Imperial College London

Imperial College Healthcare NHS Trust

Informed Consent Form

Assessing gut permeability using spectroscopy

***Study title*:** Non-invasive transcutaneous spectroscopy for the assessment of gut permeability (GutPerm)

***IRAS Project ID*:** 242462

Patient Trial ID Number: _____

Name of Principal Investigator: Dr Alex Thompson

Name of patient to whom this ICF applies: _____

Please initial boxes:

1. I confirm that I have read and understand the Patient Information Sheet "Assessing gut permeability using spectroscopy v4.2A 01-May-2019" for the above study and have had the opportunity to ask questions about the study and understand what is involved. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or other legal rights being affected, and I understand that any remaining samples will be destroyed at my request, but data collected up to the point of my withdrawal may still be used. ☐

3. If I have had an intestinal biopsy as part of my routine clinical care, I am happy for some of my tissue, if surplus to clinical need, to be given to the research team and/or approved collaborators within and outside the European Economic Area for healthcare and/or medical research purposes. I am also happy for any clinical data obtained from these biopsies and samples to be accessed and used by the research team. ☐

4. I agree to have a 'Spectroscopic gut permeability test' and understand that there is a small risk of nausea and other allergic reactions (including anaphylaxis) with this test. ☐

5. I agree to provide two 5 ml blood samples during my study visit (equivalent to approximately one teaspoon of blood for each sample). ☐

   If you do NOT consent to provide two 5 ml blood samples, please put a line through all of point 5 above, and do NOT initial the box as indicated – you can still participate in the main trial.

6. I agree to provide two urine samples during my study visit. ☐

   If you do NOT consent to provide two urine samples, please put a line through all of point 6 above, and do NOT initial the box as indicated – you can still participate in the main trial.

7. I agree to provide one or more stool samples within approximately 48 hours of my study visit. ☐

   If you do NOT consent to collection of stool samples, please put a line through all of point 7 above, and do NOT initial the box as indicated – you can still participate in the main trial.

8. I agree to have a 'PEG permeability test' and understand that there is a small risk of diarrhoea and bloating with this test. ☐

9. I understand that sections of any of my medical notes may be looked at by authorised individuals from Imperial College Healthcare NHS Trust, from Imperial College London, or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

10. I agree to allow information about me to be collected, analysed, reported and transferred to other approved collaborators within and outside the European Economic Area for healthcare and/or medical research purposes. I understand that my identity will remain anonymous. ☐

11. I give consent for any of the blood, urine, stool and tissue samples that I give that are used as part of this study to be used in future research projects that comply with regulations and which have approval from an independent research ethics committee. This may include transfer of my samples outside of the European Economic Area. Under these circumstances my samples will be retained for up to 10 years in Imperial College's secure and fully regulated Biobank. ☐

    If you do NOT consent to your samples being stored and used for future research in this way, please put a line through all of point 11 above, and do NOT initial the box as indicated – you can still participate in the main trial.

12. I give consent for the research team to inform my general practitioner (GP) of my participation in the study. ☐

13. I wish to be contacted by e-mail with a summary of the research findings once the study is complete. Your e-mail address will not be used for any other purpose. ☐

    Contact e-mail: _____

    If you do NOT wish to be contacted regarding the study results, please put a line through all of point 13 above, do NOT leave a contact e-mail address and do NOT initial the box as indicated – you can still participate in the main trial.

14. I agree to take part in the study. ☐

Please sign and date below.

_____	_____	_____
Name of Subject	Signature	Date
_____	_____	_____
Name of Person taking consent	Signature	Date

1 copy for subject; 1 copy for Principal Investigator; 1 copy to be kept with hospital notes