

AIDA : Anonymous Image Data Archive for Radiotherapy Research

Patient Information Sheet v 1.3 Adult (29/8/2012)

Introduction

We would like to invite you to become involved in a research database. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the project if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to become involved.

What is the purpose of the database?

Planning radiotherapy treatment uses a lot of information from scan images. Both CT and MRI scans are used to build a model of a patient within the computer, to plan radiotherapy treatment accurately. During the course of radiotherapy treatment, additional images and scans are used to check that treatment is being delivered accurately.

A lot of the research that is conducted in radiotherapy is aimed at developing new and improved ways to work with these images. Engineers, Physicists and Computer scientists work with clinicians to develop new ways to analyse image data. The aim is to make planning of radiotherapy treatment faster, develop new ways of delivering radiotherapy, or improve the way that we determine how well radiotherapy has worked.

In order to make sure that these new techniques work properly, researchers must test their code on real patient data. Without this step, it is not possible for new image processing techniques to be used for patient treatment. However, image data is patient data, and as such must be treated with the highest standards of patient confidentiality. This is a challenge for research. Researchers who wish to use image data from patients are required to seek the guidance of an ethical committee before proceeding with each proposed study. This process can be time consuming, especially if it needs to be repeated on many occasions.

The purpose of AIDA is to establish an archive of anonymised image data that has been donated by patients, for use exclusively within radiotherapy research. AIDA is a framework where donating patients can provide consent for their images to be anonymised and added to the archive. It describes the procedures and policies that will be held in place to maintain data security, and to define who has access to the data. The ultimate aim of the project is to promote radiotherapy image research for patient benefit.

Why have I been invited?

You have been invited to participate in this database because you are either receiving, or have completed a course of radiotherapy treatment. The information used to plan your treatment could be added to the archive of planning information available for this database.

Do I have to take part?

It is up to you to decide. We will describe the project and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

Your specialist will proceed with the process of planning your radiotherapy treatment, if this has not already been performed. The scans produced during your treatment will be anonymised, and stored in a secure database. In the future, a researcher who wishes to use your scans will apply to the AIDA project team to gain access to the data.

You will continue to be followed up by your physician in the normal way. No extra clinic appointments or visits to hospital are required.

Will the database store any information about me?

The database will not store **any** identifiable information. The project team will allocate you a unique study number which they can use to identify your scans within the database. Researchers will access the database via this study number, but will have no way of tracing this number back to you. The only other information that will be stored in the database is information about the type of tumour that you have.

What will I have to do?

You will not need to do anything. This project is just asking permission for your treatment planning data to be anonymised and added to the database. Once you have provided consent, your treatment will proceed in the normal way.

What are the possible disadvantages and risks of taking part?

As the database is simply collecting information from your treatment planning, we do not envisage any health risks associated with the database. The security of your personal data is incredibly important to us, and all the information sent to us is anonymised before being placed into the database archive. We will only accept electronic secure transfer of this information, using military strength encrypted data links.

What are the possible benefits of taking part?

The project is not aiming to help you as an individual. The aim of the project is to develop new techniques for radiotherapy treatment in the future.

It is possible that analysis of your data may produce extra information. If this happens, the AIDA project team will feed this information back to your Consultant, although it is important to understand that the analysis of your data is likely to be at an experimental stage.

What happens when the research project stops?

We will keep your information until the end of the project, and for a period of 15 years. There are new developments in radiotherapy treatment planning which are in the pipeline, and your planning information will be used to assess these new techniques in the future.

What if there is a problem?

If you have a concern about any aspect of this project, you should ask to speak to the researchers who will do their best to answer your questions. You can contact Dr. Jena, the principal investigator, on 01223 336800. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure.

It is not anticipated that anything would go wrong and for you to be harmed in this study, as it is a database for collecting images. However, in the very rare event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cambridge University Hospitals NHS Foundation trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my taking part in this project be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves your hospital will have your name and address removed so that you cannot be recognized.

What will happen to the results of the project?

Research developed using data from this database will be presented in radiotherapy conferences and scientific publications. We will also post information on the study web site at www.camradiotherapy.org.uk/aida. You will not be identified in any report or publication relating to this database.

Who is organising and funding the research?

The project is organised by Dr Rajesh Jena, Consultant in neuro-oncology at Addenbrooke's Hospital.

Who has reviewed the project?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This project has been reviewed and given favourable opinion by Cambridge Central Research Ethics Committee.

Further Information and contact details

If you do have any general questions about the study, please speak to your own specialist.

If you require more information, please contact the project lead (Dr Rajesh Jena) on 01223 336800 or email rajesh.jena@addenbrookes.nhs.uk.

To speak to someone if you are unhappy with the study, call Addenbrooke's Patient Advice and Liaison Service (PALS) on 01223 216756.

Thank you for taking time to learn about our study.