

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 Participant Information Sheet "Assessing gut permeability using spectroscopy v4.0 31-May-2018" 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. 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.
4. 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 4 above, and do NOT initial the box as indicated – you can still participate in the main trial.
5. 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 a stool sample, 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 have a 'PEG permeability test' and understand that there is a small risk of diarrhoea and bloating with this test.
7. 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.
8. I give consent for any of the blood, urine and stool 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 8 above, and do NOT initial the box as indicated – you can still participate in the main trial.

9. I agree to have a second 'Spectroscopic gut permeability test' with an additional dose of a 'hyperosmotic' solution. I understand that there is a small risk of nausea or other allergic reactions with the 'Spectroscopic gut permeability test' and that the additional risk posed by the 'hyperosmotic solution' is minimal.

If you do NOT consent to have a second 'Spectroscopic gut permeability test' or if you have not been approached about this section of the study, please put a line through all of point 9 above, and do NOT initial the box as indicated – you can still participate in the main trial.

10. 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 10 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.

11. 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