**CDCAF2**



**APPLICATION FORM**

**TO PROCESS OR FURTHER PROCESS PERSONAL DATA FOR THE PURPOSES OF HEALTH RESEARCH COMMENCED BEFORE 8 AUGUST 2018**

**(Re-Consenting)**

**PART A: APPLICANT DETAILS**

1. Name and address details (including website, if any) of data controller:

The Provost, Fellows, Foundation Scholars, and the other members of Board, of the College of the Holy and Undivided Trinity of Queen Elizabeth near Dublin ( also known as Trinity College Dublin), College Green, Dublin 2, Ireland [www.tcd.ie](http://www.tcd.ie)

* Data controllers can be either individuals or "legal persons" such as companies, government departments and voluntary organisations.
* Data controllers also include sections or units of the organisation (e.g. academic departments, research centre etc.) and employees (including research students) that control and are responsible for the data processing.

 The Data Controller determines the purpose and the means of processing. To find out who the data controller is you should ask who determines the following:

* Why are we processing this data?( e.g. To investigate inhaler compliance)
* How will we process the data in order to conduct this research?
* You are a data controller if you are the person or organization who determines the “why” and the “how” of the data processing.
* The data controller exercises overall control over the ‘why’ and the ‘how’ of a data processing activity

2. Lead contact person to receive correspondence in relation to this application:

3. Principal business of data controller:

Research and Education

4. If there are joint data controllers, please specify the name, address and principal business of joint data controllers and set out the division of responsibilities between them:

If more than one party decides the purpose of the particular study – please list. This can be multiple parties. Please note any contract in place between the controllers

5. Name of addresses of data processors, if any –please attach a copy of the contract or draft contract that will be used:

A Data processor is a third party providing a service to Trinity (testing samples for example). Examples of data processors include:

* payroll companies or accountants or similar who hold and process personal information on behalf of someone else;
* "cloud" providers are also generally data processors;
* if you hire a 3rd party to process data for your research (e.g. a transcription service to transcribe audio tapes of interviews) - the third party will be a data processor.

 Employees are not processors.

7. Name of and contact details for Principal Investigator. If the Principal Investigator is regarded as the data controller, this should be made clear and information provided to support that view.

PI is not considered a data controller by Trinity. Trinity is the Data Controller

8. Co-Investigator name and contact details:

9. Collaborator name and contact details (and role in project):

10. (a) Is it proposed to process any personal data outside of the State?

Yes: No:

(b) If Yes, please specify the countries that this will take place in.

(c) If any of those countries are outside of the European Economic Area what is the legal basis for the transfer of the personal data?

Standard Contractual Clauses appended to an MTA or DTA; or

MTA/DTA in addition to an adequacy decision if going to Andorra, Argentina, Canada (commercial organisations only), Faroe Islands, Guernsey, Japan, Israel, Isle of Man, New Zealand, Switzerland, USA (if privacy shield)

(Please delete as applicable)

If any data has been transferred, please ensure that there was an appropriate contract in place or an adequacy decision for that country. Please contact the Research DPO for any questions on this section.

11. Please specify any person, organisation or group from whom funding or other material support has been sought or is intended to be sought and indicate where such funding or support has been provided or committed at the time of this application.

12. Please specify any sponsor for the research activity (where appropriate)

13. Please specify any person (other than a joint data controller or data processor) with whom it is intended to share any of the personal data obtained or further processed (including where it has been pseudonymised or anonymised), the purpose of such sharing and the country that the person is located in.

14. Please list (below) all Research Ethics Committees involved in approval and attach copy of outcome letter from each of those RECs.

**PART B: NATURE OF HEALTH RESEARCH AND PERSONAL DATA INVOLVED**

1. Provide a lay summary of what the research is about and why the application is being made (Max 500 words)

2. Describe the nature and objective of the health research project for which the application is being made.

3. Indicate the start date and expected duration (months)

4. Specify the study endpoints/deliverables

5. Provide an overview of the design and methodology (3 pages max to be attached).

(The study design chosen should be appropriate to achieving the aims and objectives stated in response to Q4.)

“The different types/patterns and designs of research can sometimes be confusing. The purpose here is to provide definitions and explanations of the main terms.

**Types/Patterns of Research**

The terms used to describe the different types of social research are:

* Basic – to understand and describe social phenomena;
* Applied (policy/action research) – to provide useful knowledge to apply to a problem or inform change;
* Evaluative (assessment/appraisal) – to establish the efficiency, effectiveness and/or success of a program/intervention.

The terms used to describe the different types of medical research are:

* Basic – investigation of human or animal samples (e.g. biochemical, genetic) carried out in a laboratory;
* Epidemiological – the study of disease occurrence (distribution and determinants);
* Clinical – the study of patients who have a particular condition.

Other terms you may encounter are:

* + Exploratory – referring to the fact that the subject area is being explored and little is currently understood about it;
	+ Causal – referring to the fact that you are looking for ‘cause and effect’ in the subject area.

**Research Design – the broad decisions**

* Observational or Experimental

Observational research collects information on subjects with no intervention. It comprises descriptive studies (description only) and analytical studies (analysing relationships between variables; cross-sectional, case-control, cohort and ecological studies).

Experimental research is where the researcher affects what happens to the subjects by varying some factor which the researcher can control and then investigates the effects of the intervention. It comprises clinical trials and field trials (individual level and aggregated - community trials) and is also known as intervention research/studies.

* Prospective or Retrospective

Prospective means that the events to be measured have not occurred when the study commences; hence data is collected about future events.

Retrospective means that the events to be measured have already occurred when the study commences; hence data is collected about past events (and may come from existing sources).

Experimental research is prospective, whereas observational research may be either prospective or retrospective.

* Cross-sectional or Longitudinal

Cross-sectional study is where data is collected at one point in time.

Longitudinal study is where data is collected at more than one point in time – usually to investigate changes over time.

**Research Design – study types**

* Descriptive study

A simple description, based on routinely available data or on data from a dedicated survey. This is often the first step in an epidemiological study. May examine patterns but does not analyse the relationship between exposure and outcome. Includes case-study/report and case-series where the characteristics of one or more patients, respectively, are described.

* Cross-sectional study

Also known as a prevalence study. Individuals are the unit of observation. Data on both exposure(s) and outcome(s) is collected at the same single point in time. Relatively easy and economical to conduct with a short timeframe as no subject follow-up involved. May be based on a random sample from a defined population or a presenting sample of patients with a particular condition. Suitable for studying prevalence, behaviour and attitudes and estimating health needs. It is not easy to assess the reasons for the associations observed or to ascertain whether the outcome or exposure occurred first - not an issue for exposures that do not change over time; questions about past and current exposures could be asked.

* Case-control study

May (less often) be called a case-reference study. Individuals are the unit of observation. It involves comparing people with a specific outcome of interest (e.g. a particular disease) with a group of people who do not have this outcome; hence subjects are recruited based on the presence of absence of this outcome. Exposure among cases is compared to exposure among non-cases. Suited to rare/long induction diseases. Not suitable to measure incidence or the effectiveness of an intervention. Used to identify causes of disease or rare effects of treatment. Relatively easy and economical to conduct (usually smaller sample size compared to a cohort study). Retrospective in the sense that data is collected on past exposure. Prone to selection bias (must ensure that the controls are from the same study population as the cases) and information/recall bias (due to cases recalling exposures more accurately than controls or more detailed interviewing of cases). Most efficient design is an equal number of cases and controls although two or more controls (no more than four) can be taken if the number of cases is limited. Matching ensures an equal distribution of confounders among cases and controls. You can match for variables known to be associated with the exposure and the outcome, or to the outcome only but not variables associated with the exposure only or factors intermediate in the casual pathway between exposure and outcome. Matching can be paired (individual) or frequency (distribution). Over-matching can cause difficulties and cannot be adjusted at the analysis stage.

* Cohort study

Also known as a follow-up or incidence study. Individuals are the unit of observation. People (free of the outcome variable) are classified according to their exposure (either exposed/not exposed or various degrees of exposure) and followed over a period of time to determine outcome. Usually classification is done at the start of the study and is not an explicit part of the design although occasionally exposure status is identified in advance and a sample taken from each group separately. It is possible to examine multiple outcomes. It is the observational study that most closely resembles experimental studies, except that allocation of exposure is not controlled by the researcher. Expensive and time-consuming and may require long periods of follow-up (a historical cohort may be available to reduce both). Useful to investigate late or chronic effects. Can also be used to investigate different approaches to service delivery and management. Not suited to rare diseases (due to sample size problems) or to measure the effectiveness of an intervention. Follow-up time may be fixed (all subjects followed for the same, defined period) or variable (analysed using person years of follow-up or clinical life tables).

* Ecological study

Also known as a correlational study. A population or a group of people is the unit of observation. Compares different countries at the same time or the same country at different times. Usually relies on data collected for other purposes therefore full exposure data may not be available. The individual link between exposure and outcome is not possible. An association observed at the group level does not necessarily represent that which exists at the individual level. Used for estimating the frequency of disease. May lead to more detailed epidemiological work.

* Clinical Trial

More often referred to as a randomised controlled trial (RCT). Also known as a therapeutic trial or a secondary prevention trial. It is an experiment to evaluate the effectiveness of an intervention or therapy; hence individual patients are usually the unit of observation. The researcher has direct control over many aspects of the investigation, and in particular over the allocation of individuals to different treatment groups. Subjects on a treatment/therapy (called the treatment or intervention group) are followed up and their outcome compared with subjects who have the same condition who are not so treated (the control group). The control group either receives no treatment or an established treatment. The outcome may be the recovery from existing disease or the development of new disease. Defined selection criteria are required for patient enrolment into the trial. Patients are randomly allocated to the groups. Confounding and bias can be eliminated through the design of the trial and the implementation of that design using randomisation, single-blinding and double-blinding. Single-blinding refers to the patient not knowing which group s/he is allocated to and is often achieved through the use of a ‘placebo’. Double-blinding is where neither the patient nor the doctor/researcher who is managing the patient or evaluating response knows which group the patient is allocated to. All patients in the trial must be managed similarly in terms of the number of check-ups etc. A full list of criteria for withdrawing the patient from the trial (regardless of group) should be compiled before commencement. Some measure of patient compliance should be included. Should only be conducted if there is a doubt as to which treatment is better. Analysis ideally conducted on the basis of intention to treat. Many trials undertaken are too small to detect treatment effects and result in non-significant differences. The smaller the effect, the larger the trial required; the larger the trial, the greater the power to detect differences. Even if non-significant, the effect may be of clinical/medical importance.

* + Field Trial

Also known as a primary prevention trial. It involves people who are disease-free but presumed to be at risk. It evaluates if the intervention reduces the risk of developing an outcome/disease among those free from it. Usually huge logistic and financial considerations. Can be used to evaluate interventions aimed at reducing exposure without measuring the occurrence of an outcome – and therefore carried out on a small scale at lower cost. In community trials (also known as community intervention studies), the treatment groups are communities rather than individuals. Particularly appropriate for outcomes that have their origins in social conditions that can be influenced by intervention directed at group behaviour as well as at individuals. Random allocation of communities is not possible and usually only a small number of communities can be included. It is also difficult to avoid contamination, that is, to isolate the intervention communities from general social changes.

The ethical issues associated with all research should be considered. However, they are paramount in the design of experimental research and will be dealt with in a future article.”

C. Collins (2008) Irish College of General Practitioners ‘Guide to Conducting Research’

6. Describe the personal data obtained and used.

Delete as applicable and add as applicable

i. Participant’s full name & address

ii. Participant’s medical record number

iii. Participant’s date of birth

iv. Participant’s gender

v. Participants age at start of research study

vi. Clinical information sourced from the Electronic Patient Record, and/or, Patient Charts limited to (insert specifics)

vii Participant’s consent form

vii GP contact

7. Explain why the health research requires that personal data be obtained and processed rather than anonymised data.

8. Describe how you will ensure, in relation to the research, that personal data already held and to be obtained will not be processed in such a way that damage or distress is, or is likely to be, caused to the data subject.

9. Describe how you will ensure that the collection and use of the personal data will go no further than is necessary for the attainment of the research objective (data minimisation principle).

Data minimisation means you must ensure the personal data you are processing is:

* adequate – sufficient to properly fulfil your stated purpose;
* relevant – has a rational link to that purpose; and
* limited to what is necessary – you do not hold more than you need for that purpose.

Only information that is necessary to answer the clinical question posed is obtained.

10. Describe the data processing activities (data lifecycle and research lifecycle), focusing on access, storage, analysis, sharing, transfers, archiving and destruction

Please include a data flow diagram

11. Confirm that there will be no disclosure of the personal data unless that disclosure is required by law or the data subject has given his or her explicit consent to the disclosure.

The Applicant confirms that there will be no disclosure of the personal data unless that disclosure is required by law or the data subject has given his or her explicit consent to the disclosure.

12. Identify the data sources from which the personal data was obtained.

13. If the research involves data linkage between different sources of information, you must describe what is involved and its purpose.

14. Elaborate on the extent to which you have involved patient and user organisations/representatives in the development/oversight of the research to date.

Ideally you should provide two examples of this involvement and NALA if possible

15. Describe your exit strategy with timelines to address the issues that led to this application, such that the research described will no longer require support under the consent declaration process. If you will continue to require the support of a declaration over a number of years, you must set out the reasons why that is the case.

For certain research (biobanks – there is no exist strategy. This can be justified. WP29 working group on Genetic Data could be useful in this regard.

16. Identify the particular part(s) of the research for which the consent declaration is sought.

Scope will typically be for one part of a project rather than the entire project and this should be identified.

17. Set out fully the reasons why re-consenting is not practicable. This will tie in with your answers to Part D.

Justify in full why it is not possible. Refer to Study by SJH Cancer biobank if appropriate. DPO can provide details.

**PART C: LEGAL BASIS FOR THE PROCESSING OF PERSONAL DATA**

1. Identify the legal basis under Article 6 and the relevant condition under Article 9 for the processing of the personal data.

Lawful Basis Article 6: 6(1)(e) Public Interest;

Lawful Basis Article 9: 9(2) (j) Scientific Research Purposes.

**PART D: EVIDENCE THAT CONSENT WAS OBTAINED AND EFFORTS MADE TO RE-CONSENT**

1. Provide evidence (including by way of attachments, if appropriate) that consent was obtained in line with the EU Data Protection Directive and the Data Protection Acts 1988 & 2003.

Only appropriately qualified and competent persons should take informed consent. Please ensure you provide copies of any Information Leaflets, Consent Forms and Assent Forms referred to in response to this question.

2. Fully outline (including by way of attachments, if appropriate) the efforts that have been made to re-consent the data subjects involved.

**PART E: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS AND TRAINING**

1. Specify the transparency arrangements you have/will put in place to ensure that personal data are processed in a transparent manner.

Transparency is about better informing patients, public and participants about research; it is not about getting permission. Making transparency information understandable and drawing people's attention to it is key:

* Individuals have the right to be informed about the collection and use of their personal data. This is a key transparency requirement under the GDPR.
* You must provide individuals with information including: your purposes for processing their personal data, your retention periods for that personal data, and who it will be shared with. This is ‘privacy information’.
* You must provide privacy information to individuals at the time you collect their personal data.
* The information you provide must be concise, transparent, intelligible, easily accessible, and it must use clear and plain language.
* It is often most effective to provide privacy information to people using a combination of different techniques including layering, dashboards, and just-in-time notices.
* User testing is a good way to get feedback on how effective the delivery of your privacy information is.
* You must regularly review, and where necessary, update your privacy information. You must bring any new uses of an individual’s personal data to their attention before you start the processing.

2. Identify the controls in place to-

(i) limit access to the personal data undergoing processing in order to prevent unauthorised consultation, alteration, disclosure or erasure of personal data;

What security measures will be in place during processing?, password protection, encryption of desktop computers and portable devices and encryption of individual files. It is strongly advised that ‘personal’ data is not stored on portable devices or home-based desktops. However, where this is absolutely necessary, encryption software should be installed. .

Only approved members of the research team who have completed GDPR training, GCP training and signed a confidentiality agreement will be given access to the personal data

Version control will be implemented to ensure the integrity of the data, password protection will be implemented to ensure the confidentiality of data.

(ii) log persons who access personal data;

Access logs will be reviewed on a regular basis to ensure only authorised persons have accessed the data. A record will be kept of all individuals with whom personal data was shared.

 (iii) technical, organisational and physical measures to protect the security of the personal data concerned;

Each patient is given a unique identifier as part of the study and the patient sample and data is coded with this identifier. One identifiable or master file exists which links this unique identifier with the patient.

The identifiable electronic data file is currently stored on a stand-alone (not connected to internet) password protected computer in a restricted access locked room in a swipe accessed building. This is backed up on an encrypted USB which remains on site in a locked filing cabinet in a locked room.

A hard copy of the data and consent form is stored in a locked cabinet in a locked room. A copy of the consent is also stored in the patient’s chart and the patient also receives a copy.

Only coded data will be shared with external collaborators.

(iv) arrangements to anonymise, archive or destroy personal data once the health research has been completed;

This will depend on type of research and retention period.

All reasonable measures will be taken to securely destroy personal data once the research project is completed, or if a patient withdraws i.e. secure deleting the file by overwriting data in memory, physical copies of the data will be shredded and disposed of securely.

(v) any other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation, together with processes for testing and evaluating the effectiveness of such measures.

Trinity College Dublin are committed to complying with GDPR and provide guidance to all staff and students on the best ways to ensure data is protected. <https://www.tcd.ie/info_compliance/data-protection/>

3. (a) Set out below a summary (max 750 words) of the findings of the Data Protection Impact Assessment that has been carried out and ensure that you have attached a copy of the DPIA.

(b) Indicate the steps you have taken to address any risks identified in the DPIA with particular reference to the possibility of data linkages and details of any consultations undertaken with data subjects.

(c) Attach the advice of the Data Protection Officer on the research and any action taken in relation to that advice. Where the application is from joint data controllers, the advice of each data controller’s DPO must be attached.

4. Provide information on the training in data protection law and practice that has been provided to those individuals involved in carrying out the health research.

Trinity College Dublin has provided specific training on the impact of the health research regulations.

**PART F: SIGNATURES - DATA CONTROLLER(S)**

|  |
| --- |
| **DATA CONTROLLER** |
| I certify that I have been duly authorised by the data controller to forward this application by the data controller to the Health Research Consent Declaration CommitteeAPPLICATION TITLE:PRINCIPAL INVESTIGATOR NAME: |
| Name: Mr. John Coman, Secretary to CollegeOrganisation:      The Provost, Fellows, Foundation Scholars, and the other members of Board, of the College of the Holy and Undivided Trinity of Queen Elizabeth near DublinOriginal signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: |

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| **DATA CONTROLLER (where there are joint data controllers)**  |
| I certify that I have been duly authorised by the data controller to forward this application by the data controller to the Health Research Consent Declaration CommitteeAPPLICATION TITLE:PRINCIPAL INVESTIGATOR NAME: |
| Name:Organisation:     Original signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: |

**If there are more than two joint data controllers, the above box should be copied as necessary.**