

Donor (in PDF form in eTMF)

Consent Form Main Study Participant v 5.0, 24 May 2013

To be printed on the local trust headed paper

Centre Number:

Study Number:

Participant Identification Number:

DEVELOP-UK

A Study of Donor Ex-vivo Lung Perfusion
in United Kingdom Lung Transplantation

Participant Consent Form

Please initial box

1. I confirm that I have read and understand the Participant Information Sheet dated 24 May 2013 (version 5.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
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 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 Sponsor (The Newcastle upon Tyne Hospitals NHS Foundation Trust) or its representatives, or from regulatory or ethical authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
4. I understand that small samples of lung tissue will be collected from donor lungs during ex-vivo lung perfusion (EVLP). I accept that these samples will be used by the research team and by academic or industry partners some of whom may be outside the United Kingdom.
5. If as a result of transplant surgery I were to lose capacity temporarily or permanently I agree that the collection of observational data from my medical records can continue.
6. I understand that if, for any reason, I withdrew from the study, the researchers will still be able to use any data collected during the time I have been taking part in the study.

7. I agree to my GP being informed of my participation in the study.

8. I agree to take part in the above study.

Name of Participant

Date

Signature

Name of person
taking consent

Date

Signature

If a participant is able to give informed consent but unable to sign this consent form, consent should be confirmed orally in the presence of a witness.

Name of Participant

When completed: one copy to participant; one copy for hospital record; original copy to Site Investigator File.

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Interview Study

Participant Consent Form

Please initial box

1. I confirm that I have read and understand the Participant Information Sheet dated 01 November 2011 (version 1.0) for the above Interview study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I received enough information about the study and I understand what the study involves.
3. I understand that the Interview study is purely optional and I can withdraw from this study at any time and do not have to give a reason for doing so. I understand I will not be contacted again with regards to the Interview study if I choose not to be involved.
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from Sponsor (The Newcastle upon Tyne Hospitals NHS Foundation Trust) or its representatives, or from regulatory or ethical authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
5. I understand and agree to the interview being recorded.
6. I understand that I can ask for the recording to be stopped at any time without giving a reason.

- 7. I understand that I will not be personally named in any report and that anything I say will be treated with confidence.

- 8. I understand that any information collected will be kept in a secure way and that all data will be anonymised so that my name does not appear.

- 9. I understand that information collected will be managed by the study team only and will be destroyed after a period of fifteen years.

- 10. I agree to take part in an interview for the study.

Name of participant

Date

Signature

Name of person taking consent
(if different from PI)

Date

Signature

Principal Investigator

Date

Signature

When completed: one copy to participant; one copy for hospital record; original copy to Site Investigator File.

To be printed on the local trust headed paper

Centre Number:

Study Number:

Participant Identification Number:

DEVELOP-UK

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in United Kingdom Lung Transplantation

Interview Study

Nominated relative or Carer Consent Form

Please initial box

1. I confirm that I have read and understand the Participant Information Sheet dated 01 November 2011 (version 1.0) for the above interview study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I have received enough information about the study and I understand what the study involves.
3. I understand that this part of the study is purely optional. I understand I will not be contacted again with regards to the interview study if the person I care for is not to be involved.
4. I understand that data collected during the study, may be looked at by individuals from Sponsor (The Newcastle upon Tyne Hospitals NHS Foundation Trust) or its representatives, or from regulatory or ethical authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
5. I understand and agree to the interview being recorded
6. I understand that I can ask for the recording to be stopped at any time without giving a reason.

7. I understand that I will not be personally named in any report and that anything I say will be treated with confidence.
8. I understand that any information collected will be kept in a secure way and that all data will be anonymised so that my name does not appear.
9. I understand that information collected will be managed by the study team only and will be destroyed after a period of fifteen years.
10. I agree to take part in an interview for the study.

Name of Relative or Carer Date Signature

Name of person taking consent
(if different from PI) Date Signature

Principal Investigator Date Signature

When completed: one copy to relative/carer; one copy for hospital record; original copy to Site Investigator File.

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Centre Number:

Study Number:

Participant Identification Number:

DEVELOP-UK

A Study of Donor Ex-vivo Lung Perfusion
in United Kingdom Lung Transplantation

Participant Consent Form

(After Standard Lung Transplant)

Please initial box

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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 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 Sponsor (The Newcastle upon Tyne Hospitals NHS Foundation Trust) or its representatives, or from regulatory or ethical authorities 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 as a result of transplant surgery I were to lose capacity temporarily or permanently I agree that the collection of observational data from my medical records can continue.
5. I understand that if, for any reason, I withdrew from the study, the researchers will still be able to use any data collected during the time I have been taking part in the study.
6. I agree to my GP being informed of my participation in the study.

7. I agree to take part in the above study.



Name of Participant Date Signature

Name of person _____
taking consent Date Signature

If a participant is able to give informed consent but unable to sign this consent form, consent should be confirmed orally in the presence of a witness.

Name of Participant

When completed: one copy to participant; one copy for hospital record; original copy to Site Investigator File.

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**Participant Consent to Continue Form
(FOR EVLP TRANSPLANTS ONLY)**

Please initial box

1. I confirm that I have read and understand the Participant Information Sheet dated 24 May 2013 (version 5.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
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 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 Sponsor (The Newcastle upon Tyne Hospitals NHS Foundation Trust) or its representatives, or from regulatory or ethical authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
4. I understand that small samples of lung tissue will be collected from donor lungs during ex-vivo lung perfusion (EVLP). I accept that these samples will be used by the research team and by academic or industry partners some of whom may be outside the United Kingdom.
5. If as a result of transplant surgery I were to lose capacity temporarily or permanently I agree that the collection of observational data from my medical records can continue.
6. I understand that if, for any reason, I withdrew from the study, the researchers will still be able to use any data collected during the time I have been taking part in the study.
7. I agree to my GP being informed of my participation in the study.

8. I agree to take part in the above study.



Name of Participant Date Signature

Name of person _____
taking consent Date Signature

If a participant is able to give informed consent but unable to sign this consent form, consent should be confirmed orally in the presence of a witness.

Name of Participant

When completed: one copy to participant; one copy for hospital record; original copy to Site Investigator File.