

Study EudraCT number: 2018-001327-39

Study Protocol number: C/37/2017

Centre Number: <insert centre number>

Patient Study Identification Number: <insert patient number>

Cohort: \_\_\_\_

### CONSENT FORM – The CUPem Trial

**Full Title: A Phase II, Two-Stage, Trial of Pembrolizumab in Cancer of Unknown Primary**

**Short Title: CUPem**

Please initial each box:

1. I confirm that I have read and understand the participant information sheet dated _____ version _____ for the above study and have been given a copy to keep. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is entirely voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the study sponsor, Imperial College London and its representatives, Imperial College NHS Healthcare Trust and its contractors, Merck Sharp and Dohme Ltd, contracted companies conducting review of radiological imaging, regulatory authorities, or the NHS Trust/Health Board where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. If applicable, should I become pregnant during the trial, I give permission for the above individuals to have access to any of my medical notes and information collected about my pregnancy. <b>This is optional, if you do not wish to take part in this please do not initial the box – this will not affect your participation in the study.</b>	
5. I agree to my GP being informed of my participation in the study.	
6. I give permission for all the samples described in the patient information sheet (blood, urine and tissue) to be taken for the purposes of this study.	
7. I understand that the information collected about me may be used for commercial and/or non-commercial purposes in the future, and may be shared anonymously with other researchers.	

8. I agree to donate the existing/ archival tissue sample(s) taken at the cancer of unknown primary diagnosis and/or surgery for research related to this study that may include use of my DNA. I understand that I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected	
9. I agree to donate the tissue sample(s) taken from a biopsy of the cancer of unknown primary prior to starting treatment, where this is feasible. I understand that this is for research related to this study that may include use of my DNA. I understand that I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected.	
10. I agree to donate blood samples taken screening, cycle 2 and alternate treatment cycle thereafter, and within 30 days of my last trial treatment for research related to this study that will include use of my DNA. I understand that I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected.	
11. I agree that any residual blood and tissue samples, as described in the information sheet may be used for further ethically approved commercial and/or non-commercial research in the field of cancer of unknown primary. This further research may involve international partners.	
12. I agree to take part in the above study	

\_\_\_\_\_  
Name of Patient (Please Print)

\_\_\_\_\_  
Signature of Patient

\_\_\_\_\_  
Date (dd/mm/yyyy)

\_\_\_\_\_  
Name of Witness (if applicable)  
(Please print)

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date (dd/mm/yyyy)

*By signing the consent form, the witness confirms that all the information contained in the PIS/CF has been read in its entirety to, and apparently understood by the patient and that informed consent was freely given*

**CONSENT OBTAINED BY (MUST BE A PHYSICIAN OR NAMED DELEGATE):**

\_\_\_\_\_  
Name of Investigator(Please Print)

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date(dd/mm/yyyy)

**When completed: Take 2 copies. Original to be kept in medical notes, 1 copy to be kept in investigator site file, and 1 copy to be given to the patient.**