PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM FOR PREGNANT PARTNER OF TRIAL PARTICIPANTS

mulTiArm therapeutiC sTudy in pre-Icu patients admitted with Covid-19-Repurposed drugs (TACTIC-R)

1. Why have I been approached?

You are receiving this information sheet and consent form because we have been informed that you have become pregnant whilst your partner was taking part in a trial where they received Baricitinib or Ravulizumab. You are being asked to give your consent for the collection of medical information about you and your pregnancy. This information is being collected as part of the TACTIC-R trial.

We would like to collect this information so that we can better understand whether there are any effects of the Baricitinib or Ravulizumab on pregnancy. This will help to build the safety profile of the drugs to provide information for patients in the future.

There is no clinical data available of the effects in pregnancy of either Baricitinib or Ravulizumab. However, animal studies of Ravulizumab suggest toxicity to the foetus, and Baricitiniib is not recommended to be taken by pregnant women due to potential but currently unknown risks. Also, there is a potential risk in breastfeeding, therefore it is recommended that you do not breastfeed for up to 8 months after your partner has completed their treatment with either Baricitinib or Ravulizumab. To help ensure the accuracy of such information, the investigators would like to collect this information from you directly and your medical records.

We are asking for your consent as we cannot ask your partner to provide your personal and medical information on your behalf. Before deciding whether to give your consent, it is important that you understand why we are asking to collect this information and how it will be used. Please take time to read the following information carefully and discuss it with your family doctor, if you wish.

2. Do I have to share information?

No, the decision to share information about your pregnancy is completely voluntary. If you decide to share such information you will be given the opportunity to ask questions and then be asked to sign an Informed Consent Form. You will be given a copy of this information sheet and the signed consent form to keep for future reference. Please be aware that you are still free to change your mind and stop sharing information at any time without giving a reason. If you choose not to share your information then your future medical treatment and normal standard of care will not be affected in any way. Your decision will not prevent your partner from continuing in the trial.

3. What will happen to me if I give consent?

If you agree, we will collect the following information from you:

- Relevant medical history
- Details of any previous pregnancies, including outcome and any complications
- Details about your current pregnancy

- Any medications that you are taking/have taken during your pregnancy
- The outcome of your pregnancy
- Details of the birth and delivery

We will contact you around the time of your due date to enquire about the above. In addition, we would like you notify the research team if you decide to terminate the pregnancy or if you experience a miscarriage. This information will be collected as part of the trial and also be used in the evaluation of the safety information available for the trial drug.

4. What if new information becomes available?

If any new information on the effects of Baricitinib or Ravulizumab on pregnancy becomes available, the research team will contact you to discuss the new information. Even if you do not want to share information about your pregnancy, you may still contact the research team at any time to obtain updated information about the safety of Baricitinib or Raviluzumab.

5. Can I withdraw my consent?

Yes, you can withdraw your consent to provide information at any time. You can agree now and change your mind later. If you want to withdraw your consent, you should tell the Trial Doctor as soon as possible.

If you withdraw your consent to share information in this trial, no additional information will be collected. Any information already collected will be retained by *[name of site]* and Cambridge University Hospitals (the Sponsor of this trial) for safety reporting purposes.

6. Will my taking part in this trial be kept confidential?

Cambridge University Hospitals NHS Foundation Trust (CUHFT) is the Sponsor for this trial based in the United Kingdom. They will be using information from you and your medical records to support this trial and will act as the data controller for this trial. This means that they are responsible for looking after your information and using it properly.

All information collected about your pregnancy will be kept strictly confidential. Your personal and medical information will be kept securely by the clinical study team at *[ENTER SITE NAME]* and be treated in the strictest confidence. Your rights to access, change or move your information are limited, as the Sponsor organisation needs to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw your consent, *[name of site]* and the Sponsor will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how the Sponsor uses your information using the information below:

- For Cambridge University Hospitals NHS Foundation Trust, please visit: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk

Where CUH is the recruiting site:

Cambridge University Hospitals NHS Foundation Trust will keep your name, NHS number and contact details to contact you about the trial, make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Cambridge University Hospitals NHS Foundation Trust may pass these details to the Sponsor organisation, along with your DOB and pregnancy information described in section 3, collected from you and/or your medical records.

Cambridge University Hospitals NHS Foundation Trust will keep identifiable information about you from this trial for 5 years after the trial has finished.

For participating sites:

[NHS/other site] will keep your name, NHS number and contact details confidential and will not pass this information to the Sponsor. The research team at *[name of site]* will use this information as needed, to contact you about the trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. *[Site name]* will pass your DOB and pregnancy information to the Sponsor along with the information collected from you and/or your medical records as described in section 3 of this document. Individuals from the Sponsor and regulatory organisations may look at this information to check the accuracy of the research.

[Site name] will keep identifiable information about you from this trial for 5 years after the trial has finished.

The only people in the Sponsor organisation who will have access to information that identifies you will be people who need to contact you in relation to this trial and to audit the data collection process. The people who analyse your data will not be able to identify you and will not be able to find out your name, NHS number or contact details. Only anonymous trial data, without any personal information will be published at the end of the trial.

Your information collected as part of this trial will be retained by the Sponsor for at least 5 years after the trial has ended and will be securely archived according to Sponsor policy.

The information we collect about you as part of this trial either alone or combined with data from other studies, might be shared with regulatory authorities in Europe or the USA (e.g. the EMA or FDA), and similar government agencies from other countries, as well as the ethics committee overseeing this study. This is to better understand the effects of the drugs on pregnancy, the foetus and the infant when born. The sponsor works with business partners in drug development. The sponsor might share your study data with a business partner but only if the business partner signs a contract that requires it to protect your study data in the same way as the sponsor. The information we pass on would not identify you.

We would also like to inform your GP of your pregnancy and involvement in this trial so that they are aware your partner was taking Baricitinib or Ravulizumab at the time of conception.

7. Who has reviewed this trial?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by *[name of REC here]*. The Medicines and Healthcare Products Regulatory Agency (MHRA) who are responsible for regulating medicines in the UK have also reviewed and approved this trial.

8. Further information and contact details

You can contact the study team for further information using the following details:

*Study Doctor name: telephone: **********email: **********
Study nurse/coordinator name: telephone: ********** email: **********

If you wish to make a complaint or have any concerns about any aspect of the way you have been approached or treated during this trial, you can do this through the NHS complaints procedure. In the first instance, it may be helpful to contact the *(to be completed locally as appropriate - in England this will refer to the Patient Advice and Liaison Service (PALS)* at your hospital

In the event of an emergency please contact:

List 24 hour emergency contact detail here – this must match the information provided on the patient ID card and will be used to test the out of hours procedure for the trial.

TO BE PRINTED ON HEADED PAPER

INFORMED CONSENT FORM FOR PREGNANT PARTNER OF TRIAL PARTICIPANTS

Trial Title:

Principal Investigator:
Male Trial Participant Number: _____

If you agree with each sentence below, please initial the box		**INITIALS**
1	I have read and understood the Information Sheet version v 1.0, dated 27/04/2020 for the above trial. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that I may withdraw my consent at any time without giving a reason and without my medical care or legal rights being affected.	
3	I give my permission for the collection, use and disclosure of my medical and personal information in accordance with this information sheet, including transfer to countries outside of the UK.	
4	I understand that sections of my medical notes or information related directly to my pregnancy may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel where it is relevant to my partner's taking part in research and that they will keep my personal information confidential. I give permission for these individuals to have access to my records.	
5	I give my permission for my GP to be informed of my consent to provide pregnancy related information as part of this trial and be sent details of the trial drugs.	
6	I agree to provide information for the above trial and am aware that my involvement is entirely voluntary.	

_____	_____	_____
Name of pregnant partner of trial participant	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date

Time of Consent (24hr clock) _____:_____

1 copy for the pregnant partner, 1 copy to the research team.