electronically with your clinical notes. All your personal data is managed in line with data protection regulations. Please inform a member of staff if you do not consent, or consent to only part of this information being stored. Please note, we might not be able to continue, or it could delay your treatment, if we are unable to confirm your pregnancy status.

DOCUMENT ADMINISTRATION

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October 2026	1	Draft approved and finalised	SACT Clinical Working Group