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TO BE PRINTED ON LOCAL HOSPITAL HEADED PAPER





***AURORA – Pregnancy Information Sheet***

**Title of Project:** **AURORA**: **Atezolizumab in patients with urinary tract squamous cell carcinoma: a single arm, open label, multicentre, phase II clinical trial**

**Name of Researcher: Dr Simon Crabb Sponsor Reference: RHM CAN 1665**

**IRAS: 1004493 REC: 22/LO/0272**

**Why have I been approached?**

You or your partner are or were participating in a clinical trial for treatment of cancer called the AURORA Trial. As you are pregnant and the effects of the study treatment are unknown on pregnancies and their outcomes, we would like to follow your pregnancy and collect medical information about your pregnancy and its outcomes. Please read further regarding how this information will be collected and what is involved.

**In this study we will use information from your medical records and your GP. We will only use information that we need for the research study. We will let very few people know your name or contact details, and we only if they really need it for this study.**

**Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.**

**At the end of the study we will save some of the data in case we need to check it. We will make sure no-one can work out who you are from the reports we write.**

**Do I have to agree to be followed-up?**

If you decide to take part in this follow-up you are still free to withdraw at any time without giving a reason. If you decide not to participate in this follow-up your ante-natal and post-natal care will not be adversely affected.

**What will happen to me if I agree for my pregnancy to be followed up?**

If you choose to take part in this follow-up, you will be asked to meet with a study doctor or nurse to give information related to the progress of your pregnancy and again when the outcome of the pregnancy is known. This may include information related to the date your pregnancy was confirmed, expected delivery date, the outcome of your pregnancy and the health of your child at birth.

**How will my pregnancy information be used and disclosed?**

In compliance with the requirements of the study noted above, you or your partner has informed the study doctor that you are pregnant. Regulatory agencies recommend that information be collected about pregnancy in women; women who are pregnant or become pregnant while they or their partner are participating in a clinical trial. You are therefore invited to participate in an important safety monitoring activity. This may help to understand the effects, if any, that the trial drugs may have or have had on your pregnancy or your unborn child. We would also like to collect information as to whether the pregnancy went to term or not. Although the study doctor will collect information about your pregnancy and outcome, the study doctor will not be responsible for any expenses related to this pregnancy.

**How will we use information about you?**

We will need to use information from your medical records with your GP for this research project.

This information will include your initials/ NHS number/name/ contact details. For patients in Scotland, your Community Index Number (CHI) number will be used alongside your initials/name/contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Some of your information will be stored on servers in the UK, EU, and the USA. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**What are your choices about how your information is used?**

* You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

### Where can you find out more about how your information is used?

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* at <https://www.southampton.ac.uk/ctu/about/index.page>
* by asking one of the research team

**Right to withdraw authorisation to release information**

Your participation is voluntary and you are free to withdraw your authorisation at any time by informing the study doctor. If you revoke your authorisation the study doctor will not collect any new health information about you or your child. Refusal to participate in this safety monitoring activity will not adversely affect your ante-natal and post-natal care.

**Who is organising and funding this research?**

The trial that you or your partner is participating in is being coordinated by Southampton Clinical Trials Unit. The trial is being funded by Cancer Research UK. The trial drugs are being provided free of charge by Roche. None of the doctors or other staff conducting the research are being paid directly for recruiting patients into the study.

**Who has reviewed this study?**

The clinical study that you or your partner is participating in has been reviewed by number of medical specialists during its development, the National Cancer Research Institute Clinical Studies Group, Cancer Research UK and Roche. The study has been reviewed and approved by the Medicines and Healthcare Regulatory Authority (MHRA), Local Research and Development Department and the Research Ethics Committee to confirm that this study considered the patients’ rights and protection of patients’ health.

**If I would like to take part in the pregnancy follow-up, what do I need to do?**

If you sign the AURORA Pregnancy Informed Consent Form, you are giving permission for the study team to undertake pregnancy follow-up with you for the purposes of the safety monitoring activity. You do not have to give this permission. The consent form will be filed at the hospital securely and kept separate from any non-identifiable information, a copy provided to you and a copy will be sent to the Southampton Clinical Trials Unit (SCTU) via secure e-mail and held securely. At the end of the trial the original consent form will be archived by the hospital who took the consent for a period of 25 years and will be stored separately from any non-identifiable information provided. The copy sent to the SCTU will be destroyed as confidential waste prior to the trial being archived.

**What happens if something goes wrong?**

If you have a concern about any aspect of this study, you should contact your research doctor/nurse as soon as possible. Your clinical research team will do their best to help you and answer your questions. [Insert site phone number].

If you wish to complain, or have any concerns about the way you have been approached or treated during this trial, the normal complaints system will be available to you; this service is called the Patients Advice and Liaison Service (PALS) in England and Wales. The service available to patients in Scotland is the Health Boards Complaints Team. For the contact details and further information please check [www.nhs.uk](file:///%5C%5Csoton.ac.uk%5Cresource%5CMedicine%5CCTU%5CTrials%5C07%20Trials%20in%20development%20for%20submission%5COELIXIR%20TRIALS%5C1.%20CRUK%20APPLICATION%202019%5C3a%20Rise%5Cwww.nhs.uk%20) or your local trust’s website.

[Delete as appropriate]

Local PALS contact details [insert here]

Local Health Boards Complaints Team contact details [insert here]

The study Sponsor, the University Hospital Southampton NHS Foundation Trust (UHS), takes overall responsibility for the trial. If you remain unhappy or have a complaint about any aspect of this study, please contact the Research Governance Manager at researchmanagement@uhs.nhs.uk.

Please be aware that if you are harmed as a result of taking part in the AURORA trial, there are no special compensation arrangements. The University Hospital Southampton NHS Foundation Trust provides clinical trials indemnity insurance for negligence in its management or design of the trial. If you are harmed because of someone’s negligence, you may be able to take legal action, but you may have to pay your own legal costs.

**Contact for further information**

If you have further questions about taking part, please discuss them with you or your partner’s doctor or nurse.

If you would like independent advice of further information you may also find it useful to contact Macmillan Cancer Support, an independent patient advisory group (Freephone 0808 808 0000; address: 89 Albert Embankment, London, SE1 7UQ or the Cancer Research UK website (http://www.cancerresearchuk.org).

If during the course of your participation you have any questions or would like further information before making your decision please contact:

**Doctor:** [insert local information here]

**Name:** [insert local information here]

**Telephone Number** [insert local information here]

**Research Nurse:** [insert local information here]

**Name:** [insert local information here]

**Telephone number:** [insert local information here]

If you find the wording difficult to understand or would like us to explain things to you once more, please feel free to ask you or your partners doctor or nurse.

**Thank you for taking the time to read this information sheet. If you wish to take part you will be given a copy of this information sheet and a signed consent form to keep.**