

The Twin Research & Genetic Epidemiology Unit (TRU) Policy Document for Collaboration

Introduction

This document summarises the management and policies of the Twin Research & Genetic Epidemiology Unit (TRU). The TRU is part of King's College London, based at St. Thomas' Hospital and part of Guys and St Thomas' NHS foundation Trust (GSTT). Further details of the TRU and the TwinsUK database can be found on our website (<http://www.twinsuk.ac.uk>). Briefly, around 10,000 twins are registered on our database, approximately equal numbers of identical (MZ) and non-identical (DZ) twins, predominantly female (80%) for historical reasons. Detailed physical, physiological, behavioural and lifestyle data have been collected from twin visits to the TRU and from self-administered questionnaires. In addition, DNA samples have been taken and the range of variables collected can be found on our website (see "phenotypes"). Genome wide linkage and association scans have been performed on a subset of our twins. All studies have ethical approval from GSTT Ethics committee.

Management

Professor Tim Spector is the **Scientific Director** of the TRU. The day-to-day running of the unit is the responsibility of the **TRU steering committee (TRUSC)**. The committee currently comprises Tim Spector (Director); Ursula Perks (Business Manager); Frances Williams (Senior Lecturer/Honorary Consultant); Kourosh Ahmadi (Senior Lecturer); Lynn Cherkas (Genetic Analyst) and Emad Qweitin (Database Manager).

The steering committee usually meets weekly to consider proposals and papers. If you would like them to consider a proposal for use of existing data or collection of new data or to approve a paper for submission, please follow the guidance below and send through your proposal or paper to the TRUSC e-mail address: lynn.cherkas@kcl.ac.uk or ursula.perks@kcl.ac.uk.

Collaboration – general issues

The TRU twin register is run as resource for the research community. The resource is set up as a **supported access resource** rather than as an open access resource. If you wish to work on the resource you should look at the study website which contains details of the resource (<http://www.twinsuk.ac.uk>). Please then complete a **TRU proposal form** (Appendix 1) describing your proposed collaboration and send the completed form to the TRUSC (lynn.cherkas@kcl.ac.uk or ursula.perks@kcl.ac.uk).

The TRU steering committee will review your proposal at their weekly meeting and then get back to you, usually within three weeks, to let you know if the collaboration is possible (i.e. does TRU have the relevant data or biological samples or can they obtain the data) and to provide advice on the next stages. If there is a possibility of overlap with other investigators or other groups are working on related topics then the TRUSC may put you in touch with these groups and invite you to discuss your ideas before you proceed with your request. The committee will also estimate the cost of the collaboration (see **Collaboration – costs and grants**).

If your proposal is accepted, our Grants Manager (Christel Barnetson) will complete a Transfer Information Form (TIF) and may contact you if further information is required. Once complete this will be passed on to the KCL Business team who will then contact your legal department with regard to the appropriate Contract. Please note – at this stage, negotiations will not be taking place between yourself and the TRU, but between the appropriate departments within KCL and your organisation. The agreement will be signed by these departments on behalf of yourself and the TRU. Once the agreement has been signed, KCL Business will send a copy to the TRU and the data/material will be released.

Depending on the nature of the collaboration, this contract will refer to:

- (i) **a data transfer agreement (DTA) for new or existing data only**
- (ii) **a material transfer agreement (MTA) for samples only or**
- (iii) **a Collaboration Agreement for new or existing data or samples, where further assistance may be requested for analysis or writing the paper.**

N.B. If both data and samples are requested, then more than one contract may need to be signed. Neither data nor samples (including DNA) will be released until all relevant forms have been completed and signed. Examples of a DTA, a MTA and a Collaboration Agreement are included in appendix 2, 3 and 4 respectively.

Collaborators will have six months of protected access from the point at which the relevant dataset is provided for use. After that period other investigators will be free to apply to use these data. Collaborators must return a copy of the final dataset used in their analyses along with derived variables and descriptions of these variables. We reserve the right to impose additional restrictions we feel are appropriate.

Collaboration - initial contact

The initial contact for any possible Collaborators interested working with the Twin Research Unit (TRU) will need to be made via contact with either Lynn Cherkas (lynn.cherkas@kcl.ac.uk) or Ursula Perks (ursula.perks@kcl.ac.uk).

Any proposals for collaboration will need to be made in writing using the **TRU Proposal Form** on the website (www.twinsuk.ac.uk), Appendix 1. The proposal will need to address the following areas:

- a. **Funding:** Where is the funding for the Collaboration coming from? Any funding which has been applied for, e.g. Grant funded via Wellcome, MRC, ARC, etc, will require a member of the TRU staff as a Co-Applicant
- b. **Ethical approval:** Ethical approval may be required from the Collaborators own Ethics Committee. A copy of the agreement letter –if relevant - will need to be included with the proposal. If necessary, the TRU will obtain Ethical Approval from their own Ethics Committee.
- c. **TRU resources required:** Are any additional staff (TRU own staff or via Collaborator placed at TRU) required in this Collaboration? Any request for data which directly involves the Twins, e.g. ECG, will be undertaken by the TRU staff. Funding for extra staff, resources and extra time will need to be available.

- d. Data: What data are required by the Collaborator? Is it for phenotypic data which are already available or to collect a new phenotype? Is genotype data required?
- e. Analysis: Is help from the TRU statisticians expected with the analysis of the data? If so, to what extent will help be required and over what time frame?

Collaboration – (i) analysis of existing data

Once the collaboration for analysis of existing data has been approved and the necessary contract/s signed (see **Collaboration – general issues**), the relevant data will be released and – if requested - advice on analysis of the dataset will be provided.

Depending on the size of the dataset required, files may be sent by email (password protected) or made available via our secure FTP site. In both cases, the Collaborator will require a password for access and the Collaborator will need to apply for the password in writing with the following information given:

- a. specify names of people needing access to the data
- b. average time access is required for, e.g. 6 month, 1 year.

The Password is not transferable and breach of this will result in termination of the Collaboration agreement. It is the responsibility of the Collaborator to inform the Twin Research Unit of any changes to persons working on the data.

Data quality and standards

All data are collected via standard SOPs which are adhered to by all staff involved in the data collection. This includes staff at the TRU as well as outside collaborators who may be involved in the data collection for a particular project. Information on phenotype collection is generally available from our existing publications which are available from our website or additional information is available on request.

- a. Intellectual property
Currently the IP rights for existing data from TwinsUK rest with KCL and Guys and St Thomas' NHS Foundation Trust. In the case of Intellectual property rights occurring as part of a research project, KCL enterprises will be happy to discuss sharing of rights and assist in advising on and preparing patent applications. However we are keen primarily to publish results as soon as possible.
- b. Protection of Research Participants
In order to assure confidentiality of our study participants is ensured at all times, we will only supply the data with relation to the study number and date of birth. If further information is required, this needs to be requested formally in the proposal form. All our twins are aware that the data collected from them may be shared with other research collaborators but the TRU has agreed to ensure that their personal data is kept confidential at all times.

c. Long-term preservation and sustainability

All data collected as part of a visit to TRU are identified by the date of visit, study type and the visit month and incorporated into our final databases only when checked and cleaned by our statisticians.

The TRU envisages that data will be made available to the research community at the earliest opportunity. Should there be any publications arising during the duration of the project, these will be made publicly available on the website as soon as they have appeared in press.

Collaboration – (ii) collection of new data

The TRU study team collect new data from the twins using self- completed questionnaires and TRU twin visits. These questionnaires and visits (often involving an overnight stay) require **funding** (see **Costs** section below) so where you have suggestions for new data collection you need to complete a collaborator's **Proposal form** (Appendix 1) describing your proposed collaboration and ensure you complete the specific sections on new data collection and send the completed form to the TRU steering committee (lynn.cherkas@kcl.ac.uk or ursula.perks@kcl.ac.uk).

If we approve your proposal, we will then complete and send to you the appropriate agreement form/s (see **Collaboration – general issues**).

Collaboration – (iii) assays on biological samples and genotyping

To use biological samples or to carry out genotyping on TRU DNA you need to complete the TRU **proposal form** (Appendix 1) describing your proposed collaboration. You must ensure you complete the specific sections on the biological samples and genotyping including details of the type of sample required, amount needed and in case of DNA the minimum concentration required. We will be unable to process requests which do not supply this information. Please send the completed form to the TRUSC, (lynn.cherkas@kcl.ac.uk or ursula.perks@kcl.ac.uk). If you would like further information about samples or laboratory procedures please contact the TRUSC. Decisions on the use of biological samples will take account of the amount of the stored sample required, the amount in storage and the perceived scientific value of the proposed study.

After a project is approved collaborating laboratories will need to complete either a Material Transfer Agreement (MTA) or Collaboration Agreement. This agreement will include a project specific appendix detailing the samples the TRU will supply and the analysis to be completed. Samples, including DNA, will not be released until an agreement has been completed and signed (see **Collaboration – general issues**).

Collaboration – costs and grants

TRU receives funding from the Wellcome Trust and other grant funding bodies to support core activities. This does not extend to support for individual projects and collaborators will be expected to meet additional costs. These will be determined on a project-by-project basis and will reflect only the true costs to the TRU of providing the resources requested (“cost recovery”). Once we have agreed that a collaboration can proceed we will let you know how much it will cost. We will also agree distribution of indirect income at this stage.

If you are submitting a grant to cover the costs of an agreed collaboration we require that you send the final copy of the grant including the finances for approval at least three weeks before the submission date. Proposals received less than three weeks before the submission deadline will not usually be approved. We are happy to provide a letter of collaboration once we have approved the collaboration and agreed the budget. For proposals to collect new data we prefer (unless there is a good reason) that a member of the TRUSC be a co-applicant so they can act as guarantor for the proposed new data. You should send us a copy of the award letter when you receive this and we will then arrange a start up meeting followed by annual review meetings to agree the objectives, timetable and staff required to meet the grant commitments.

If funding for the Collaboration is via a specific grant, the TRU will be set up as a sub-contractor to this grant.

Contact with twins

No collaborators are allowed to contact twins directly.. Only members of the TRU research team will be allowed to contact study participants directly and this can only be done in exceptional circumstances with the knowledge and approval of the TRUSC.

Confidentiality

Protecting the confidentiality of the twins is a primary concern of the TRUSC and the TRU research team.

Documentation

A description of the TRU resource is available on the study website (<http://www.twinsuk.ac.uk>).

Results of Collaboration - Authorship and publication

a. Any publications, abstracts, posters etc which have come out of the Collaboration will need to be sent to the TRUSC for approval, at least 30 days prior to the deadline of submission for papers - with a minimum of 7 working days for abstracts or posters

We expect to process all papers within two weeks of receipt. We read all papers to check confidentiality is protected; to ensure that the paper will not bring the study into disrepute; to try to identify overlap with other papers published or in preparation. We also provide advice and feedback to authors where we feel this may be helpful but our role is not primarily to provide formal peer review.

b. The TRU has the right to withhold permission of publication of the above and will give reasons for doing so.

c. Authorship on papers should follow standard practice. All publications should reflect the involvement of the TRU and if there has been a designated person involved in the collaboration, they should be included as a co-author.

d. Specific acknowledgement within the text is required. We have agreed a standard acknowledgements section that should be included as is or in a modified form to fit the journal requirements for all papers:

“We would like to thank the twins for their voluntary contribution to this research project. We would also like to thank the staff of the Twin Research Unit for their help and support in undertaking this project, especially staff in areas such as(if only specific area covered). The Wellcome Trust provides core support for TRU. This research was specifically funded by *<INSERT DETAILS FOR SPECIFIC PROJECT WHERE APPROPRIATE, including grant number>*.”

A checklist of requirements for papers using TRU data and containing appropriate text to insert is contained in “Papers checklist” (Appendix 5). A completed checklist should be included with each paper submitted for approval. Collaborators should send us copies of the final submitted draft and subsequent revised drafts. Collaborators should let us know when a paper is accepted and send through an electronic copy of the final published version. It is the authors responsibility to ensure papers are freely available for research funded by the Wellcome Trust and other funding bodies that require open access to publications arising from their funding. Authors are strongly advised to look at the following website on open access www.wellcome.ac.uk/openaccess. A list of publications arising from the study can be found on the TRU website (<http://www.twinsuk.ac.uk>).

Results of Collaboration - PR policy

All press releases on research arising from the study should be seen and approved by the TRUSC. We may decide to press release certain articles and will expect the lead author on the paper to agree the press release with the KCL public relations team and to be available to deal with media enquiries and interviews. We may also ask authors to prepare a précis of important papers to include in reports to funders and future applications for future core support.

Results of Collaboration - Intellectual property

Intellectual property rights belong to the TRU, King's College London. We will consider dividing intellectual property rights where collaborators will be making a particular contribution. Any such division must be considered and agreed before the collaboration starts.

Feedback

This policy was last updated in April 2008. We welcome feedback, comments and suggestions. Please send to lynn.cherkas@kcl.ac.uk or ursula.perks@kcl.ac.uk .

Appendices

Appendix 1 – TRU Proposal form

Appendix 2 – sample Data Transfer Agreement (DTA)

Appendix 3 – sample Material Transfer Agreement (MTA)

Appendix 4 – sample Collaboration Agreement

Appendix 5 – TRU Papers checklist