

MesobanK

Mick Knighton Mesothelioma Tissue Bank

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it will involve for you. Please take time to read this information and to discuss with others if you wish.

What is MesobanK?

MesobanK has been funded by the British Lung Foundation and The Victor Dahdaleh Foundation to collect and store samples of tissue, blood and pleural fluid from patients who have come into contact with asbestos and who have either been diagnosed with mesothelioma or who are being investigated for possible mesothelioma. MesobanK is working with hospitals in the UK which regularly treat patients like you so that we can build a collection of samples that can be used by researchers investigating the causes, development and treatment of mesothelioma. It is hoped that the resulting knowledge will help patients in the future.

Why have I been invited?

Your doctor has agreed to help MesobanK collect samples from patients such as yourself. Research Tissue Banks are very useful to allow researchers to study samples from patients in the laboratory. You are being asked because you are having a procedure that involves the removal of some lung lining tissue and/or fluid from around the lung. We would like to take a small amount of extra tissue and/or fluid, along with a blood sample and some information about your case, for research.

Do I have to take part?

No. Participation is entirely voluntary. It is up to you to decide whether to donate these extra samples. If you do decide to take part, we will then ask you to sign a consent form. If you decide not to take part, you do not have to give a reason. Whatever your decision, it will not affect the standard of care that you receive.

What will happen if I choose to take part?

If you choose to take part we will ask for your written permission (consent) by asking you to sign the form attached to this leaflet. Please keep this information sheet to remind you of what you were asked to do.

Once you have agreed to take part, the following will happen:

- If you need to undergo a biopsy procedure a doctor will remove pieces of lung tissue from your body during the procedure, as is normal practice. This tissue will be sent to a laboratory in the hospital to be tested to help diagnose your medical condition. Up to 6 extra samples (each no bigger than a 5 pence coin) of tissue will be taken to donate to MesobanK. We would also like your consent to retain any material that has been removed as a necessary part of your procedure and which is surplus to diagnostic requirements and would normally be discarded.

- As part of your treatment, blood samples and samples of pleural fluid may be taken. We would like your consent to allow us to take additional samples of blood and fluid at the same time.
- We would also like your consent to allow research staff at the hospital to look at your personal medical records in order to obtain information about your current illness and any previous illnesses and treatments you have had. The information collected from your medical records will include: your past medical history, the diagnostic tests you have undertaken and the results, any treatments you have received and CT scans taken at the time of diagnosis and during treatment. This information may be in various formats including paper, electronic records or radiological images. We may also wish to collect data about your treatment and illness in the future. We can collect this data from other NHS Organisations, such as NHS Digital and Public Health England (National Cancer Registration and Analysis Service) for example. Because this information is already being collected routinely, it is unlikely that you would be contacted again to answer any further questions; however, very occasionally we may ask you to answer some additional questions about your medical history. This information will be provided to Mesobank to help the researchers who receive the tissue interpret the results of the work they undertake. Mesobank is legally obliged to maintain the highest level of confidentiality with all personal information so that there is no chance that any researchers can ever identify who you are.
- If no evidence of mesothelioma is detected in your biopsies, we would still like to retain your samples which could be very useful to researchers. We would also like your consent to collect any pleural biopsy tissue that you have a) had taken in the past (for example at a different hospital) or b) might have taken in the future, that is surplus to diagnostic need and stored in local hospital archives. These samples may help doctors to understand how the disease/mesothelioma may be diagnosed earlier.

If you agree to take part you will be giving samples and information that will be treated as gifts which could help with research to benefit those affected in the future.

What are the benefits and risks of taking part?

It is unlikely that you will directly benefit from the research as it usually takes many years for research to produce advances in the way diseases are diagnosed, treated or prevented. The results of research will NOT be put in your health records or told to you, your relatives or your doctors because the researchers will not know who you are and your details are kept secret from them.

The risk of taking extra biopsies for research is very small and extra biopsies will only be taken by your doctor if it is felt it is safe and appropriate to do so. If at any stage during your biopsy procedure, your doctor feels it is unsafe for you to donate extra samples, they will not be taken.

Donation of a blood sample carries no more risk than giving any routine blood sample.

What if there is a problem?

If you are concerned about any aspect of this project, you should ask to speak to your hospital doctor or a member of the Tissue Bank staff at the hospital, who will do their best to answer any questions you may have. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS) which you can contact by telephone on xxxxxxxxxxxx or email xxxxxxxxxxxx

If something goes wrong and you are harmed as a result of taking extra research biopsies due to someone's negligence then you may have grounds for legal action for compensation against the hospital involved, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

NHS hospitals are unable to agree in advance to pay compensation for non-negligent harm (situations where no one can be blamed for what happened). However, NHS Trusts are able to consider offering an ex-gratia payment in the case of a claim.

What happens if I change my mind?

You can change your mind at any time by contacting MesobanK or your original hospital. You do not need to say why you have changed your mind. Your doctor will then contact MesobanK and all samples in storage will be destroyed in the way that human tissues in hospitals are normally destroyed. Similarly, the information we store about you will be deleted so that it cannot be used again. If you change your mind a long time after the samples were donated, then some research may have already taken place on your samples. MesobanK would not be able to recall samples and information once they have been used, but would request the return of any unused, original samples for disposal. This would ensure that no further research work will be undertaken on your tissue.

What will happen to the samples I donate to MesobanK?

The tissue and information you have gifted will be made available to researchers who may be based in the UK, within the European Union (EU), or outside of the EU. Countries outside of the EU have different data protection laws. To ensure that your original samples and data are stored, used and disposed of in accordance with legal requirements, we check that equivalent laws are in place and agree a contract with all researchers to ensure that UK legal standards are followed. All of your samples and data will be anonymised. The researchers may work in universities, hospitals or commercial companies that undertake medical research. You will not receive any personal financial reward for making your gift.

Sometimes samples are used for genetic research (which involves extracting, analysing and storing the DNA and RNA from your tissue), and to discover the order of every single 'letter' of your DNA code (which is called genomic analysis or whole genome sequencing). The results of this genetic research will NOT be fed back to you or your doctors as your samples will be anonymised. We would like to maximise the benefit of the samples you gift to us by publishing the linked (coded) anonymised results of any genetic/genomic analysis in scientific journals or in research databases. The anonymised results will be kept in the databases indefinitely and will be shared with other researchers around the world by a 'managed access process', which means that researchers accessing the data will have to sign a legally-binding agreement in which they promise not to try to re-identify sample donors. The researchers will access the data for wide-ranging scientific purposes and biomedical research.

Some of your tissue may be used to isolate and grow cells to produce a 'cell line' which can be used for future research. Scientists are able to separate individual cells from a piece of tissue and keep these alive in the laboratory. These cells can grow and multiply, creating a cell line. Most cells have a limited lifespan even as cell lines, but some cells do not and can be kept for research indefinitely. Cell lines are used to study new drugs, therapies or diagnostic tests without risking any harm to a patient. These linked (coded) anonymised cultured cells/cell lines may be shared with other researchers for any research use. The cell lines may also be transferred to cell repositories ('banks') who are able to distribute them for general scientific purposes or for use in biomedical research around the world.

Your original donation will be used only for research into mesothelioma/asbestos related disease and will not be provided for any other purpose. MesobanK currently supports biomedical research in the following areas: Basic science, genetic research, drug discovery, identifying targets for novel treatments and diagnostic testing and the generation of new cell lines.

Tissue used for research can also be stored for many years before it is used. Your samples and data may be stored indefinitely. The biorepository where your samples are stored is licensed by the Human Tissue Authority and is strictly regulated. The favourable ethical opinion for the research tissue bank is reviewed every 5 years.

Research studies using the samples may take several years and results may be made available to other researchers at scientific meetings or in scientific publications. You cannot be identified if any research is published or discussed at meetings as all your personal information is kept confidential.

MesobankK may ask researchers for fees to cover some of the costs it incurs in collecting the samples. This is known as "cost recovery" as it is entirely for reinvestment into MesobankK to allow the tissue bank to continue to operate. The samples you have gifted will never be sold for profit.

If you have any questions or concerns about the donation of samples and information or the possible uses of them, please ask the person discussing donation with you and seeking your consent.

Will my information be kept confidential?

Your hospital, medical team and MesobankK will take every security precaution to prevent researchers from obtaining any information that identifies who you are. The only people who will know your identity are the hospital staff who initially treated you and they are bound by a professional duty to protect your privacy. All your samples and data will be fully anonymised before they leave the hospital.

Researchers will NOT be provided with any personal information such as your name, address or phone number. The information that they will be given for their work relates to your illness and treatment only and will NOT be directly linked to your identity. Therefore, researchers will NOT be able to contact you directly about their research in the future.

When MesobankK provides samples to researchers, they are obliged to use the samples only for the research they said they would do. Researchers will be bound by a strict agreement to ensure this.

Who has reviewed the study?

The collection and storage of tissue and blood samples by MesobankK has been ethically approved by the NHS Research Ethics Service, an independent body external to MesobankK.

This study has been reviewed and given a favourable opinion by NRES Committee East of England, Cambridge Central on 6th October 2020.

MesobankK stores all samples of tissue and blood on premises licensed by the Human Tissue Authority, as legally required.

How to Contact Us

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