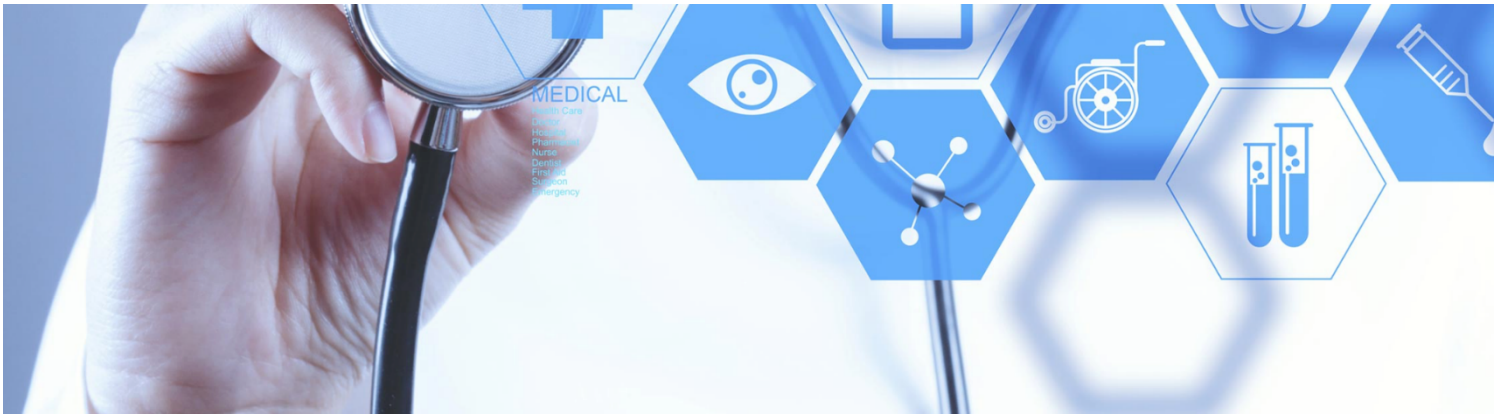
The Research Registry®
Guidebook



April 2018

www.researchregistry.com

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Section 1: Registering a study on the Research Registry®

An Introduction to the Research Registry®

The Research Registry® is a one-stop shop for registering all types of research studies, from 'first in man' case reports to observational/interventional studies to systematic reviews and meta-analyses. Whilst the focus in the past has been on registering randomised controlled trials (RCTs), there has been tremendous growth in observational studies, many of which are not registered. Whilst some trial registries do allow for the registration of observational studies, only a small fraction are actually registered. However, the World Medical Association's Declaration of Helsinki 2013 provides a strong ethical mandate for registering all types of research studies, not just trials. At the Research Registry, we accept all types of research studies involving human participants. The process is simple, easy and takes less than five minutes. As of March 2017, we have received over 1900 registrations, with over 4 million patients registered from over 80 different countries.

Support and endorsements

The Research Registry® has received an endorsement from the IDEAL Collaboration, the group working to improve the quality of surgical research and is a member of the Health Research Authority's Research Transparency Forum. The Research Registry is also a supporter of the AllTrials Campaign.

Data security

The Research Registry® is built around a cloud infrastructure designed to maximize availability, reliability, and security. A full list of the systems used for data security measured are given below:

- Data Storage: MongoDB
- Data Encryption: all data transfer is encrypted with SSL at each transfer stage.
- Data Indexing: Solr
- Application Rendering: JavaScript
- Application Processing: Node.js
- Servers: Amazon Web Services (cloud computing services)
- Redundancy: All of the application rendering and processing is done with failover and load balancing in place. The Mongo data stores are replicated on additional servers in different locations for higher availability.
- Backups: Multiple backups of all app data are securely made daily to both on and offsite locations.

Scalability: We use a distributed cloud-based system, which means that scalability can be achieved by simply adding capacity as needed. Record size or bandwidth usage has no impact on performance.

What kind of studies are registered on the Research Registry®

The Research Registry® invites registration of any study type involving human participants. The only study types not included in the Research Registry® are case reports that are not first-in-man and animal studies. If your study is deemed inappropriate, it will be removed through the weekly data curation process.

Curation policy

Data curation takes place on a weekly basis through a rota. Curators report the anomalous registration identification code to the Director, Riaz Agha, who reviews the information and take action as appropriate e.g. remove the entry. Data curators assess registrations for the following:

1. Duplicates
2. Animal studies
3. Case reports that are not 'first in man'
4. Bizarre, inappropriate or spam entries
5. Any other relevant issue – e.g. blank mandatory fields

Accessing and filling out the registration form

The registration form can be accessed here after creating an account on the Research Registry® website. Simply enter the required fields and click to complete your registration.

Can I update or amend my registration?

It is possible to amend a registration on the Research Registry® after a registration is made. Simply log-on, access your registration and edit. This is designed to enable uploading of results, or updates to the research study as it progresses.

Section 2: Rationale for the Research Registry®

The World Medical Association's Declaration of Helsinki 2013 states in article 35:

Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

Practical and scientific benefits to registering research include:

- Reduce unnecessary duplication preventing wasted effort and precious research funds
- Encourage global collaboration between researchers
- Increase transparency
- Improve quality and allow study reports to be compliant with established reporting criteria
- Allow peer-reviewers to compare the manuscript findings with the registered study
- Help shed light on negative studies and thus reduces reporting or publication bias
- Aid patients and encourages patient/public participation in research
- Aid clinical decision-making
- Aid guideline development
- Aids the wider scientific and scholarly community by allowing for open and early peer-review of study objectives and methods, allowing for adjustments and refinement and to ensure the question asked is the right one.
- Aids commissioners and funders of research allowing them to identify ongoing studies in their field of interest

Why register your study with the Research Registry®

- Register a wide range of study types - more comprehensive than any other registry
- Quick, simple and easy to use
- Immediate registration
- Allows prospective and retrospective registration
- Curated weekly by our expert team
- Add images, video, tables as well as text to describe your intervention
- Conforms to WHO requirements and international reporting guidelines

Section 3: Guide to completing a registration

This section provides a brief description of each item on the Research Registry® dataset, and an example of each. Please note that these have not been adapted for registration of a systematic review or meta-analysis to the Research Registry®, which must be registered in the appropriate section of the website. Mandatory fields are indicated with an asterisk: *

Prior to making a registration, please create an account on www.researchregistry.com. ***This will require entering your email address and choosing a password.***

Item of dataset	Description and *Example*
Title of research	Include a concise and informative title for the research study. We recommend that you include the study type in the title: *Use of Autologous Fat Grafting for Reconstruction Post-mastectomy and Breast Conserving Surgery: A Systematic Review Protocol*
Key research questions and objectives	Specifically, and concisely, outline the main questions your research study aims to answer, and the objectives you seek to meet. These may be included as a list, or in prose: *How much of a role does the consumption of red meat have in developing colon cancer in adults over the age of 65?*
Lay summary	Please describe your project in simple terms avoiding scientific jargon allowing the public to understand the aims, methods and (if completed) results of the research study: *Craniosynostosis is a term for the early fusion of the bones of the skull in babies. Surgical treatments use plates and screws that can cause complications. We propose a new surgical technique, cranial orbital buttress (COB) to remodel the early fusing of bones without the need to use expensive hardware. We have utilised this method on 79 individuals and subsequently recorded any complications after the operation.*

Study type	Please choose one of the following options which best describes your research study: *Randomised Controlled Trial; Non-randomised Trial; Prospective Cohort; Retrospective Cohort; Before and After Study; Cross-sectional Study; Diagnostic Study; Economic Evaluation; Tumour Marker Prognostic Study; Case-Controlled Study; Case Series; Feasibility Study; Quality Improvement Study; IDEAL Stage 1-4; Audit; Other*
Study type (if other is selected above)	Please indicate the type of study to be registered if *Other* was selected as your primary study type: *Protocol*
Primary investigator	State the full name of the primary investigator responsible for the research project. This is not necessarily the same investigator who makes a registration: *Alexander J Fowler*
Other investigator	State the full name of the second investigator responsible for the research project. This must be different from the primary investigator: *Riaz A Agha*
Additional investigators	Please list all the other investigators involved in the research. Include full names, and separate the names of the investigators using semi-colons: *Daniyal Jafree; Reem Farwana; Harkiran Sagoo*
Participating institutions	State the address of the participating institutions involved in this research. These may be the affiliations of each of the investigators of the research study: *King's College Hospital, London, UK*

Contact details for public / scientific enquiries	Please give the most convenient contact details through which you may be contacted regarding your registration. Please be aware that this will be publically accessible, once registration is made: *Organisation's address: 123 Hammersmith Road, London, AA01 2AA; Organisation's number: 012 3456 7891*
Email	Please enter a valid email address. You may be contacted for public and scientific enquiries, or asked for feedback about your experience of the Research Registry®: *johnsmith@example.com*
Countries of recruitment	Please list all countries from which participants were recruited for the research study: *United Kingdom, China*
Health condition or problem studied	Please provide a short description of the health condition, domain or disease being investigated by the research: *Acute kidney injury*
Patient population	Please describe, briefly but succinctly, the patient population studied by the research: *Males between 45-60 years of age with a diagnosis of colorectal carcinoma made after January 2014*
Intervention(s) – please describe in detail	Please describe, in as much detail as is relevant, the intervention, test or investigation being studied by the research. For novel interventions, a detailed description is required
Inclusion criteria	Please list all the criteria required for inclusion of a participant in the research study

Exclusion criteria	Please list all the criteria required for exclusion of a participant in the research study. This will include missing patient consent
Control or comparator	If applicable, please provide details about the control population, or the comparative intervention applied to the participants in the research study
Primary outcome(s)	Please list the primary outcomes(s) which the study sought to determine. This should include the outcome measure, how the outcome was measured and how long the outcome was measured for after commencement of the study: *HIV retroviral RNA, measured by RT-qPCR from isolated blood samples, two months after the administration of acyclovir*
Key secondary outcomes	As the primary outcome, please list the secondary outcomes which the study sought to determine. This should also include the outcome measure, how the outcome was measured and how long the outcome was measured for after commencement of the study
Target sample size	Please indicate the number of participants required for the research study. If possible, please also indicate a justification of the sample size: *72,*
Recruitment status	Please select the stage at which your study was at the time of registration. Select from the following list: *Planning; Enrolment started; Enrolment completed; Enrolment on hold (please specify below)*
Other recruitment status	If *Enrolment on hold (please specify below)* was selected for Recruitment status, please indicate in detail the stage of the research study at the time of registration

Date of first enrolment	Please indicate the date upon which the first participant was or will be recruited to the research study. Include date, month and year
Date enrolment expect to complete / completed	Please indicate the date upon which the final participant will be recruited to the study. If the study is being retrospectively registered, please indicate the final enrolment date. Include date, month and year
Date research expected to be completed (or date complete)	Please indicate the date upon which the research study was deemed to be completed, or is expected to be completed by the investigators. Include date, month and year
Link / reference / DOI or protocol and / or full paper once published	Once the research study been published, please provide a link to the protocol or paper. If possible, please include identifiable information, such as DOI or PubMed ID
Ethical Approval	Please indicate the current status of ethical approval for the research study. Select from the following list: *Granted, Pending, Not Needed*
Ethical Approval Judgement Date and Reference / If not needed, why not?	Please provide further details about the ethical approval, including the date of approval and a reference code for approval. If *Not Needed* was selected for Ethical Approval, please justify this here
IRB or Ethical Committee Judgement (upload file)	Please upload the IRB of Ethical Committee Approval here. Commonly used file types are preferable i.e.: *.doc, .docx, .pdf*

Sources of monetary / material support	Please declare all support, both funding and material, required for the completion of the research study. If appropriate, please include conflicts of interest here
Research study website	If the research study has an associated website, please provide a web link here
Open data – upload results (upload file)	In the interest of transparency, please upload your study results. Commonly used file types are preferable.: *.xslx, .spss*
Post study results (once available)	We strongly encourage investigators to state the results of the research study, after the completion of the study and acquisition of data.

Section 4: Guide to editing a registration

The Research Registry® gives the ability to edit and amend your own registrations, once they have been made. The three steps in this section serve as a guide of how a registration can be edited. Please note that all amendments to a registration will be automatically documented in an Edit Log, which other users will be able to view.

Step 1

Once your registration has been created, log-on to your account on the Research Registry®. Click on the *User – Research Registry* tab to access all your registrations. Note and click upon the *Edit* function of the registration you would like to amend.

Step 2

Date research expected to be completed (or date completed if already done so) *

01/08/2017

IRB or Ethical Committee Judgement

Choose file No file chosen

Ethical Approval *

Granted

Ethical Approval Details - Judgement Date and Reference/If not needed - why not? *

Test

Source(s) of Monetary or Material Support *

Test

Research Study Website

Open Data - upload your results data if you wish

Choose file No file chosen

Link/Reference/DOI of Protocol and/or full paper once published

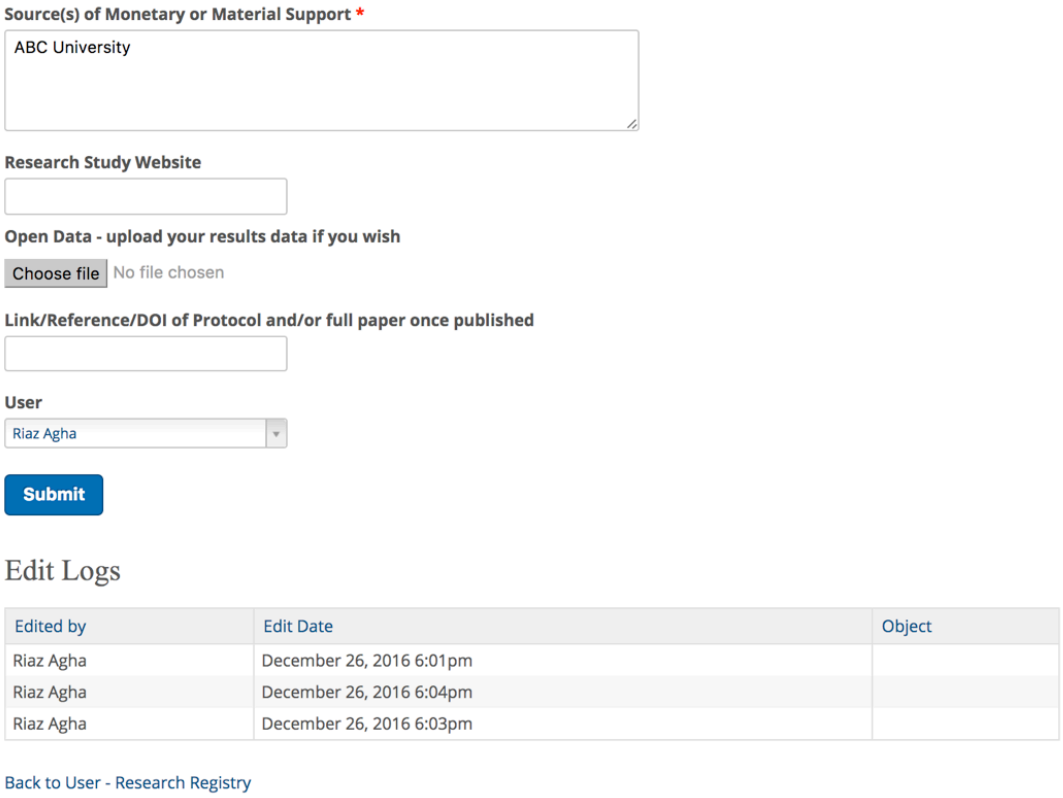
User

Riaz Agha

Submit

Once selected, you can edit your registration appropriately. As per initial registration, complete each section on the Research Registry® form as appropriate.

Step 3



Once all appropriate parts of the form have been edited, scroll down and click *Submit*. Your amendment will appear on the Edit Log, including the name of the Editor and the Edit Date.