



The CO2 study: Carbon Dioxide Insufflation and Brain Protection During Open Heart Surgery

Frequently asked questions about remote consent

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❖ How will I know when my local research team are calling me?

Your local research team will call you after you have had a few days to read the patient information leaflet. Sometimes hospital phone numbers can display as 'withheld' or 'private number'.

They will always introduce themselves, say where they are calling from and explain what they are calling about. They may ask you to confirm your name, date of birth and/or hospital number to make sure you are the correct person taking the call.



❖ **Can I arrange a time that suits me for my local research team to contact me?**

Yes, please feel free to contact your local research team to arrange a time to discuss the study in more detail and if you would like to join the study. Your local research team's contact details are in your patient information leaflet and invitation letter.

❖ **I would like to have someone with me for the call, is that ok?**

Yes, you are welcome to have someone with you when you speak to your local research team about the study. You may need to arrange a time for your local research team to call you when you and your partner/ family member / friend are also available.

If you decide to join the study, you are welcome to have someone with you when you give your consent, but it must be your decision and you must sign the form yourself.

❖ **How do I decide which consent process to use?**

If you decide to join the study once you have spoken to your local research team you can either give your consent using the paper copy of the consent form that was provided with your patient information sheet, or using a special electronic database.

If you would like to use the electronic consent database, you will need to have access to a computer or tablet and your emails. Your local research team will ask you for your email address and send you an email containing the link to access the electronic consent database. They will talk through the process over the phone

It is completely up to you which consent process you would like to use.

❖ **What initials should I use on the consent form?**

Please use the initials you normally use. It is up to you if you want to include your middle name(s) and there is no limit on the number of initials you can use.



❖ **How can I send my signed consent form back?**

Telephone consent

If you have given your consent to join the study using the paper consent form that was included with your patient information leaflet, you will need to send your signed consent form to your local research team for them to check and confirm they took your consent.

You can do this by either;

- Posting the consent form to your local research team using the pre-paid postage envelope that was included with the patient information leaflet, consent form; or
- Scan or photograph your signed consent form and email it to your local research team. Your local research team's email address should be on the last page of the patient information leaflet.

Electronic consent

If you have given your consent to join the study using the electronic consent form you do not need to send a copy to your local research team as they will have received an email of the completed consent form at the same time you do.

❖ **What happens after I have sent back a paper copy of my consent form?**

Once you send your consent form back to the local research team, the person that took your consent will check you have completed all the necessary parts and signed and dated the form. They will also sign the form to confirm they obtained your consent and send you a copy of the completed form for your records.

Your local research team will file a copy of your consent form in your medical notes; they will also upload a copy onto the study database so that the Bristol Trial Centre, who are coordinating the study, have a record that you have actually consented to the study. Any information about you will be treated in confidence and stored and used in compliance with the relevant and current data protection laws; Data Protection Act 2018 and General Data Protection Regulation (GDPR) 2016.



❖ Can I stop taking part in the study if I have signed the consent form?

Yes, your participation in the study is voluntary and you are free to stop taking part at any time. There is more information in your patient information leaflet about what happens if you do not want to carry on in the study.

❖ If I have a question about the study after I have consented who do I ask?

Please contact your local research team if you have any questions about the study at any point in the study. Your local research teams contact details are in the patient information leaflet.

Although your GP will be notified of your involvement in the study, they will not know the study in as much detail as your local research team, so it would be better to ask your local research team any questions about the study.

❖ What happens when I arrive for my surgery?

As you have consented to the CO2 study without visiting the hospital, a member of your local research team will meet you before you have your surgery and make sure you are the same person that consented to join the study. They will then complete the assessments which are part of the study before your operation.