National Institute for Health Research

NIHR BIORESOURCE- ADULT INFECTIOUS DISEASE (BioAID)

PATIENT INFORMATION LEAFLET

Introduction

Infectious diseases are a significant problem in the UK. To improve healthcare for patients with infectious diseases, we need to improve our tests to diagnose specific problems and make better predictions about how individual patients may be affected.

Why have I been invited to join BioAID?

You have come to hospital with problems suggesting that you may have an infection. You have also had a number of blood tests taken to try to work out what the particular infection may be due to and how the illness has affected you. A small volume of the blood (2.5 mL, equivalent to half a teaspoon) has been kept aside for research purposes, but will only be used if you agree to participate in BioAID. If you do not agree, then this blood sample will be destroyed immediately.

Do I have to join BioAID?

No. It is completely up to you to decide whether or not you wish to join. If you decide not to join your decision will not affect the healthcare you receive in any way. If you agree to participate, you will still be free to withdraw at any time and without having to give a reason.

What will I have to do if I join BioAID?

Taking part in this study will not affect your treatment in any way. If you agree to join BioAID, we will ask you to sign a consent form. A copy of the signed consent form and this information sheet will be given to you to keep. The small volume of stored blood collected at the same time as routine blood tests when you arrived in hospital will be transferred to the research laboratory.

We will also collect another blood sample of 5 mL equivalent to one teaspoon, and ask you some questions about your illness. After about three months, we will contact you again to check that your illness has resolved, and ask you to re-attend the hospital by appointment to obtain a blood sample of about 7.5mL (equivalent to one and a half teaspoons).

We will also ask your permission to invite you to participate in future studies approved by the Health Research Authority based on information obtained from the blood samples and other information collected about you. You will be provided with full information regarding these studies and you will be free to decide whether or not to participate.

What will happen to the samples and the information collected from me?

BioAID will keep a store of samples taken from people who were believed to have an infectious disease, to address future studies about how people's genes and the infectious microbes interact to develop disease. Their genetic (DNA) code will be recorded and stored in a database. Other parts of their blood samples called 'RNA' and 'serum', and any microbes which are identified as part of the routine care they receive, will also be stored.

In addition, we will collect data about you and your illness from your NHS records in the hospital and the community. These data will include details about your background, your medical history, laboratory tests and radiology tests, medical treatment you receive and outcome of your illness. BioAID will be responsible for the safekeeping of all these data and samples.

Researchers inside and outside the UK, including commercial companies, will be able to apply to BioAID for access to the samples or data needed to answer specific research questions related to infectious diseases or the bodies response to infection. The lead investigators within BioAID will be responsible for controlling access to all the samples and data collected by BioAID.

Are there disadvantages or risks to taking part?

The only physical risk to participating in BioAID is minor discomfort or bruising as a result of blood sampling. If possible, research samples will be taken at the same time as samples obtained as part of your routine clinical

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care. Blood samples will only be taken by fully trained and experienced staff. Joining BioAID will not affect your health care in any way.

What are the benefits of joining BioAID?

There will be no direct benefit to you by joining but you will be making a contribution to science. The information we will gain from BioAID will help lead to a better understanding of the links between genes and environmental factors in causing disease. These studies will contribute to improving healthcare and the prevention or treatment of infectious diseases in particular. You will not benefit financially if this research leads to new treatments or medical tests.

Will my details be kept confidential?

Yes. Best ethical and legal practice will be followed to ensure that all information collected about you will be handled in confidence. Your samples will be labelled with a unique study number before being transferred to the laboratory for testing and information from genetic and other tests will be stored separately from your personal details. Access to the database linking sample study numbers to personal details will only be accessed by members of BioAID. No identifiable data will be disclosed to any other party. The samples and the information collected about you will only be used for research that has been approved by UK ethics committees and for which you have given consent. You will not be identified personally in any report or publication.

Can I know the results obtained from my study samples?

No. The information obtained from your samples will only be used for research and will not affect your care in any way.

What if I no longer want to participate in BioAID or NIHR BioResource?

You are free to withdraw from BioAID at any time without giving a reason. You can inform us by phone, email or in writing at any time.

What if there is a problem?

If you have a concern about any aspect of this study, you should write to the BioAID study coordinator using the contact details provided at the end of this information sheet.

If you remain unhappy and wish to complain formally, you can contact the Research Governance Sponsor of this study by writing to UCLH/UCL Joint Biomedical Research Unit, R&D Directorate, Rosenheim Wing, Ground Floor, 25 Grafton Way, London WC1E 5DB quoting reference BRD/06/132.

The sponsor has indemnity arrangements in place for no-fault compensation, in the unlikely event that something goes wrong and you are harmed during the research study. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against but you may have to pay your legal costs.

Who funds and sponsors BioAID?

BioAID is supported by funding from the National Institute for Health Research. BioAID is sponsored by xxx.

Who has reviewed this study?'

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the South-Central Oxford C Research Ethics Committee.

Who can I contact if I have more questions?

Please contact the BioAID study research nurses at University College London:

Michelle Berkeley

UCL Division of Infection and Immunity

2nd Floor Maple House, 149 Tottenham court Road, London W1T 7NE

Tel: 0203 447 5979 / 0755 739 3218

NHS
National Institute for Health Research

General Data Protection Regulation for health and care research.

xxx is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. UCL will keep identifiable information about you for 25 years after the study.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Our Data Protection Officer is Lee Shailer and you can contact them at data-protection@ucl.ac.uk

We will collect information about the participant for this research study from your current hospital trust provider [hospital label sticker]. This information will include your name, Hospital number, contact details, blood and x-ray results, current medications and other health diagnosis, which is regarded as a special category of information. We will use this information to check if you are eligible for the study monitor your disease progression, contact you for follow up study visits and oversee the quality of the study.

Individuals from UCL and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in UCL who will have access to information that identifies you will be people who need to contact you to discuss the study and arrange study visits or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name and contact details.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.