





# AURORA PREGNANCY INFORMED CONSENT FORM

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**Patient ID Number of study participant:**

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

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

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

***Please initial each box***

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| **1.** I confirm that I have read and understand the AURORA Pregnancy Patient Information Sheet dated **[date], [version]** for the above study. I understand that I am being asked for my pregnancy to be followed up. I agree to my pregnancy and outcome of my pregnancy to be followed up in accordance with the procedure highlighted in the patient information sheet. I have had the opportunity to ask questions and these have been answered satisfactorily. |
| **2.** I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without mine or my partner’s medical care or legal rights being affected.  |
| **3.** I give permission for relevant sections of my medical notes and data collected during this follow-up, to be looked at by individuals from Southampton Clinical Trials Unit, Study Sponsor organisation, regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research and understand that pseudo-anonymised data being held on servers located in the UK, EU, and USA. Access to data managed by Southampton Clinical Trials Unit (SCTU) will be strictly controlled and applicable Data Protection Legislation will be abided by. |
| **4.** I understand that the information collected about me will/may be used to support other research in the future and may be shared anonymously with other researchers.  |
| **5.** I agree to my General Practitioner being informed of my participation in the follow-up. |

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| **6.** I understand that non-identifiable data collected about my pregnancy will be archived and stored securely at the end of the trial for up to 25 years, which may be on servers in the UK, EU, and USA  |
| **7.** I understand that I shall not benefit financially in any way by taking part in this follow-up. |
| **8.** I give permission for a copy of this consent form to be sent to the Southampton Clinical Trials Unit (where it will be kept securely), to allow confirmation of my consent. |
| **9.** I agree to take part in the follow-up necessary as a pregnant participant or partner of a study participant in the above study. |

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|  Name of Pregnant Participant | Signature | Date |
| Name of Person taking consent | Signature | Date |

