Data Access Policy

Department of Twin Research, King's College London

This document summarizes the management and data access policy of the Department of Twin Research & Genetic Epidemiology (DTR) to facilitate the sharing of data and material with the world scientific community

TwinsUK Resource Executive Committee
March 2018

TABLE OF CONTENTS

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Data Access committees

TwinsUK Resource Executive Committee (TREC)

Twin Advisory Panel (VAP)

Managing Ethico-social, Technical and Administrative issues in Data Access (METADAC)

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The Department of Twin Research & Genetic Epidemiology (DTR) Data Access Policy

DATA ACCESS GENERAL

Introduction

This document summarises the management and data access/sharing policy of the Department of Twin Research & Genetic Epidemiology (DTR). The DTR is part of King's College London, and it is based at St. Thomas' Hospital, part of Guys and St Thomas' NHS foundation Trust (GSTT). It encompasses the biggest adult twin registry in the UK (TwinsUK) with 13,000 twins used to study the genetic and environmental aetiology of age related complex traits and diseases. The cohort has extensive biological and questionnaire data available on several hundred phenotypes and it is one of the most genotyped in the world. Further details on the DTR and the TwinsUK cohort can be found on our website (http://www.twinsuk.ac.uk)

The DTR twin register is currently set up as a **supported access resource** for the research community rather than as an open access resource. All data access requests are overseen by the TwinsUK Resource Executive Committee (TREC).

We are currently working within the guidelines of the Wellcome Trust Open Access policy programme and an **open access** data download for selected phenotypes is directly available from the DTR website.

Maintenance of our cohort is funded by the Wellcome Trust. For more information please go to the Wellcome Trust website (www.wellcome.ac.uk)

Data Access– Overview

The department is looking to facilitate and encourage the access and sharing of data and material with the world scientific community in view to promote and contribute to further scientific research and generate new ideas and knowledge.

Specifically the Department of Twin Research is committed to currently supported access and full open access long term with the aim of:

I. Facilitating multidisciplinary research and general access to both phenotypic and genotypic data for a diverse set of clinically related traits

II. Publishing in peer reviewed journals as well as creating an open forum to interact with the scientific community

Cohort Description

Our cohort currently comprises 13,000 twins registered on our database, of which 7,000 are active participants aged 16 to 100 with approximately equal numbers of identical (MZ) and non-identical (DZ) twins. The cohort is predominantly female (80%) for historical reasons. Detailed collection of physical, physiological, behavioural and lifestyle data is carried out via twin visits to the DTR by a highly experienced clinical team. Self-administered questionnaires are also sent to the volunteers every six to twelve months. All studies have ethical approval from Guys & St Thomas' Trust (GSTT) Ethics Committee.

Data

We have collected extensive biological and questionnaire data on several hundred phenotypes related to common diseases or intermediate traits. The cohort is also the most highly and deeply genotyped twin resource in the world.

All applicants can access a list of phenotype descriptions held at the DTR via our website http://www.twinsuk.ac.uk/phenotypes.html

A summary of data available on a large number of twins is listed below:

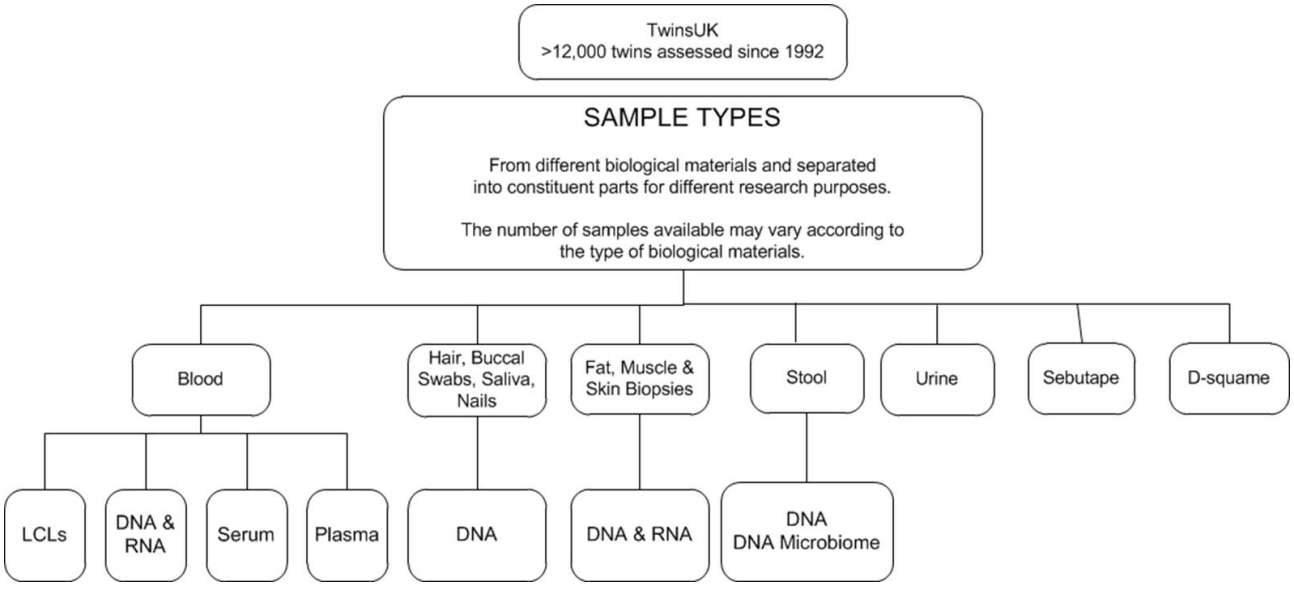


Figure 2 Biological samples

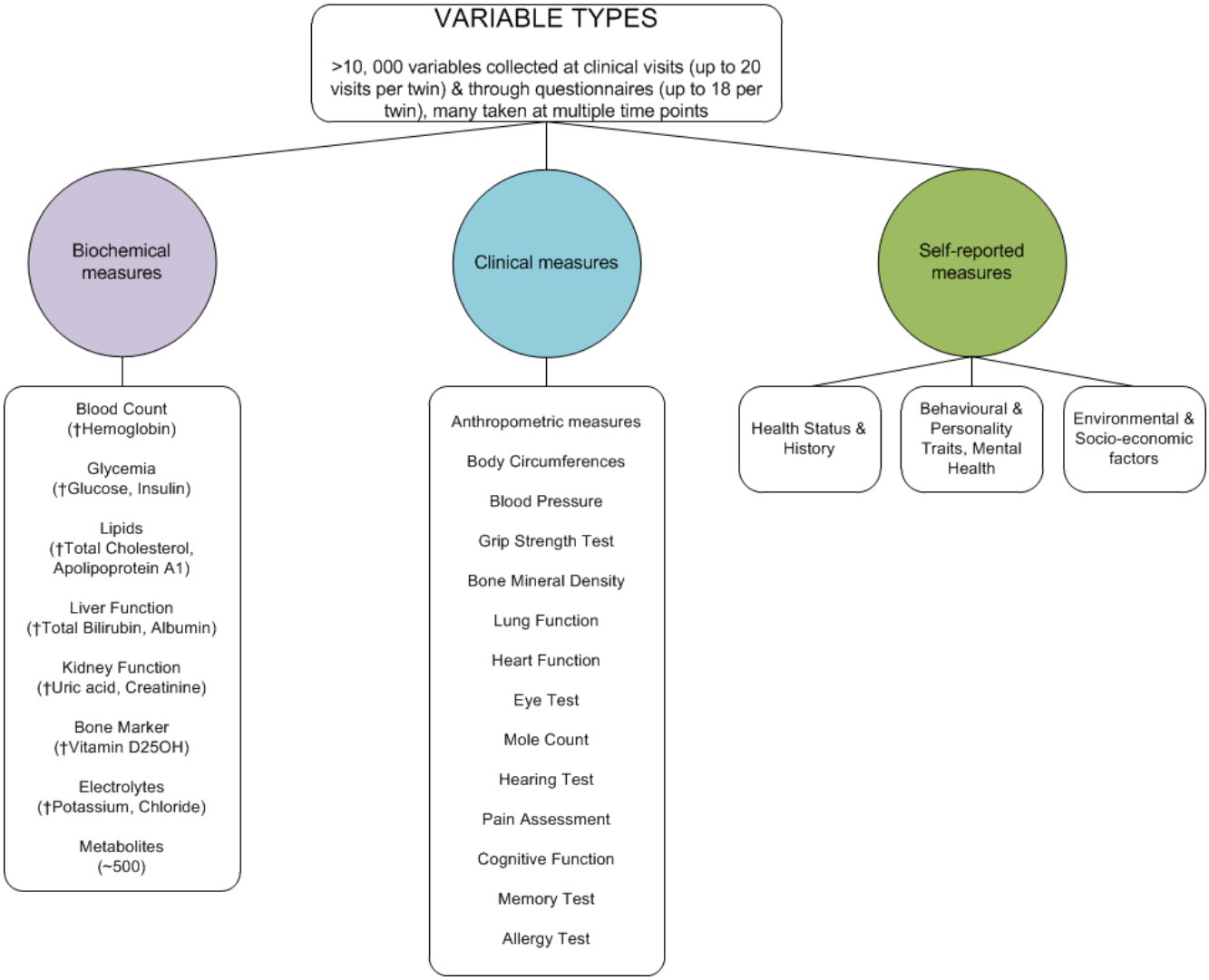


Figure 1 Phenotypic data collected during twin visits and self-reported questionnaires

As well as clinical data and self-reported data from questionnaires, the DTR has collected extensive molecular and biochemical data as summarised below.

<u>Genomic data</u>

- GWAS Illumina ~6000 twins
- Gene Expression ~850 twins (fat, LCL, skin)
- Sequence Data (Released through EGA)
- Metabolic Data (~6000 twins)
- Epigenetic (Med Seq and 450K)
- Immunophenotypes
- Microbiome
- Glycomics
- Omics
- Proteomics

Sharing of Data

The DTR would like to state that it cannot guarantee data exclusivity.

If there is a possibility of projects overlapping or other investigators/groups working on related topics, the TwinsUK Resource Executive Committee (TREC) may advise you to contact these groups and invite you to discuss your ideas before you proceed with your request. In certain instances where the applicant funds the collection of specific data, we will establish an embargo period to work exclusively on the data of either twelve months or after the first publication is accepted (whichever comes first) before the data are made available to other applicants.

Once Access to the data is granted, the data cannot be shared with third parties, including journals, without prior permission from the TwinsUK Resource Executive Committee

Management

Professor Tim Spector is the **Scientific Director** of the DTR and management of the department is the responsibility of the **TwinsUK Resource Executive Committee (TREC).** The committee currently is comprised of *Tim Spector (Director*); *Deborah Hart (Executive Director/Chair); Frances Williams (Senior Lecturer/Honorary Consultant); Massimo Mangino (Bioinformatician), Gabriela Surdulescu (Laboratory Manager), Chris Hammond (Frost Professor of Ophthalmology), Christel Barnetson (Finance Manager), Mario Falchi (Senior Lecturer), Claire Steves (Senior Lecturer), Darioush Yarand (IT Manager) and Victoria Vazquez (Collaborations and Data Sharing Manager)*

The TwinsUK Resource Executive Committee meets weekly to consider submission of data request proposals and papers. Decisions on the most complex proposals will be overseen by METADAC, Managing Ethico-social, Technical and Administrative issues in Data Access, which oversees our data requests. For more information on METADAC please refer to http://www.metadac.ac.uk/

Alternatively we may contact our Twin Advisory Panel (VAP). The VAP is a consultative body formed of twenty four pair of twins, identical and non identical, which aim to represent the views of the cohort. Further information on management of this committee can be found on http://www.twinsuk.ac.uk/collaborations.html

SUBMISSION PROCEDURE

Requests for collection of new or existing data/material should be processed by submitting a completed **DTR Data/Material Access Proposal Form** (*Appendix 1*) (also found on http://www.twinsuk.ac.uk/submission.html) describing your scientific proposition to the TREC.

The proposal should describe the hypothesis and specify the data and/or samples required clearly. Individual variables need to be listed with an appropriate justification describing the aims/hypothesis of the project for which the data is requested.

On completion, forms should be sent via email to the Collaborations and Data Access Manager, Victoria Vazquez (victoria.vazquez@kcl.ac.uk) who will then submit the forms for discussion at the next available meeting.

Data Access –Proposal Form

All the forms should have a comprehensible description of the below areas:

Science:
Describe clearly the hypothesis, methods and aims of the scientific project for which the data is required

Data:
List and describe clearly the data and samples required indicating if you require new or existing data, phenotypic or genotypic data and if so from which subset. Individual variables need to be specified.

Funding:
Please indicate the source of funding for the project. When considering applying for a grant, please specify if you require a member of the DTR to be a co-applicant.

Ethical approval:
Please indicate if you have ethical approval and provide us with the name of the Ethics Committee. If relevant a copy of the ethical approval letter will need to be submitted with the proposal. If necessary, the DTR will obtain ethical approval from their Ethics Committee.

DTR resources required:
Please indicate if additional DTR resources will be required in the form of statistical or logistical support and specify the level of support needed.

Data Access Request- Outcome

Upon submission of the Data/Material Access Proposal form, the TREC will review the proposal at their next weekly meeting and information on the outcome will be provided (approved, rejected or pending) within three weeks. You will be informed of the feasibility of the proposal and advice on the next stage will be promptly provided. The committee will take different factors into account when deciding the outcome of the data / access request:

1. Scientific and practical feasibility of proposed project
2. Costs that that the project may entail (see COSTS below)
3. Ethical approval for this project

Proposal Approved

Once the request is approved by the TREC you will be informed promptly by our Collaborations and Data Access Manager. As part of our cost recovery process a data sharing management fee would be applied and you will be asked to confirm agreement. Requests for biological data or new data, will require a material transfer agreement (MTA) between King's College London and the applicant's institution. The Collaborations and Data Access Manager will complete a Transfer Information Form (TIF) (*Appendix 2*) with details of your proposal and send it to the KCL Enabling Agreements Section team, who will then contact you or your institution's legal department to process the appropriate agreement. *Please note – at this stage, negotiations will not be taking place between yourself and the DTR, but between the appropriate departments within KCL and your organisation. The agreement will be signed by these departments on behalf of yourself and the DTR. Once the agreement has been signed, KCL Enabling agreements will send a copy to the DTR and the data/material will be released.*

Depending on the nature of the data/material access request this contract will refer to:

(i) **Transfer agreement for new data**
(ii) **Transfer agreement for new or existing biological samples**

Once the agreement is in place a representative from our Information Technology, Laboratory or Academic team will contact you to grant access to the data and/or material requested so you can start working on your project.

Requests for existing data will not require the implementation of an agreement between King's College London and your institution. The applicant is only required to sign the agreement section as indicated on the Data Request Proposal Form.

New data collection funded by the applicant is subjected to a twelve month protected period 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.

Applicants must return a copy of the final dataset used in their analyses along with derived variables and descriptions of these variables on completion of the project or after submission of first publication. **The data cannot be used for any other project or shared with third parties, including journals without prior consent from the TREC.**

Proposal Rejected

The DTR strives at all times to facilitate the sharing of data within the scientific community. However in a few cases data requests or proposals may be rejected or deferred.

Potential reasons for submission rejections are listed below:

I. The DTR does not store the data that the applicant requests

II. The DTR may reject requests for depletable resources when the scientific aims of the project do not justify this. This will mainly apply to biological samples requests

III. The request of data may be deferred, not rejected, in order to comply with the embargo period awarded to another previous request for the same data

IV. Collection of the requested data/samples conflicts with our duty of care to not overburden the twins. When applicable requests may be deferred to the GSTT ethics committee for their input and/or our Twin Advisory Committee (VAP)

A decision on data access rejections will be overseen by the METADAC oversight committee who will do an independent assessment of your application before a final decision is reached.

Proposal Pending

You may be asked to provide further information on your project so a decision can be reached if the initial information proved insufficient. When there is a possibility of overlap with other investigators or other groups are working on related topics, then the TREC may put you in touch with these groups and invite you to discuss your ideas with them before you proceed with your request.

Proposal – Proposed Audit

On project completion it is compulsory for every scientist using our data to send back to the DTR the list of new variables resulting from the project and a list of publications emanating from the research.

The DTR will contact you twelve months after approval of your submission and ask you to fill in an audit form (*Appendix 3*). This form will aim to ascertain if the project reached the targets listed in the initial proposal, expected date of completion, list of publications, and also a request to submit new variables resulting from the project to the DTR as well as scientific abstracts and press releases.

If the project has not been completed, a further audit form will be sent to you every six months until completion

The Audit Forms will be sent to you by the Collaborations and Data Access Manager.

TYPES OF DATA REQUESTS

(i) Analysis of Existing Data

Once the request for analysis of existing data has been approved and the necessary contract/s signed, 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 applicant will require a password for access. The applicant will need to apply for the password in writing providing the following information:

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 condition will result in termination of the relevant agreement. It is the responsibility of the applicant to inform the DTR of any changes to individuals working on the data.

(ii) Collection of New Data

The DTR study team collects new data from the twins via self-completed questionnaires posted or emailed to the twins and DTR clinical twin visits. These questionnaires and twin visits will require **funding** (see **Costs** section below) and a summary of costs will need to be revised and agreed by both parties before the new data collection can commence. Collection of new data via a questionnaire or clinical test will be coordinated by the DTR in order to guarantee the confidentiality of our twins. Further information on questionnaire guidelines can be found at http://www.twinsuk.ac.uk/collaborations.html

(iii) Assays on Biological Samples and Genotyping

To request biological samples or to carry out genotyping on DTR DNA you will need to provide us with 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. If you would like further information about samples or laboratory procedures please contact the TREC. 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.

It is our general policy that when DNA samples are requested for tests TREC requires that the test is extended to the full 6,000 samples stored in order to enhance the data to be of relevance to the wider community rather than a unique project and maximise the use of what is a depletable resource

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 DTR 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. Protection of Research Participants
In order to ensure confidentiality of our study participants is protected 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 DTR has agreed to ensure that their personal data is kept confidential at all times.

b. Long-term preservation and sustainability

All data collected as part of a visit to DTR 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 staff.

The DTR 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.

COSTS

DTR receives funding from the Wellcome Trust and other grant funding bodies to support core activities. This funding cannot be used for individual projects and all applicants will be expected to meet a mandatory project management fee for the sum of £700.00 plus VAT on all projects. Potential additional costs may apply depending on the nature of the project and the level of involvement required from the DTR team. These will be determined on a project-by-project basis and will reflect only the true costs to the DTR of providing the resources requested ("cost recovery"). Once we have approved a data request proposal 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 project 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 support for the proposed project described in your grant. On approval of the grant a formal data request needs to be submitted for consideration of the TREC. For proposals to collect new data we prefer (unless there is a good reason) that a member of the TREC 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 proposal is via a specific grant, the DTR will be set up as a sub-contractor to this grant.

CONTACT WITH TWINS

We have a duty of care to the twins and it is an ethical requirement that the twins are not overburdened. Therefore no applicants are allowed to contact twins directly. Only members of the DTR research team will be allowed to contact study participants directly and this will only be done in exceptional circumstances with the knowledge and approval of the TREC

CONFIDENTIALITY

Protecting the confidentiality of the twins is a primary concern of the TREC and the DTR research team. Therefore no contact or tracing attempts will be made or identifiable details passed to third parties

AUTHORSHIP AND PUBLICATION

a. Any publications such as papers, abstracts, and posters, which have arisen from the project for which data has been granted will need to be sent to the TREC 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 Department into disrepute; and 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 DTR 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 DTR and if there has been a designated DTR member of staff involved in the project, 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:

> *TwinsUK is funded by the Wellcome Trust, Medical Research Council, European Union, the National Institute for Health Research (NIHR)-funded BioResource,*

Clinical Research Facility and Biomedical Research Centre based at Guy's and St Thomas' NHS Foundation Trust in partnership with King's College London.

Applicants should send us copies of the final submitted draft and subsequent revised drafts as well as inform us when a paper is accepted. An electronic copy of the final published version will be requested for our records. It is the author's 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 DTR publications to date can be found on the DTR website http://www.twinsuk.ac.uk/publications.html.

PR POLICY

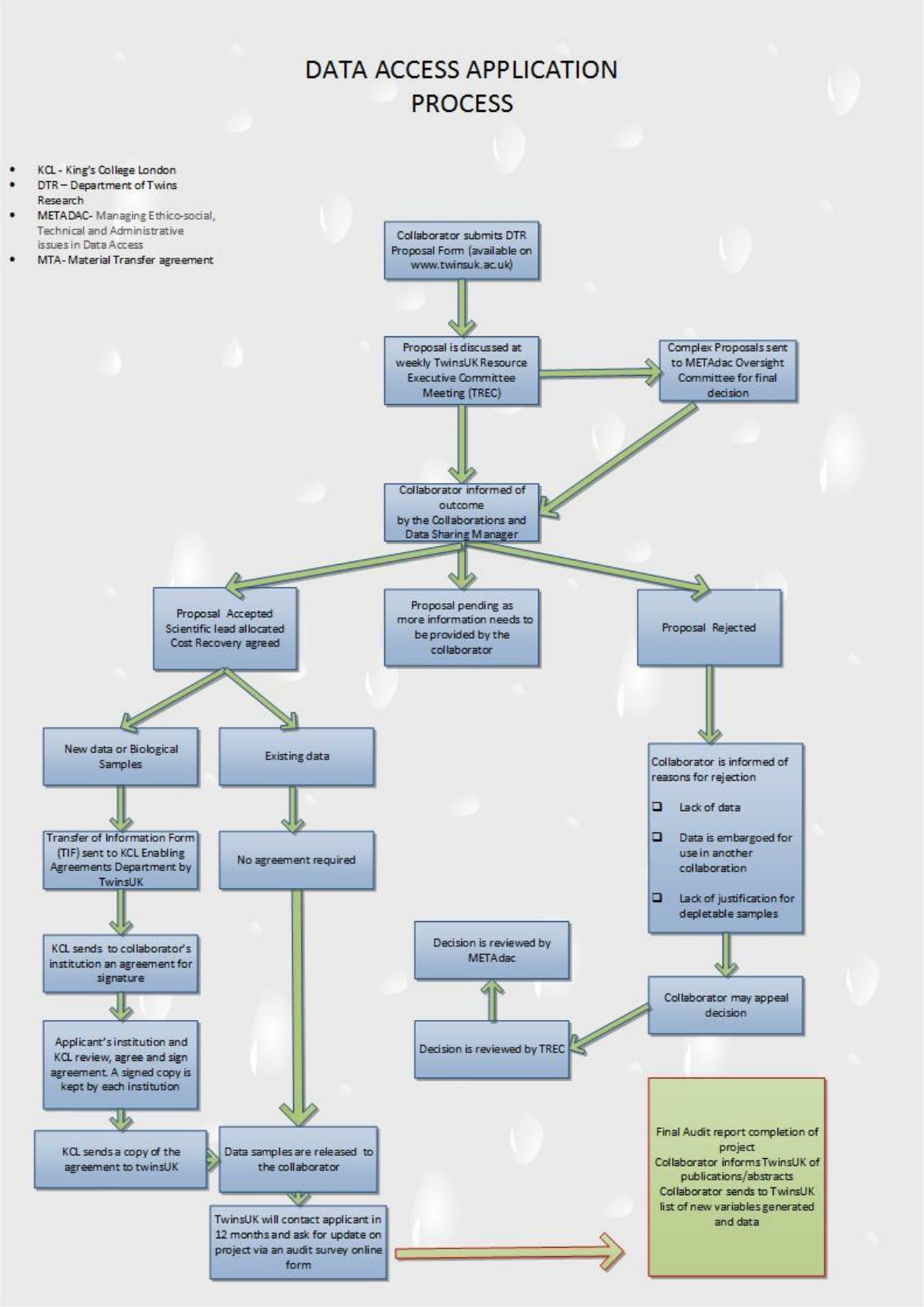
All press releases on research arising from the study should be seen and approved by the TREC. We expect the lead author on the paper to agree the press release with the KCL public relations team via the Collaborations and Data Access Manager, Victoria Vazquez and to be available to deal with media enquiries 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.

INTELLECTUAL PROPERTY

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

FEEDBACK

This policy was last updated in March 2016. We welcome feedback, comments and suggestions. Please send your comments to victoria.vazquez@kcl.ac.uk.


DATA ACCESS APPLICATION PROCESS
KCL - King's College London
DTR – Department of Twins Research
METADAC- Managing Ethico-social, Technical and Administrative issues in Data Access
MTA- Material Transfer agreement
Collaborator submits DTR Proposal Form (available on www.twinsuk.ac.uk)
Proposal is discussed at weekly TwinsUK Resource Executive Committee Meeting (TREC)
Complex Proposals sent to METAdac Oversight Committee for final decision
Collaborator informed of outcome by the Collaborations and Data Sharing Manager
Proposal Accepted Scientific lead allocated Cost Recovery agreed
Proposal pending as more information needs to be provided by the collaborator
Proposal Rejected
New data or Biological Samples
Existing data
Collaborator is informed of reasons for rejection
Lack of data
Data is embargoed for use in another collaboration
Lack of justification for depletable samples
Transfer of Information Form (TIF) sent to KCL Enabling Agreements Department by TwinsUK
No agreement required
KCL sends to collaborator's institution an agreement for signature
Decision is reviewed by METAdac
Collaborator may appeal decision
Applicant's institution and KCL review, agree and sign agreement. A signed copy is kept by each institution
Decision is reviewed by TREC
KCL sends a copy of the agreement to twinsUK
Data samples are released to the collaborator
Final Audit report completion of project
Collaborator informs TwinsUK of publications/abstracts
Collaborator sends to TwinsUK list of new variables generated and data
TwinsUK will contact applicant in 12 months and ask for update on project via an audit survey online form

INDEX

DOCUMENTS NEEDED FOR COLLABORATIONS

- DTR Proposal form (Appendix 1)
- Transfer Information Form (Appendix 2)
- Audit form (Appendix 3)

DEPARTMENT OF TWIN RESEARCH (DTR)

Data/Material Access Request Form

King's College London

Instructions:
Applicants and collaborators requesting use of existing DTR data and /or biological samples or requesting collection of new data are expected to provide information within each of the sections of this form. **Please submit fully completed form and signed agreement (page 7) via email to victoria.vazquez@kcl.ac.uk and annotate "Data Access Request" in the subject line. Incomplete and/ or UNSIGNED forms will delay the request process.**

Section 1 - Data Applicant Details & Institutional Information		
Request Number (To be assigned by DTR)**:**		
1.1	**Applicant Details**	Title: Position: Name: Email: Telephone Number:
1.2	**Co Applicant/ Supervisor Details**	Title: Position: Name: Email: Telephone Number:
1.3	**Institution Details**	Name: Department: Postal Address:
1.4	**Date of Request**	Click here to enter a date.
1.5	**Have you requested data/material from DTR before?**	☐ Yes – Please provide project title of previous request: ☐ No

Section 2 - Project Details		
2.1	**Project Title**	
2.2	**Proposed Start Date**	Click here to enter a date.
2.3	**Proposed End Date**	Click here to enter a date.

Section 3 - Funding and Costs		
Please note that applications for funding must be reviewed by DTR prior to submission to a funding body; require a DTR member to be a co-applicant and must be received at least three weeks before the funder submission deadline. All researchers accessing TwinsUK data will be charged on a cost recovery basis: This cost will vary depending on the amount and type of data.		
3.1	**Source of Funding**	Name:

Section 4 - Ethical Approval		
4.1	**Does the study supporting your project have ethical approval from an Ethics Committee or an Institutional Review Board?**	☐ Yes (Please append a copy of the approval) ☐ In Process (Please go to 4.2) ☐ Not Applicable (You may tick this box if you intend to carry out analysis of existing data where generic DTR ethics approval will operate)
4.2	**Please specify arrangements for obtaining appropriate ethical approval**	

Section 5 - Scientific Project Details		
Data/ Material Specifications		**Required?**
5.1	**Existing data from twin visits & Questionnaires**	☐ Go to 5.2
	Existing biological samples	☐ Go to 5.4
	Collection of new data from twin visits & questionnaires	☐ Go to 5.3
	New biological samples (eg. serum, plasma)	☐ Go to 5.4
	Raw genotype data	☐ Please specify in the scientific outline (section 6)
	GWAS Results	☐ Please specify in the scientific outline (section 6)
	Expression data	☐ Please specify in the scientific outline (section 6)
	Epigenetic data	☐ Please specify in the scientific outline (section 6)
	Metabolomic data	☐ Please specify in the scientific outline (section 6)

	Existing Data	
5.2	**Please indicate phenotype details required**	Domain: Select desired P codes from http://www.twinsuk.ac.uk/data-access/phenotypes/ and include them in your scientific outline -5.4
	Please indicate twins required	☐ All twins ☐ Subset (Please provide full description in the scientific outline)
	Will you require help from DTR statisticians for data analysis?	Choose an item.
	If Yes **to the above, please indicate the extent of help required**	
	New Data	
5.3	**Via Questionnaires**	Questionnaire Title: Total number of questions: ☐ All twins ☐ Subset Please provide full description in the scientific outline ☐ Researcher Data Collection Tools (please append questionnaires with this form)

5.3	**Via twin visits**	Phenotypes required:
	Please indicate research subjects as appropriate	☐ All twins ☐ Subset ☐ DZ ☐ MZ ☐ Opposite sex Please provide full description in the scientific outline
	Will you require help from DTR statisticians for data analysis?	Choose an item.
	If Yes **to the above, please indicate the extent of help required**	
	Biological Samples	
5.4	**Please indicate samples required**	☐ **Existing** ☐ **New**
	Please indicate sample type	☐ DNA ☐ PBLs/Cell lines ☐ Serum ☐ Plasma ☐ Urine ☐ Faecal ☐ Other

Section 6 - Scientific Outline

Please provide a 1-2 page outline of your proposal highlighting the specific project requirements for the DTR data specified above stating the rationale for using this data, including other study methods considered. Please be as precise as possible with regards to phenotype data required listing DTR variable codes of interest, either P (phenotype) or Q (questionnaire) or give a summary of variables. (Please see the phenotype list http://www.twinsuk.ac.uk/data-access/phenotypes/)

Please sign on page 7

Please sign on page 7

Section 7 - Agreement

By signing this form, I confirm that I understand and agree to comply with the conditions stipulated below.

The Department of Twin Research in accordance with King's College London policy will not be permitted to release new and /or identifiable data/samples until a Material Transfer Agreement (MTA) has been finalized for identifiable material or a Data Transfer Agreement (DTA) has been finalized for new (non-identifiable) data.

I. The data may only be used for non-commercial academic research. The data and the results of the research may not be used for commercial purposes unless a revenue-sharing agreement or commercial license is drafted and processed by King's College London Business.

II. No data will be passed to third parties or journals without written permission from the Department of Twin Research.

III. The data remains the property of King's College London and if any new variables are derived from the data and /or any changes are made to the data, these will be returned to the Department of Twin Research upon acceptance for publication by a Journal or at the latest within six months from the end of the project, and any new variables derived from the data and/or changes made to the data shall be the property of King's College London.

IV. No attempt should be made to link or combine the data provided under this agreement to other information or archived data available for the data sets provided, even if access to that data has been formally granted to you, or it is freely available without restriction, unless specific permission to do so has been received from the relevant access committee(s) or sample custodians.

V. The Department of Twin Research and its funder's contribution to this project will be acknowledged in any resulting publications or dissemination material.

VI. All manuscripts and drafts of oral presentations will be submitted to the Department of Twin Research for review and approval at least 15 days before submission or presentation. A final version of the manuscript and summary of any oral presentations will be sent to the department on final submission.

VII. Authorship will be agreed by mutual consent. All publications will have to acknowledge the TwinsUK resource. Standard acknowledgements are available at http://www.twinsuk.ac.uk/data-access/

VIII. The identity of the twins should be protected at all times and no contact or tracing attempts will be made.

Main Applicant's/Supervisor's signature and position: (electronic signature acceptable)

Date: Click here to enter a date.

Co-Applicant/ Student:

Date: Click here to enter a date.

Thank you

Please note that for students' applications, main supervisor must countersign

Appendix 2: OUTGOING MTA INFORMATION FORM

There are explanatory notes at the back of this form. *Please give full answers to the questions below so we can draft the terms of the MTA to match the recipient's needs and any requirements that may have been placed on you and the College during the development of the material (e.g. by external organisations who have helped fund its development).*

CONTACT DETAILS OF LEAD ACADEMIC AT KING'S

Name:	Tim Spector	**School:**	
Division / Dept:	Twin Research	**E-mail:**	Victoria.vazquez@kcl.ac.uk
Telephone:	+44 (0)20 7188 6765	**Mailing address:**	Department of Twin Research St Thomas' Hospital, Westminster Bridge Road London SE1 7EH

CONTACT DETAILS OF ORGANISATION RECEIVING MATERIAL

Organisation:		**Contact name:**	
E-mail:		**Telephone:**	
Role (e.g. scientist, business manager)**:**			

Project Title and DTR reference number

ABOUT THE MATERIAL

1. What is the material (e.g. antibody, cell line, tissue, vector, compound, DNA, data, GMO etc.)? Please give a brief description, a name and an approximate date of creation.	
2. What quantities of the material are to be supplied?	
3. How long do you wish to let the recipient use the material?	
4. Was the material originally created at the College or elsewhere? If elsewhere, please specify.	
5. If any external funding or support was used to create the material, give details including Aptos account code/s if this took place at King's.	
6. If the material was received by you as a gift or is subject to any written agreement, please give details.	
7. Please indicate whether you wish to charge the recipient a fee to cover the costs of your preparing and sending the materials to them and how much it should be. **See notes**	
8. Has there been (or are you planning) any publication describing the material, or is the material confidential information / know-how?	
9. If you know that the recipient intends to use the material in research supported by an external funding body (e.g. a Research Council, a charitable foundation or the EU), please give details.	

10. Please provide below a brief outline of the work the recipient will be undertaking with the material. **Where the recipient will use the material for evaluation purposes only rather than to carry out a programme of research, please make this clear.**

	Yes	No
11. Do you have the necessary ethical approvals and Participant Informed Consents forms required to transfer this material to another organisation? (*N/A if not applicable*) If 'No' please clarify. **See notes**	√	

12. If the Recipient is a commercial organisations or else needs to use the material with or for a commercial organisation (e.g. in a research collaboration / contract / clinical trial), do you have the full ethical approvals and Participant Informed Consent forms necessary to grant such rights for commercial use and access? (*N/A if not applicable*) If 'No' please clarify.		
13. Did any collaborators outside King's contribute to the generation of the material? If so, please specify.		
14. Were there any materials used in creating the material or incorporated into the material brought here from / supplied to you by another institution? (*e.g. if the requested material is a plasmid, were any parts of that plasmid such as a promoter or an IRES or marker obtained from elsewhere*?). **If yes, has permission been obtained allowing you to supply the material?**		
15. Are you aware of any other existing agreements relating to the materials (e.g. research grants / contracts, clinical trials, collaboration agreements, consultancies, confidentiality agreements, other MTAs)? If yes, provide further details.		
16. Where this material been published in a journal, has the journal imposed a duty on the author/s to make any materials described in the publication freely available for non-commercial research?		
17. Will the recipient use the material in humans or for clinical or diagnostic purposes? If 'Yes' please give details.		
18. Is the material for use in a clinical trial?		
19. Is the material of human origin? **See notes**		
20. Is the material toxic, pathogenic or a GMO? If 'Yes', please specify.		
21. Does the material requires more than standard laboratory precautions or safety measures? If 'Yes', please specify.		
22. Has the material been developed using material or input under license from a third party (e.g. GFPs?) **If 'Yes', has permission been granted to you to supply the material to other organisations?**		
23. Is there any reason why the Recipient's research with the material should not be publishable according to normal academic practice (subject to College approval, any reasonable delays we may request and giving due academic credit to you and the College), or why the Recipient should not be free to use its findings for further academic purposes (e.g. if the recipient is a commercial organisation using the material for evaluation purposes only) If 'Yes' please specify.		
24. Is this material covered by any patent or other intellectual property right held by King's or a College spin-out company? If 'Yes' please specify.		
25. Do you think that this material is commercially valuable or useful? If 'yes', do you know of any companies interested in the material?		

If you have any particular concerns regarding the material or the MTA , please indicate them below:-

NOTES - Outgoing Material Transfer Agreements

MTAs can only be signed by authorised signatories of the College.

If you would like to transfer College material to an organisation outside the College, an outgoing MTA should be put in place to set out terms such as the following:

- ownership of the materials
- the purpose for which the recipient of the material can use the material and restrictions / prohibitions on any other use
- the College, as the provider of the material will be acknowledged as the source of the material in publications
- the recipient cannot transfer the material to any other parties without express permission
- liability, warranties and indemnities covering use of the material to protect you and College in the case of negligent use

MTAs must be signed by both parties before sending the material to the other organisation.

PIs are responsible for ensuring that they have all relevant ethical approvals, participant informed consents and regulatory permissions or licenses before transferring materials out of the College.

DRAFTING YOUR MTA

In order to draft and negotiate your MTA, we need you to send us -

1. A completed copy of the first two pages of this Outgoing MTA Information Form (i.e. excluding the notes at the back). Please give suitably detailed answers to the questions otherwise this may delay the assessment of the MTA.
2. Any relevant correspondence

NB outgoing MTAs to commercial organisations will be negotiated by King's Business rather than Research Grants & Contracts as they are effectively commercial licensing agreements; however, the Enabling Agreements Section should still be your first point of contact for all outgoing MTAs, and we will pass your request promptly to the appropriate Technology Transfer manager in King's Business.

Please send the above information to:-

Joanne Leather (joanne.leather@kcl.ac.uk) or
Siau Bai (siau.bai@kcl.ac.uk)

in the Enabling Agreements Section

FURTHER INFORMATION ABOUT OUTGOING MTAs

Each MTA is individually worded to cover the material being transferred and the other organisation's needs. In order to do this, we need certain information about the material to ensure that the College is legally able to transfer the material and can send a suitable MTA. Below are some of the factors taken into consideration:

- who created the material and from what, if relevant
- the terms of the funding body for the research that led to the creation of the material (which may affect how the MTA is drafted)
- interests of any collaborators
- whether you have full ethics approval for the transfer and use of the material by the other organisation, especially if it is a commercial organisation (see also notes on human tissue below)
- whether it is intended to use the material in humans
- who the material is being transferred to
- other factors which may be particular to the academic and impact on the situation

It is also common to ask recipients of materials to pay a fee to cover the costs of your preparing and sending the materials to the them, and you should advise us if you wish to charge such a fee and what it should be.

We will draft the MTA based on the information you provide and send it to you for you to check prior to being forwarded to the recipient institution. We will deal with any proposed modifications to the agreement suggested by the recipient institution and seek to negotiate mutually acceptable terms. Once the MTA has been signed on behalf of the other organisation, you will receive a copy of the MTA for your records and will then be free to send the material.

There may be restrictions on the terms that we can grant to organisations wanting access to your material, for example where the material has been created from grants funded by one of the major research charities (e.g. Wellcome Trust or BHF), there may be issues in negotiating the terms of the MTA to ensure that they are compatible with those of the funder. This is because the funder may have placed restrictions on the rights that we are able to give anyone wanting to use the material (for example where the recipient is a commercial organisation, or where, even if they are another research organisation, they want rights to jointly-own, use or exploit their findings based on their use of the material for commercial purposes); such terms are incompatible with some funder's terms and conditions and/or which require their express prior consent before we could give such rights.

Human Tissue

Where human tissue is involved, it is important that not only you have the ethical approvals and Participant Informed Consent forms, but that the approvals cover supplying the material to another organisation for them to use as well as to the Recipient's' intended use of the material. The Human Tissue Act makes consent the fundamental principal underpinning the lawful storage and use of human bodies, organs and tissue and applies to the storage and use of tissue from living people and the taking, storage and use of tissue from the dead. Consent for research is not a legal requirement if (i) the samples are anonymised to the researcher and (ii) the research has been approved by a suitable Research Ethics Committee. **It is illegal even to hold "bodily material" (i.e. material consisting of or including human cells such as includes hair, blood, nail and gametes) with the intention of undertaking DNA analysis on it without consent. So, unless these exceptions apply, if there is any intention of the recipient doing genetic analysis on identifiable material, consent for this has to be obtained at the time the sample is taken.** Extracted DNA and RNA (where no whole cells remain) are not classed as Bodily Material.

NB in the Human Tissue Act the definition of 'Bodily Material' is different from 'Relevant Material' and is far more restrictive.

Appendix 3: Data Access Audit Survey

From time to time all collaborators will be expected to fill in an online form with information as below:

Project number:
Title of the project:
Date of the approval:

Name of the main applicant:
Name of the institution:

Q1 What is the status of this project?

- ○ Completed (2)
- ○ Ongoing (1)
- ○ Abandoned (0)

Skip To: Q2 If Q1 = 1
Skip To: Q3 If Q1 = 0
Skip To: Q4 If Q1 = 2

Q2 What is the expected date of completion of this project? (DD/MM/YYYY)
(If you can't refer to a specific day (DD), please write down '01'. e.g. 01/12/2020)

_____

Skip To: End of the questionnaire If Q2 Is Displayed

Q3 For what reason(s) did you abandoned this project?

_____

_____

_____

_____

Skip To: End of the questionnaire If Q3 Is Displayed

Q4 When did you complete this project? (DD/MM/YYYY)
(If you can't refer to a specific day (DD), please write down '01'. e.g. 01/12/2011)

_____

Q5 Have you derived any new variables/datasets from the data/samples provided by TwinsUK for this project?

- ○ No (0)
- ○ Yes (1)

Skip To: Q8 If Q5 = 0

Q6 Have you sent us back the new derived variables/datasets?

- ○ No (0)
- ○ Yes (1)

Skip To: Q9 If Q6 = 1

Q7
As per our open access policy, all new variables/datasets derived from the data/samples requested for this project shall be the property of King's College London. All new variables/datasets must be return to the Department of Twin Research no later than upon acceptance for publication of the first paper or within six months from the completion of the project. Thank you for sending us these data.

Please contact our Data Manager (genevieve.lachance@kcl.ac.uk) who will assist you with the transfer of your data.

Please specify if there is any reason that prevents you from sending the data:

_____

_____

_____

Skip To: Q10 If Q7 Is Displayed

Q8 Please specify the reason:

_____

_____

_____

Skip To: Q10 If Q8 Is Displayed

Q9 When did you send us back the variables/datasets? (DD/MM/YYYY)
(If you can't refer to a specific day (DD), please write down '01'. e.g. 01/12/2011)

_____

Q10 Have you got any publication(s) arising from this project?

- ○ No, no publications are planned (0)
- ○ No, but we are in the planning/writing stage (1)
- ○ Yes (2)

Display the following question:
If Q10 = 2

Q11 Please list all your publications using the Digital Object Identifier (DOI) number of each publication.(e.g. 10.1017/thg.2012.89)

- ○ DOI 1 (1) _____
- ○ DOI 2 (2) _____
- ○ DOI 3 (3) _____
- ○ DOI 4 (4) _____
- ○ DOI 5 (5) _____

Q12 Have you presented or are you planning to present an abstract that includes TwinsUK data at any conference for this project?

- ○ No (0)
- ○ Yes (1)

Display the following question:

If Q12 = 1

Q13 Please list the name(s), countrie(s) and date(s) of the conferences you attended and those you are planning to attend in the near future.

	Name of the conference	Name of the country	Date of conference (DD/MM/YYYY)
1) (1)			
2) (2)			
3) (3)			
4) (4)			
5) (5)			

Q14 Have you launched or are you planning to launch a press release or any media activity for this project?

- ○ No (0)
- ○ Yes (1)

Display the following question:

If Q14 = 1

Q15 Please list the type of media activities you have been involved along with titles and dates. Use the drop down box to select the type of activity you are referring to.

	Type of activity	Title	Date (DD/MM/YYYY)
1) (1)	Press release (1) TV (2) Radio (3) Written press (4) Other (5)		
2) (2)	Press release (1) TV (2) Radio (3) Written press (4) Other (5)		
3) (3)	Press release (1) TV (2) Radio (3) Written press (4) Other (5)		
4) (4)	Press release (1) TV (2) Radio (3) Written press (4) Other (5)		
5) (5)	Press release (1) TV (2) Radio (3) Written press (4) Other (5)		
6) (6)	Press release (1) TV (2) Radio (3) Written press (4) Other (5)		

Display the following question:

If Q6 = 0

As a reminder, if you need to send us back variables/datasets, please contact our Data Manager (genevieve.lachance@kcl.ac.uk) who will as assist you with the transfer of your data.

END OF THE QUESTIONNAIRE. Display the following question to everyone:

If you have any queries about your data access proposal, please contact our Data Access & Collaborations Manager (victoria.vazquez@kcl.ac.uk)

Press SUBMIT to complete your survey, otherwise, press BACK button to modify your answers.