

Anonymous Image Data Archive

Project Protocol 1.3 29th August 2012

**Background**

AIDA (anonymous image data archive) is a research database project which will construct an archive of radiotherapy related image data for use in radiotherapy research, for which consent has been obtained from the patient.

Advanced radiotherapy treatment is heavily dependent on the use of patient imaging. Diagnostic CT and MRI scans are used to generate virtual representation of the patient in computerised treatment planning systems. These images are used to plan high precision radiotherapy treatment. Once treatment has commenced, images are generated by the treatment machines in order to verify the accuracy of treatment delivery. On completion of radiotherapy treatment, patients may undergo further imaging in order to confirm response of the tumour to radiotherapy. For each patient passing through their treatment journey, a wealth of image information is generated.

Radiotherapy research is dependent of the development of new techniques to process images. Engineers, Physicists and Computer scientists work with clinicians to develop new ways to analyse image data. The techniques may lead to tools that accelerate the process of radiotherapy treatment, or may even present new ways of delivering treatment and assessing treatment response.

In order to validate these new techniques, researchers must test their code on real patient data. Without this validation, it is not possible for new image processing techniques to enter into clinical practice. However, image data is patient data, and as such must be treated with the highest standards of patient confidentiality in the hospital. This generates 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.

The purpose of AIDA is to establish an archive of anonymised image data that has been donated by patients, for use within radiotherapy research. It presents 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 manage access rights to the archive in a transparent fashion. The ultimate aim of the project is to promote radiotherapy image research for patient benefit by publishing results in high quality peer reviewed journals.

Access to data in AIDA will be defined according on one of three roles:

* Project team. Members of the project team would have full access to data for audit and governance purposes.
* Clinical researchers. Clinical researchers are Doctors, Radiographers, Nurses and Physics staff based in the Department of Oncology with access to clinical information systems. Appropriately trained research staff would be responsible for obtaining consent from patients wishing to donate data to the database. Clinical researchers may also have their own research projects and be granted access to anonymised data held on the AIDA database.
* External researchers. External researchers are collaborators in research projects who do not work within the Department of Oncology, but are based within the NHS or a UK academic institution. The AIDA database presents these researchers with a valuable source of anonymised patient data, that can be used for development of new image processing techniques. External researchers would be required to submit a brief research proposal and comply with the research governance rules of the project.

Another important benefit of the AIDA database would be for teaching outside the hospital. A number of multiprofessional teaching courses are run by the project team, and the availability of an anonymised image database would greatly enhance these activities.

**Project objectives**

The objectives of the project are:

* To establish an ethical and legal framework for anonymous image donation by patients receiving radiotherapy in Cambridge University Hospitals NHS Foundation trust
* To establish working practice for acquisition, anonymisation, storage and curation of these images in an archive.
* To use these data to produce high quality research for publication in peer reviewed journals

**Project Design**

The study is an information gathering exercise and is therefore statistically unpowered. No patient intervention is required for this project, as only existing radiotherapy treatment and diagnostic imaging data from the referring clinician will be used. The study is process-mapped in Figure 1. It is envisaged that the study will run over a period of five years.

**Patient Selection Criteria**

Part of the project objective is to develop an archive of cases that highlight the difficulties in advanced radiotherapy treatment within current clinical practice. For this reason, all patients who are deemed suitable for radiotherapy by a referring radiation oncologist will be eligible for the project. As this is a statistically unpowered data collection project, no formal size has been defined on the total number of patients.

**Methodology**

**Process map**

The AIDA project process map is as follows:



**Image Data transfer**

Information security is of paramount importance in this project, and no physical data transfer media (hard drives, CD Roms, Memory sticks) will be permitted for data sharing. The patient’s treatment will be planned in the normal way by the referring team, and a copy of the planning data (DICOM images, Planning CT, Dicom RT Structure set and dose) will be anonymised at source. A tool for replacing patient identification data with a study number will be utilised by the project team for this purpose. The data storage will exist on the radiotherapy data network in the Oncology Centre.

Data transfer outside the radiotherapy network will be conducted using a fully encrypted 128 bit SCP / SFTP (Secure Communication Protocol / Secure File transfer Protocol). Electronic access will only be provided to hosts residing on the NHS N3 secure network or the University & Research Councils joint academic network (JANET). The communication and transfer protocol exceeds that of established links for the transfer of PACS data between institutions, and is the highest grade of encryption available for non-military use. In order to establish the clinical context of the images, the image data will be accompanied by anonymous clinical information:

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| --- | --- | --- |
| Patient demographics* Patient referral number
* Age
* Gender
 | Clinical details* Diagnosis
* Stage
* Previous treatment
* Response to treatment
 | Planning details* Defined regions of interest
* Desired dose for targets (optional)
* Maximum dose for critical normal structures (optional)
* Plan statistics (Dose Volume Histogram Data)
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**Access control to data**

The access control system will maintain a log of access requests for research projects, linked to the data sets that have been released to each project. Patients will be able to view their donated image data, together with details of all projects which have been granted access to their data. Researchers will be required to submit a brief description of the project for which image data is requested, together with a citation list for any dissemination of the project. Authorisation for data access will be given by the AIDA project team.

**Treatment planning & dosimetry studies *(applies only to clinical researchers)***

Some of the research studies will involve treatment planning research, where existing data files for radiotherapy treatment planning reside on clinical information systems, and would be extended by the inclusion of additional planning structures of radiotherapy treatment plans. This research by necessity involves access to patient identifiable data residing within the clinical information systems. Such research studies would only be conducted by clinical researchers within the department. Where such research studies are to be conducted, the completed planning data sets would be anonymised and transferred into the AIDA database. Subsequently, access to data for dissemination or publication would only be permitted via the AIDA database.

**Project Outcome Measures & Goals**

This is a data gathering study for hypothesis generation. Project endpoints will include research presentations, publication in peer-reviewed journals.

**Project size**

This is an information gathering project with no intervention and is therefore statistically unpowered. We propose to establish a clinical pathway where the offer of recruitment of patients into the AIDA database will become part of the normal practice. We anticipate recruiting 1000 patient data sets over the five year period. We believe that this can be achieved easily, by involvement of the multidisciplinary radiotherapy team into the AIDA project (*vide infra*).

**Obtaining consent**

In order to streamline the process of adding patients to the AIDA database, we envisage utilising our multidisciplinary team to discuss and obtain consent at various potential points in the radiotherapy treatment pathway. For example, a patient may discuss the project with their clinician, receive project information from a clinical nurse specialist, and be consented for the project before their planning CT scan by a therapy radiographer. We will use poster materials (appendix 1) within the department waiting areas and display boards to inform patients of the project. Patients will be given a copy of the appropriate information sheet (adult & child versions are available, appendix 2) and consent for the project will be obtained by the referring physician or a member of the project team (appendix 3).

**Project Team**

The principal investigator of this project will be Dr Raj Jena, Consultant Oncologist at Addenbrooke’s Hospital. Co-investigators will include Mr Michael Simmons (Project Coordinator, University of Cambridge Centre for Scientific Computing), Dr. Andrew Hoole (Head of Computing, Department of Medical Physics, Addenbrooke's Hospital), Dr. Charlotte Coles (Clinical Trials Lead for Radiotherapy) and Dr Neil Burnet (Academic Radiotherapy). The project team will be supervised by the Cambridge Clinical Trials Centre staff.

**Ethics Considerations**

Local ethics committee approval will be obtained for this project. This is a data collection project which does not involve any patient intervention, so no specific ethical difficulties relating to the primary objective are envisaged.

We do propose to use poster materials and electronic display boards to notify patients about the project. These materials will be submitted for review to the Trust PALS office and discussed with a patient information advisory group (PIAG) for equipoise and transparency.

**Research Governance & Finance Issues**

This research will be supervised by the staff of the Cambridge Clinical Trials Centre, and Cambridge University Hospitals NHS Foundation trust will act as sponsor for the research. Consumables costs for the project will be met from the Principal Investigator’s research fund.

**Project Dissemination**

The project will have a patient facing web site at www.camradiotherapy.org.uk/aida outlining project progress and any milestones.

Projects disseminating results from image analysis will be required to submit details to a dissemination log.

 **Safety Considerations**

This is a data collection project which does not involve any patient intervention, so no specific safety considerations are envisaged. The research governance aspects of the project will be monitored by the Cambridge Clinical Trials Centre staff.

**Appendix 1 : AIDA poster for display in department**



Appendix 2 : Patient Info Sheet (Adult, Parent & Child)

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 useing 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](http://www.camradiotherapy.org.uk/participate). 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.*

Appendix 2 : Patient Info Sheet (Adult & Child)

AIDA : Anonymous Image Data Archive for Radiotherapy Research

**Patient Information Sheet v 1.0 TYA (3/4/2012)**

**Introduction**

We are trying to build a database of scans from people who have completed radiotherapy. The scans will be used in research projects to try and improve the way in which we deliver radiotherapy. The scans are anonymised before they are placed in the database.

Before you decide if you want to join in it’s important to understand why the research is being done and what it will involve for you. So please consider this leaflet carefully. Talk about it with your family, friends, doctor or nurse if you want to.

**Why are we building this database?**

We use a lot of image data to prepare radiotherapy treatments, and to find out how well the treatment has worked. New radiotherapy treatments are being developed all the time. The researchers working on these developments need to test their work on real patient data to ensure they perform properly. Each researcher has to go through a very long process to obtain permission to use real patient data. It takes many months, often longer than it took them to develop the new technique in the first place. Many researchers find this difficult, but without this step, they are not allowed to publish their results. By building a database of scans, which have been donated to research by patients, we make it much easier for researchers to get access to the data they need. This is the reason we are developing AIDA as a research database.

**Why have I been invited to take part?**

You have been invited to participate in this project because your specialist has recommended that you have radiotherapy treatment, or you have already completed radiotherapy treatment. The information used to plan your treatment could be added to the database of information used in this project.

**Do I have to take part?**

No. It is up to you. If you do, your doctor will ask you to sign a form giving your consent or assent. You will be given a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive.

**What will I have to do?**

**You will not need to do anything.** We are asking permission for your scans to be anonymised and added to the study database. Once you have provided consent to this study, your treatment will proceed in the normal way.

**Will the database store any information about me?**

The database will not store **any** information that identifies you such as your name, date of birth or hospital number. The project team will make 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.

**Is there anything to be worried about if I take part?**

As the database is simply collecting information from your treatment planning, we do not see any health risks in this study. The security of your personal data is incredibly important to us, and all the information sent to us is anonymised at source.

**What are the possible benefits of taking part?**

We cannot promise the database will help you but the information we get might help treat young people who need radiotherapy in the future.

**What happens if new information about my tumour comes along.?**

If a research project produces new information about your tumour, the information will be given to your specialist. Please remember that the information is generated by an experimental technique and must be treated as such.

**What will happen if I don’t want to carry on with the project?**

You can withdraw from the project whenever you wish. This would not affect the treatment you receive.

**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, you can do this through the NHS Complaints Procedure. This project will build a database of patient images and is unlikely to cause you harm. If in the very 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 anyone else know I’m doing this?**

Your name and personal details will be removed from the information before it is placed in the database. We will keep your information in confidence.

**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?**

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. This project has been checked by the Cambridge Central Research Ethics Committee.

*Thank you for reading this- please ask any questions if you need to.*

Appendix 3 : Consent form

Patient Number \_\_\_\_\_\_\_

**CONSENT FORM (Adult)**

**AIDA : Anonymous Image Data Archive for Radiotherapy Research (v1.3 29/8/12)**

Name of Researcher: Dr R Jena

 **Please initial here**

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| --- | --- |
| I confirm that I have read and understand the information sheet dated March 2012 (version 1.3) for the above database. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. |  |
| 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. |  |
| I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.  |  |
| I agree to take part in the above database. |  |

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Name of Patient Date Signature

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Name of Person taking consent Date Signature

(if different from researcher)

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Researcher Date Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

Patient Number \_\_\_\_\_\_\_

**CONSENT FORM (Parent / Guardian)**

**AIDA : Anonymous Image Data Archive for Radiotherapy Research (v1.3 29/8/12)**

Name of Researcher: Dr R Jena

 **Please initial here**

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| --- | --- |
| I confirm that I have read and understand the information sheet dated March 2012 (version 1.3) for the above database. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. |  |
| I understand that my child's 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. |  |
| I understand that relevant sections of any of my child's medical notes and data collected during the study, may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.  |  |
| I agree to my child taking part in the above database. |  |

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Name of Patient Date Signature

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Name of Person taking consent Date Signature

(if different from researcher)

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Researcher Date Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

Patient Number \_\_\_\_\_\_\_

**ASSENT FORM (Child / TYA)**

**AIDA : Anonymous Image Data Archive for Radiotherapy Research (v1.3 29/8/12)**

Name of Researcher: Dr R Jena

 **Please initial here**

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| I confirm that I have read and understand the information sheet dated March 2012 (version 1.3) for the above database. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. |  |
| 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. |  |
| I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.  |  |
| I agree to take part in the above database. |  |

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Name of Patient Date Signature

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Name of Person taking assent Date Signature

(if different from researcher)

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Researcher Date Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes