Management, Access and Publications Policy

Introduction

This document summarises the management and policies of the GoDARTS collection and the continuous collection of samples under the aegis of the Tayside Tissue Bank

GoDARTS has created a biomedical and genetic resource (Resource) for the study of type 2 diabetes and related disorders. A description of the resource and a list of publications to date arising from use of the Resource are available on the Study website http://diabetesgenetics.dundee.ac,uk In brief, detailed information has been collected using questionnaires, gathering baseline data and data extraction from medical notes. With participant consent anonymous linkage to routine NHS information systems is also possible. Ethical approval for this Resource has been obtained from the Tayside Research Ethics Committees in Scotland.

Over 9000 patients with type 2 diabetes and over 8,000 age-matched controls have participated to date in the Tayside region of Scotland. At the end of the Wellcome Trust funding it was agreed to continue recruitment using an identical protocol and ethics approvals under the aegis of the Tayside Tissue Bank.

This document therefore refers to 3 related collections:

1. Genetics of Diabetes Audit and Research in Tayside 1 (Go DARTS 1) January 1997-October 2004
2. Wellcome Trust Type 2 Diabetes Case Control Collection – WTCCC (GoDARTS 2) October 2004-May 2009
3. WTCCC extension (GoDARTS 3) October 2009 ongoing

For the purposes of clarity the term GoDARTS will be used to define the collective biologic resources and the cross-sectional phenotypic data collected at the time of recruitment.

Management

The **Scientific Committee** is responsible for all matters associated with the operational management of the Study and meets frequently (at least quarterly) in person or teleconference to consider operational issues. The Scientific Committee of GoDARTS has executive responsibility for the strategic direction of the Study and is ultimately accountable to the public and funders for the performance of the Study. The Scientific Committee consists of a group of senior investigators from the Study partner institutions across the United Kingdom who have helped create the Resource. The terms of reference of the Scientific Committee are contained in Appendix 3. Details of the Chair and members of the Scientific Committee are also listed. If you would like to contact the Scientific

Committee for information on WTT2DM activities or scientific strategy please send your e-mail to nuclear-receptor@dundee.ac.uk

The Resource is overseen by Tayside Tissue Bank.

The Scientific Committee will also act as the **Access Group (AG).** The AG, which comprises a subset of the Scientific Committee, is responsible for the execution of this Management, Access and Publications Policy (MAPP). Its terms of reference are given in Appendix 5. The AG's decision making on the disbursement of the Resource shall be informed by any third party funder's terms and conditions where applicable. The AG will meet frequently (on a bi- monthly basis or as required), either in person or by teleconference/email to consider requests for use of the Resource which includes both Data and Samples. If you would like the AG to consider a proposal for use of existing Data or Samples, or the collection of new Data or Samples (Future Project), or to approve a paper for submission, please follow the guidance below and send your proposal or paper to the AG administrator, Caroline Glen e-mail address c.glen@dundee.ac.uk

Access Schematic is given in Appendix 2 .Details of the Chair and members of the AG are listed in Appendix 5

Collaboration – general issues

WTT2DM is run as a Resource for the research community to be used in new research projects (Future Projects) the outcomes of which will be included in the Resource. It is anticipated that requests to use the Resource will be made from researchers throughout the world. International researchers will collaborate through a researcher based in the UK. All access will be made through members of the Access Group, following the procedures laid down in this Access Policy.

Commercial Organisations: specific arrangements have been defined to allow commercial organisations to access the GoDARTS Resources. The Commercial Access and Intellectual Property Policy is shown in Appendix 6.

The Resource is set up as a **supported** Access resource rather than as an entirely open Access Resource. If you wish to work on the Resource you should look at the website which contains details of the particular Resource available.

(http://diabetesgenetics.dundee.ac,uk)

If you want to apply for Access to the Resource for use in a Future Project, please complete a Collaboration Proposal Form describing your proposed project/collaboration (see Appendix 7) and send the completed form to the AG. The AG will respond no later than 30 days after the next scheduled AG meeting to let you know if the collaboration is possible

- Does the Resource have the relevant Data or Samples
- Is any proposed third party funding and/or involvement in a proposed project commensurate with the terms and conditions governing the WTT2DM initiative

and to provide advice on the next stages. If there is a possibility of overlap with other investigators or other groups who are utilising the Resource on related topics the AG may

put you in touch with these groups and invite you to discuss your ideas before you proceed with your request. The AG will also estimate the cost of the use of the Resource for a proposed collaboration

Each agreement is specific to an individual proposal.

Requests from researchers for contact of GoDARTS participants to invite into new projects is managed through the Health Informatics Centre (HIC) after approval from the AG-see flow on Appendix 8

Once access has been agreed by the Access Group, the researcher should proceed as per access flow diagram. See Appendix 2

- The Health Informatics Centre (HIC) for the supply of data to researchers – baseline, longitudinal follow up www.dundee.ac.uk/hic
- The Access Group and Tayside Tissue Bank (TTB) for the supply of tissue to researchers – DNA, RNA, serum, urine http://diabetesgenetics.dundee.ac,uk and www.tissuebank.dundee.ac.uk
- The Health Informatics Centre for request for re-contact of WTT2DM participants for invitation into new project.

The datasets available and the procedures required to access HIC datasets can be found on the HIC website. All tissue from this Resource is managed by the TTB.

Collaboration - analysis of existing Data in Future Projects

To use Data in Future Projects applicants need to complete a Collaboration Proposal Form (Appendix 7) to detail the Resource required for the Future Project. Please send the completed Collaboration Proposal Form to the AG e-mail address: c.glen@dundee.ac.uk

Informal contact by applicants with the AG for discussion on a proposed collaboration is strongly encouraged when considering an application and before the form is submitted. Once an analysis has been agreed you will be allocated a "Research Facilitator**".** This is a member of the GoDARTS team who is qualified to guide you on the use of the Resource and associated meta-data. The Research Facilitator will provide you with a brief description of key variables used in most analyses and access to meta-data that will allow you to identify the variables you require. Once approval from the Access Group and Tayside Tissue Bank has been given, HIC will be informed in writing. The researcher will then proceed through the HIC Standard Operating Procedures in their request for data. www.dundee.ac.uk/hic

Collaboration – assays on Samples and genotyping

To use biological samples (tissue) or to carry out genotyping on DNA as part of a Future Project applicants need to complete the Collaboration Proposal (Appendix 7) describing the proposed collaboration. Applicants must ensure they complete the specific sections on the tissue and genotyping including details of the type of tissue required, amount needed and in case of DNA the minimum concentration required. The AG will be unable to process requests which do not supply this information. Please send the completed Collaboration Proposal Form to the AG e-mail address: c.glen@dundee.ac.uk

Informal contact by applicants with the AG for discussion on a proposed collaboration is strongly encouraged when considering an application and before the form is submitted. For further information about tissue or laboratory procedures please contact the research laboratory, Professor Colin Palmer at nuclear-receptor@dundee.ac.uk. Decisions by the AG on the use of tissue will take account of the amount of the stored tissue required, the amount in storage, the appropriateness of the project according to patient consent and the perceived scientific value of the proposed study. The terms of any third party involvement will also be taken into consideration.

The DNA Samples themselves will not normally be provided for genotyping. Rather, we encourage applicants to use the Genetics Infrastructure of the Consortium at the Universities of Exeter, Dundee and Oxford, or an external provider approved by us. This ensures an efficient, cost-effective service that maximally protects the Resource for long term and wide spread use. Any order to genotype DNA must be placed via the AG. After a Future Project is approved applicants must apply to the TTB under whose governance the samples are managed. The Collaboration Proposal should be attached to this application. A clear description of the TTB application process can be found on the website www.tissuebank.dundee.ac.uk

Collaboration - collection of new Data and/or Samples

Any new Data or Sample collection required as part of a Future Project would require separate funding and relevant approvals (see section below). Any applications for the collection of new Data or Samples (Future Projects) must be submitted on a Collaboration Proposal Form (Appendix 7) describing the proposed Future Project The completed Collaboration Proposal Form should be sent to the AG. c.glen@dundee.ac.uk

We encourage applicants to apply for funding for new Data and/or Sample collection one to two years in advance of the proposed project start date to secure a commitment to include these Data and/or Samples in the GoDARTS Resource. New Data and/or Samples would become the property of GoDARTS.

Collaboration – costs and grants

The Resource received funding from the Wellcome Trust and Tenovus Tayside to support core activities. These do not extend to support for individual projects or Future Projects and applicants will be expected to meet additional costs of accessing the Resource. These will be determined on a project-by-project basis. Once it has been agreed that a Future Project can proceed you will be informed by the Access Group of how much it will cost. If you are submitting a grant to an external funding body to cover the costs of Access to the Resource we require that you send the final copy of the grant to the AG with the Collaboration Proposal Form. The AG will respond no later than 30 days after the next scheduled AG meeting to let you know if the collaboration is possible. The AG will, on request of the applicant, provide a letter in support of the Future Project once it has been approved by the AG and the Access fee has been agreed. For proposals to collect new Data and/or Samples as part of a Future Project the AG insists that at least one member of the Scientific Committee (or a scientist nominated by the WTT2DM) be a co-applicant so they can act as guarantor for the proposed new Data and/or Sample collection. You should send the AG a copy of the award letter when you receive this and the AG 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.

Applications to use the Resource from commercial organisations will be subject to pay a commercial rate to be determined by the AG .

The Commercial Access and Intellectual Property Policy (Appendix 6) details the ownership, management and subsequent commercial exploitation of intellectual property relating to the Study and Future Projects.

Contact with Study Participants

All GoDARTS participants are consented for re-contact for future projects at time of participation. The consent given stipulates that it must always be a member of the study team who makes this contact and all letters of invitation should be approved by the ethics committee. The protocol of the new project must state that one of the methods of recruitment is by letter of invitation to GoDARTS participants who fit the study specific inclusion criteria and have consented to re-contact. A written request must be sent to the Access Group for consideration. Help will be provided through the process by the AG and is described in the flow diagram in Appendix 8. All requests will be managed following the Health Informatics Centre SOPs.

To ensure that patients who have consented to be re-contacted during participation in the Wellcome Trust Case Control Study are not written to repeatedly or inappropriately, HIC has set up a Patient Recruitment System that will record

- All patients written to and when
- All responses, positive and negative
- All non responders
- All patients who have participated
- Nature of research

Contact frequency will depend on the nature of the research

- Postal questionnaire – 6 months
- Single visit for blood sample etc (non interventional) – 6 months
- More than 1 visit for blood sample etc (non interventional)-annually from last visit
- More than 1 visit (interventional) – annually from last visit

Confidentiality

Protecting the confidentiality of the Study Participants is a primary concern of the Scientific Committee and AG. Collaborators will therefore have to be bound by an agreement to treat all information with utmost confidentiality.

Documentation

A description of the GoDARTS Resource is available on the Study website (http://diabetesgenetics.dundee.ac,uk) More detailed information is available on variables once collaboration has been agreed. There will always be a minor backlog of Data and/or

Samples that has been collected but that is not yet available for use. Our aim is to clear this backlog within six months of collection so that it is coded, checked and cleaned and new data processed in a timely fashion. This does not include text Data from questionnaires that will only be entered as text and not routinely coded.

PR policy

All press releases on research arising from the Study or Future Projects should be seen and approved by the AG. We may decide to press release certain articles and will expect the lead author on the paper to agree the press release with the AG 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 applications for future core support or to put on the Study web page.

Authorship and publication

Authorship on papers arising from GoDARTS studies and Future Projects should follow standard practice-see Appendix 9. All full papers have to be sent to the AG and may not be submitted until approval is given by the AG. The AG will respond within 30 days of the next AG meeting. We read all papers to check confidentiality is protected and to assist in the identification of patentable results; to ensure that the paper will not bring the Resource 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 to provide formal peer review.

The AG must be given the opportunity to review all abstracts before submission for presentation at conferences, scientific meetings, etc. Whilst we understand that this can be problematic it is essential to ensure proper governance of outputs. Fast track processes for clearing abstracts and posters, and for certain other forms of publication, will be implemented by the AG.

A checklist of requirements for papers arising from WTT2DM studies and Future Projects along with some accompanying notes explaining these requirements and containing appropriate text to insert is contained in Appendix 9. A completed checklist should be included with each paper submitted to the AG for approval. Collaborators should send the AG copies of the final submitted draft and subsequent revised drafts. Collaborators should let the AG know when a paper is accepted and send 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 Resource can be found on the website http://diabetesgenetics.dundee.ac,uk

Acknowledgements in publications

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 are extremely grateful to all the participants who took part in this Study, the general practitioners and workplaces throughout Tayside for their help in recruiting them, and the whole of the Study team, which includes computer and laboratory technicians, clerical workers, diabetic clinic and General Practitioner staff, research scientists, volunteers, and nurses. The Wellcome Trust provide core support for the UK Type 2 Diabetes Case Control Collection. This publication is the work of the authors and Resource Access Group will serve as guarantors for the contents of this paper. This research was initially funded by The Wellcome Trust – Grant No 072960/Z/03/Z."

If the publication has been dependent on funding from a third party, this should also be acknowledged subject to any confidentiality provisions with the third party.

Intellectual property

The intellectual property used in the Resource and arising from Future Projects is governed by the UK Type 2 Diabetes Genetics Consortium Case-Control Collection Commercial Access and intellectual Property Policy shown in Appendix 6.

Feedback

This policy was last updated in May 2011 and will be reviewed annually (could you review?). We welcome feedback, comments and suggestions which should be submitted to Bridget Shepherd, Research Nurse, Diabetic Support Centre, Ninewells Hospital, Dundee, DD1 9SY Tel: 01382 383280 b.z.shepherd@dundee.ac.uk

Definitions

For ease of reference a Glossary of Defined Terms is appended at Appendix 10

APPENDIX 1

Description of UK Type 2 Diabetes Genetics of Diabetes Research and Audit in Tayside GoDARTS

The Resource

Study Methodology

GoDARTS has created a biomedical and genetic resource (Resource) for the study of type 2 diabetes and related disorders. Over 16,000 participants have been recruited in Tayside, both cases (patients with Type 2 diabetes) and controls. Baseline data consists of written informed consent, blood pressure, waist measurement, BMI, family history of diabetes, diabetes treatment and a lifestyle questionnaire plus blood samples for biochemical measurements and samples from which DNA and RNA is extracted. Serum is taken for biomarkers and stored for future investigation. Urine is stored for proteomics and metabolomics. The study also takes advantage of established population-based record linkage capability to allow anonymous longitudinal tracking.

The baseline data, study samples and longitudinal follow up forms a Resource for use by UK and International scientists working to improve the care of patients with Type 2 diabetes

To date there are 3 related collections named collectively as GoDARTS:

- Genetics of Diabetes Audit and Research in Tayside 1 (Go DARTS 1) January 1997-October 2004
- Wellcome Trust Type 2 Diabetes Case Control Collection – WTCCC (Go DARTS 2) October 2004-May 2009
- WTCCC extension (GoDARTS 3) October 2009 ongoing

UK Type 2 Diabetes Genetics Consortium

Professor Andrew Morris University of Dundee

Professor Andrew Hattersley; University of Exeter

Professor Mark McCarthy; University of Oxford

Professor Tim Frayling; University of Exeter

Professor Colin Palmer; University of Dundee

Professor Helen Colhoun, University of Dundee

Professor Ewan Pearson; University of Dundee

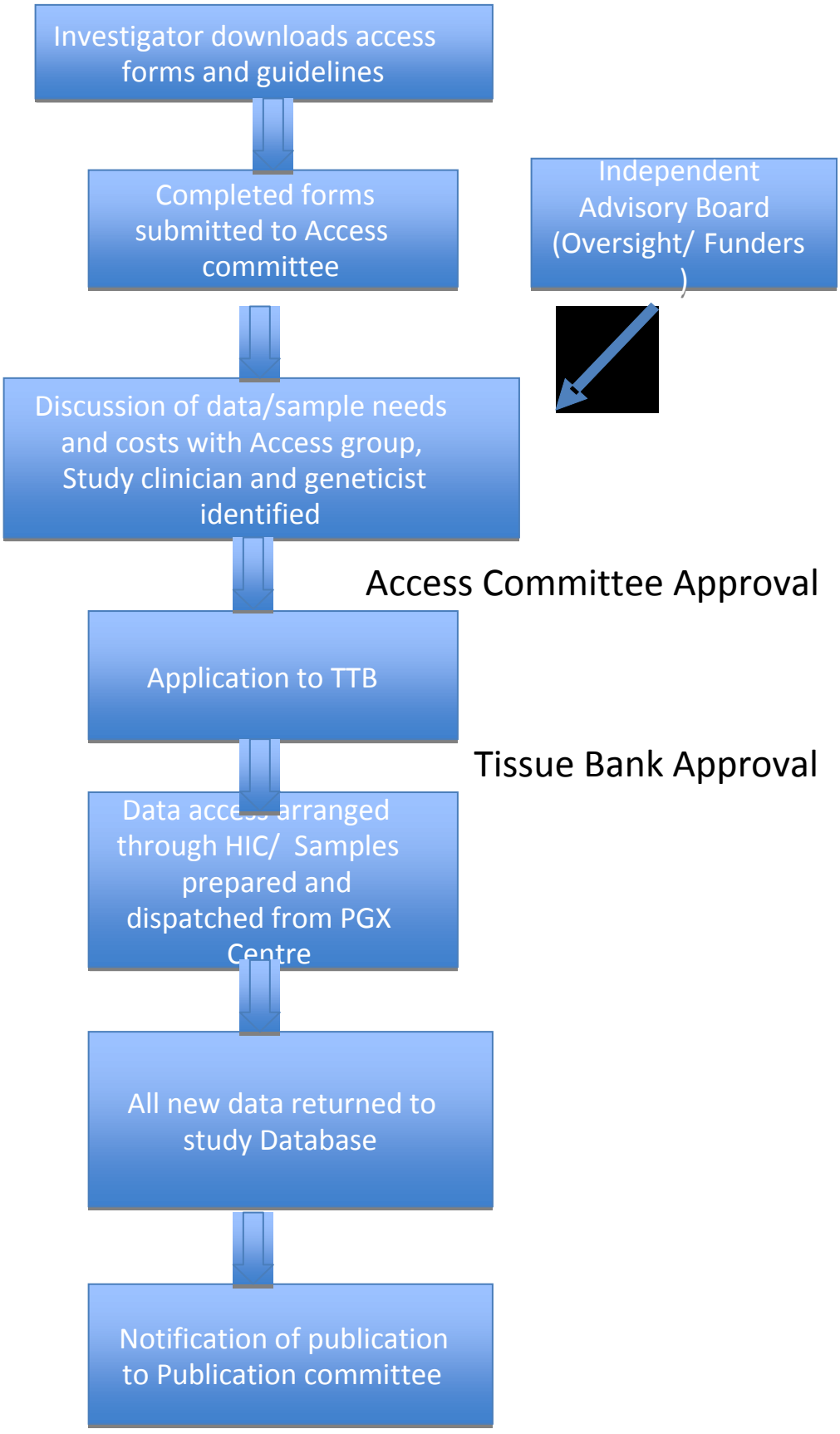
Dr Alex Doney; University of Dundee

Professor Graeme Leese, University of Dundee

Dr Ellie Dow, University of Dundee

Professor Frank Sullivan, University of Dundee

GoDARTS Collection



APPENDIX 3

TERMS OF REFERENCE OF GoDARTS COLLECTION

SCIENTIFIC COMMITTEE

Role and Responsibilities

To provide the strategic and operational management of GoDARTS and future collections.
To define the governance arrangements of GoDARTS and future collections.
To define the scientific rationale for GoDARTS and research into genetic causes of disease.
To define the ethical issues involved and how these might be addressed.
To define the conditions under which researchers will be given Access to the Resource or new Data and/or Samples as part of Future Projects.
To define the conditions under which researchers seek approval for publications arising from GoDARTS studies and Future Projects.
To supervise the operational detail of establishing WTT2DM and the Access Group (AG)
Establish a costing policy for Access to the Resource or new Data and/or Samples as part of Future Projects.
To review the process and outcomes of all requests for Access to the Resource or for Future Projects managed by AG .
To review the process and outcomes of all requests for publications arising from WTT2DM studies or Future Projects managed by AG.
To report to the Advisory Board on the management of the Resource and requests to Access the Resource, approval for Future Projects and publications.
To develop the research potential of the GoDARTS Resource.
To ensure the Resource is not brought into disrepute and that Participant confidentiality is respected

Membership

<u>Executive Committee members:</u>

Professor Andrew Morris (Chair); University of Dundee

Professor Andrew Hattersley; University of Exeter

Professor Mark McCarthy; University of Oxford

Professor Tim Frayling; University of Exeter

Professor Colin Palmer; University of Dundee

Professor Helen Colhoun, University of Dundee

Professor Ewan Pearson; University of Dundee

Dr Alex Doney; University of Dundee

Appendix 4

TERMS OF REFERENCE FOR THE THE GoDARTS COLLECTION

ADVISORY BOARD

The Advisory Board is appointed by The University of Dundee and Wellcome Trust.
The Advisory Board does not have executive powers. Its role is to comment on and provide advice for the Wellcome Trust and the Scientific Committee on the Study and Future Projects and its implications for the research community.
Although the Advisory Board will have an advisory role on ethics as in other matters of public interest, it will not assume a regulatory function as this is the responsibility of other bodies.
It will usually meet yearly but not all dialogue will be conducted through formal meetings.
The Advisory Board may request information relevant to the discussions of the Advisory Board.
The Advisory Board will address the public through the Wellcome Trust and public statements.
Complaints will be referred to those with executive powers, usually the Scientific Committee.
The Advisory Board is independent of the Scientific Committee.
The Advisory Board will receive a report from the Scientific Committee on all requests for Access to the Resource, Future Projects and publications and the outcome of such requests such requests being managed by the Access Group on behalf of the Scientific Committee..

Chair: To be assigned by the Wellcome Trust

Members To be confirmed

Appendix 5

TERMS OF REFERENCE FOR THE GoDARTS COLLECTION

Access Group (AG)

1. On behalf of the Scientific Committee, to record, review and assess (approve or otherwise) all applications to GoDARTS and subsequent collections for access to the Resource, including patient re contact

.

2. On behalf of the Scientific Committee, to record, review and assess (approve or otherwise) all requests for the collection of new Data and/or Samples or Future Projects.

3. On behalf of the Scientific Committee, to record, review and assess (approve or otherwise) all publications arising from the use of the Resource, Future Projects or the collection of new Data and/or Samples.

4. On behalf of the Scientific Committee, to co-ordinate the completion by all parties of Data and Material transfer.

5. To report to the Scientific Committee and Advisory Board on requests and subsequent outcomes for Access to the Resource, collection of new Data and/or Samples, Future Projects and publications

6. To ensure the Resource, through its collaborations, is not brought into disrepute and that participant confidentiality is respected.

7. To consult with Scientific Committee and Advisory Board concerning any need for revision of the Management, Access and Publications Policy and any of the agreements and forms contained therein.

Rotating Chair

Professor Andrew Morris University of Dundee

Professor Colin Palmer; University of Dundee

Professor Helen Colhoun, University of Dundee

Professor Ewan Pearson; University of Dundee

Dr Alex Doney; University of Dundee

Professor Graeme Lees, University of Dundee

Professor Chim Lang, University of Dundee

Ms Bridget Shepherd, University of Dundee

Mrs Caroline Glen, University of Dundee

Appendix 6

THE GoDARTS COLLECTION

COMMERCIAL ACCESS AND INTELLECTUAL PROPERTY POLICY

This GoDARTS Commercial Access and Intellectual Property Policy covers (i) the intellectual property brought to the Study or Future Projects by the collaborating institutions (Background Information and Background Rights) and (ii) the intellectual property arising from the Resource and Future Projects (Foreground Information and Foreground Rights).

Principles of Agreement on Intellectual Property:

1.1 Background Information and Background Rights is owned by the party bringing it to the Study and Future Projects; non-exclusive royalty free licence to Background Information and Background Rights is granted between the parties of the Type 2 Diabetes Genetics Consortium Case-Control Collection for the purposes of carrying out the Study and Future Projects subject to third party rights;

1.2 Project Results and Project Rights arising from the Resource and Future Projects shall be owned by the party generating them; identification, protection and management of Project Results and Project Rights, and associated costs, will be the responsibility of the party or parties owning the Project Results and Project Rights.

1.3 Each party grants the other parties a non-exclusive royalty free licence to use its share in the Project Results and Project Rights (other than Project Results and Project Rights arising from Future Projects) for the purposes of (i) undertaking the Study and (ii) internal, non-commercial research, teaching and/or clinical applications subject to review in light of any commercial/licensing opportunity in respect to a particular Project Results or Project Rights

1.4 Should a party wish to commercially exploit the Project Rights generated by another party during the project it may request a licence to do so on terms to be agreed;

1.5 Access to Project Results and Project Rights arising from Future Projects shall be negotiated between parties on a case by case basis.

Responsibilities of the Parties in the Commercial Exploitation of Results

It is envisaged that the output of the GoDARTS and Future Projects will generate new Project Results including but not limited to genetic analysis capability, informatics tools, educational tools, novel drug targets and novel diagnostic methods;

Any commercial exploitation of the outputs of the Study or Future Projects will be without payment to the Participants or their heirs and without any acknowledgement of individual patient contribution;

Each party shall be responsible for the commercial exploitation of Project Results and Project Rights generated by that party; regular updates on such commercial exploitation must be submitted to the AG. In the case of jointly owned Project Results and Project Rights it shall be agreed between the parties who should take the lead.

Each party shall give due consideration to requests for Access to its Background Information and/or Background Rights for the purposes of allowing another party to commercially exploit Project Rights generated by it; such Access shall be on terms and conditions to be agreed.

Each party shall give due consideration to requests from another party to commercially exploit its Project Results or Project Rights; such Access shall be on terms and conditions to be agreed.

Should a party choose not to commercialise Project Rights the AG may seek assignation of such Project Rights to another party subject to agreement by both parties, to allow commercial exploitation to proceed; the party originally generating the Project Rights will share in any commercial income stream arising from this arrangement on terms and conditions to be agreed.

Approval of third party (including commercial) collaborations:

Data and Samples arising from the Study can only be provided to third parties with the prior written approval of the GoDARTS Scientific Committee; a function that has been delegated to the Access Group

The Scientific Committee shall be responsible for understanding the costs of maintaining and developing the GoDARTS Resource in order to inform a pricing structure for commercial Access and which is commensurate with long term financial sustainability;

The "price" paid for commercial Access to the Resource shall vary depending on the nature of the interaction. Service style agreements whereby GoDARTS is unlikely to enjoy benefits additional to the payment for release of Data or Samples will normally be priced at a higher rate than where longer term benefits for the Resource are perceived. The Scientific Committee shall be charged with ensuring that commercial price negotiations are undertaken by appropriately skilled and informed individuals, perhaps drawing on the skills extant within the Study partners, NHS R&D Offices and the University Technology Transfer offices.

Appendix 7

GoDARTS

COLLABORATION PROPOSAL

Informal discussion is welcomed in advance of submitting this form. Please contact the Access Group (see Study web page http://diabetesgenetics.dundee.ac,ukfor contact details)

COLLABORATION PROPOSAL FORM

Collaborator's request to Access data and/or biological samples from the GoDARTS Collection

A collaboration between the University of Dundee, University of Oxford, University of Exeter

Oversight of Resource Provided by the Access Group, Tayside Tissue Bank and Health Informatics Centre.

1. Name of all applicants and affiliations.

Principal Applicant (name, affiliation, full contact details)
Name
Affiliation
Address
Email
Telephone

Secondary contact person (name, affiliation, full contact details)
Name
Affiliation
Address
Email
Telephone

Co-applicant 1 (name, affiliation):Name, Affiliation
Co-applicant 2 (name, affiliation):Name, Affiliation
Co-applicant 3 (name, affiliation):Name, Affiliation
Co-applicant 4 (name, affiliation):Name, Affiliation
Co-applicant 5 (name, affiliation):Name, Affiliation

2. Title of project (less than 30 words):

Project Title

Start date: Finish date:

3. Brief description of project (no more than 1-2 sides A4 with up to 10 key references)

Project Description

4. Funding: Has/will the project be(en) peer reviewed and funded?

☐ YES
☐ NO

Approximately when was the project reviewed and by which organisation:

Final decision: (*Please indicate the final decision of the funders*)

5. DNA: Will the project require Access to DNA from the GoDARTS?

☐ YES
☐ NO

If YES please complete the following:

Quantity of DNA required: (μg) per sample/subject

Minimum concentration: (ng/μl)

Number of subjects:

If your request is for greater than 2 μg per samples please justify the size of the sample you have requested:

Please also indicate whether the DNA is for:

☐ SNP analysis How many SNPs (approx)

☐ Micro-satellites How many micro-satellites (approx)

☐ Sequencing What length (approx)

☐ Structural DNA work (including copy number variation)

The request indicated here should be consistent with the project description (section 3)

a) *Will the project analyse samples from all available subjects in the cohort study?*
☐ YES
☐ NO

IF NO, please define the subset required (this information is important, please read the guidance document):

b) *Will your DNA have any special requirements for preparation, storage or transport?*

☐ YES
☐ NO

If YES please specify what special preparation, storage or transport requirements are needed:

c) *Please provide a copy of the protocol(s) to be used for laboratory processing and analysis, including Q.A./Q.C. documentation. If you are seeking Access to a finite resource, protocols may be sent in confidence for external scientific peer-review.*

☐ I confirm that I have read the information and guidelines. I agree to return the genotypes that are generated under this project to GoDARTS to support future research based on the resource,

See *Policy for use and oversight of samples and data arising from GoDARTS*

6. Biological samples: Will the project require Access to serum from the subjects

a) *On how many subjects?*

b) *What minimum quantity is required from eAGh subject?*

c) *What is the justification for the volume/quantity requested?*

d) *Will the project process all available samples from the cohort study?*

☐ YES
☐ NO

e) *Will the biological samples have any special requirements for preparation, storage or transport?*

☐ YES
☐ NO

If YES please specify what special preparation, storage or transport requirements are needed:

f) *Please provide a copy of the protocol(s) to be used for laboratory processing and analysis. If you are seeking Access to a finite resource, protocols may be sent in confidence for external scientific peer-review.*

☐ I agree to return the results of assays that are undertaken during this project to GoDARTS to

support future research based on the resource. See *Policy for use and oversight of samples and data arising from the Resource*

7. Genome wide genotype data

The genome wide genotype data from the study of genetic deteriminants of statin response are held on the European Genetic Archive (EGA) on the campus of the Wellcome Trust Sanger Centre in Hinxton.

a) Does your project require Access to genotype data from the available genome wide scans?

☐ YES
☐ NO

If YES:

b) Does your project require Access ***solely*** to genotype data generated by the Genome Wide Analysis (GWA) undertaken as part of one or more of the following projects: Wellcome Trust Case Control Consortium (WTCCC), WTCCC2, Wellcome Trust Sanger Institute extended Illumina genotyping of the WTT2DM study of statin response

☐ YES
☐ NO

If YES:

You should redirect your application the Consortium Data Access Committee of WTCCC (cdAG@wellcome.AG.uk)

If NO (that is you want ***anything else*** other than just the individual level genotypes with indicators of sex and region of residence), you should continue completing this form as the application will be dealt with by the Access Committee

You should only respond to question 7c if you have answered YES to question 7a and NO to question 7b.

c) Which subsets of GoDARTS data do you require from the GWA archive at EGA? Please read the guidance document.

8. Other genotype data:

IF NO, please define the subset required (this information is important, please read guidance):

a) *If your request is for genotypes generated by a previous primary user of GoDARTS samples or data, please indicate where those data are stored and under whose administration. If you have discussed your proposal with that primary user, please outline their response:*

b) *Please specify which genotypes you need:*

9. Other data

Non-genotype data are held at the Health Informatic Centre Data Archive at Dundee University. Default variables collected at baseline are available . If these are the ***only*** variables you require, you do ***not*** need to complete this section (see section 7).

Does your project require Access to non-genotypic data other than the default baseline data set ?

☐ YES
☐ NO

If YES, please indicate which variables and carefully justify your request. This information is important, please read the guidance material.

10. New variables to be created by your project

a) Will any new variables be derived or produced under the project that would be of value to other users of the resource in future? Please see guidance material.

☐ YES
☐ NO

If YES, *please describe what variables*

If YES, *please describe which variables, and please indicate how long an embargo period you would like to specify before other users can Access the data (up to 1 year from the date on which the data/samples are awarded to you):*

11. Additional information that may be used in judging applications for a finite resource (*e.g.* blood samples other than from cell lines) or with a focus on a scientific question that may be judged as particularly sensitive.

If you have already provided the information requested in your project description, please just state "see section 3" in the relevant boxes below.

a) Does your project seek Access to a finite resource, or is it likely to be judged as sensitive in some other way?

☐ YES
☐ NO

If NO, please proceed to section 12

b) Does your laboratory have formal protocols for quality control and quality assessment? If so, you may be requested to provide them and, with your consent, we might need to send them for confidential independent external peer review.

c) *Who will be responsible for statistical analysis (please indicate name and expertise)?*

Agreement (to be completed by the Principal Applicant)

☐ I confirm that I have read the above application and that the information contained in it is true to the best of my knowledge

☐ I understand that data and samples from the GoDARTS resource can be used for commercial purposes. I am aware that if I do use them for such a purpose *without* obtaining prior approval from the Access Committee, I will be in breach of agreements, and that this might result in my being excluded from using the GoDARTS resource or any other Tayside Tissue Bank Resource in the future. I understand that if I undertake work that might *potentially* be viewed as commercial, it is *my* responsibility to seek the advice of the Access Committee

☐ I understand that I must not pass on any data or samples that I am awarded, or any derived variables or genotypes) generated by this application to a third party (*i.e.* to anybody that is not included in the list of applicants on my project nor is a direct employee of one of the applicants). I realise that any third party seeking to use the data, samples, derived variables or genotypes must approach the GoDARTS Access Committee to obtain Access permission of their own.

☐ I understand that if a problem arises involving any misuse of the GoDARTS data or samples provided for my project - I (as the principal applicant) will be held responsible and that this might result in my being excluded from using the resource or any other Tayside Tissue Bank Resource in the future.

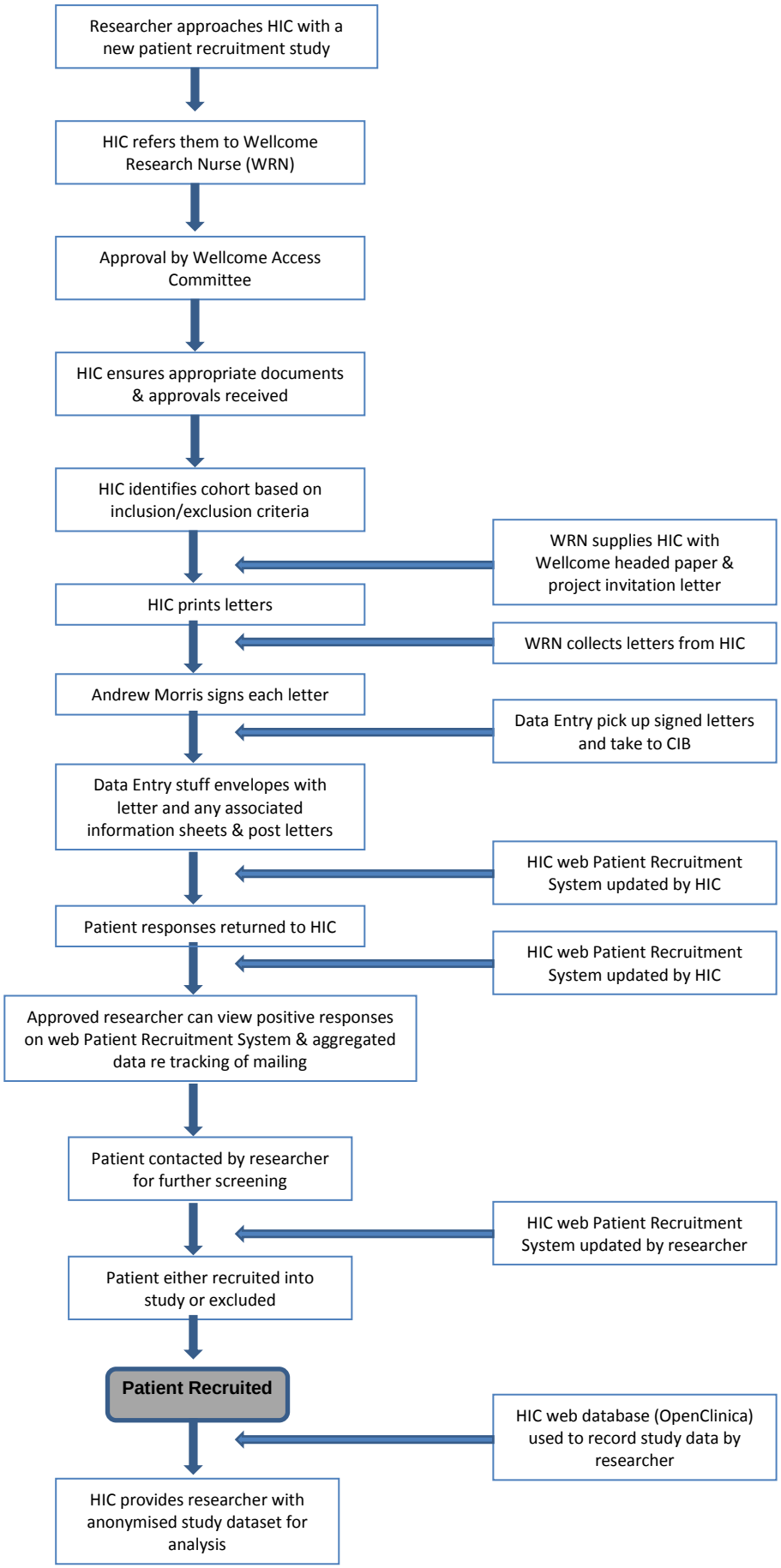
Signature _____ Date _____

Print Name _____

Please include pdf of signed application in the electronic application to Tayside Tissue Bank.

Key Contacts:

GoDARTS Principal Investigator: Professor Andrew D Morris MD FRCP FRSE FMedSci a.d.morris@dundee.ac.uk	GoDARTS Laboratory Director: Professor Colin Palmer PhD Nuclear-receptor@dundee.ac.uk
Tayside Tissue Bank Manager Dr Ian Forgie PhD i.m.forgie@dundee.ac.uk	Health Informatics Centre Operations Manager Mr Duncan Heather d.heather@dundee.ac.uk


Researcher approaches HIC with a new patient recruitment study
HIC refers them to Wellcome Research Nurse (WRN)
Approval by Wellcome Access Committee
HIC ensures appropriate documents & approvals received
HIC identifies cohort based on inclusion/exclusion criteria
WRN supplies HIC with Wellcome headed paper & project invitation letter
HIC prints letters
WRN collects letters from HIC
Andrew Morris signs each letter
Data Entry pick up signed letters and take to CIB
Data Entry stuff envelopes with letter and any associated information sheets & post letters
HIC web Patient Recruitment System updated by HIC
Patient responses returned to HIC
HIC web Patient Recruitment System updated by HIC
Approved researcher can view positive responses on web Patient Recruitment System & aggregated data re tracking of mailing
Patient contacted by researcher for further screening
HIC web Patient Recruitment System updated by researcher
Patient either recruited into study or excluded
Patient Recruited
HIC web database (OpenClinica) used to record study data by researcher
HIC provides researcher with anonymised study dataset for analysis

APPENDIX 9

GoDARTS

AUTHORSHIP, PUBLICATIONS AND PAPERS CHECKLIST

Checklist for papers arising from use of the use of the GoDARTS Resource for Future Projects

All GoDARTS papers have to be sent to the GoDARTS Access Group for approval. The AG will respond with 30 days of the next AG meeting. The AG reviews all papers to check confidentiality is protected; to assist in the identification of patentable results to ensure that the paper will not bring the Resource into disrepute; to try to identify overlap with other papers published or in preparation. The AG also provides advice and feedback to authors where we feel this may be helpful. The AG has prepared a checklist of requirements for GoDARTS papers along with some accompanying notes either explaining these requirements and/or containing appropriate text to insert. A signed and completed checklist should be included with each paper submitted to the AG for approval. Please send to Access Committee administrator c.glen@dundee.ac.uk

CHECKLIST FOR WTT2DM PAPERS

Name of first or main author……

Title of paper…… ……

WTT2DM Research Facilitator …… ……..

Checklist

- I have included GoDARTS as a keyword
- I have included an accurate description of the study numbers
- I have included an accurate description of the ethical approval
- I have included an acknowledgements section
- I have returned a copy of the final dataset I have used to my research facilitator
- I will send a copy of the final submitted manuscript and revised versions
- I will let the GoDARTS Access Group know when the paper is accepted for publication
- I will submit a paper and electronic copy of the final paper to GoDARTS AC
- I will liaise with the GoDARTS public relations team over media coverage
- I will provide a short scientific summary of this paper if required by the GoDARTS Access Group
- I will provide a lay summary for the GoDARTS Access Group before publication

Signature…… …….. Date……..

NOTES

Ethical approval

GoDARTS has received ethical permission for the core fieldwork. GoDARTS is registered with the tissue bank in NHS Scotland that reviews all proposals for new data collection and approves policies for data handling and analysis. Proposals for new data collection are also approved by the NHS Research Ethics Service. A statement describing this that should be included in all papers is shown below:

"Ethical approval for the study was obtained from the Tissue Bank Committee and Tayside Committee on Medical Research Ethics (on behalf of the National Health Service)." ***Every project may not require additional ethics approval***

Acknowledgements section

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 are extremely grateful to all the participants who took part in this Study, the general practitioners for their help in recruiting them, and the whole of the Study team, which includes computer and laboratory technicians, clerical workers, diabetic clinic and General Practitioner staff, research scientists, volunteers, and nurses. The Wellcome Trust provide core support for the GoDARTS collection. This publication is the work of the authors and Resource Access Group will serve as guarantors for the contents of this paper. This research was initially funded by The Wellcome Trust – Grant No 072960/Z/03/Z. If the publication has been dependent on funding from a third party, this should also be acknowledged subject to any confidentiality provisions with the third party.

Final dataset

Not applicable if in-house analysis used.

Media coverage of WTT2DM publications

Where appropriate we encourage media coverage of GoDARTS papers to raise the study's profile and in particular to show study members that the study is producing interesting and valuable findings. Please contact the GoDARTS executive if you know there is going to be a press release or if you have given any press interviews.

Short scientific summary of the paper

We may ask you to prepare a short summary of your paper that we can include with reports to our funders.

Lay summary of the paper

Once your paper is accepted for publication we will ask you to prepare a lay summary of your paper for circulation to GoDARTS staff. This may also to be used to publicise your paper, and will be placed on the GoDARTS website.

APPENDIX 10

GoDARTS

GLOSSARY OF TERMS

Advisory Board means the Advisory Board as detailed in Appendix 4 to be appointed by the University of Dundee and the Wellcome Trust to oversee the activities of the Study Scientific Committee as detailed in Appendix 4;

Background Information means Information which at the commencement date of the Study or Future Projects is in, or during the continuance of the Study or Future Projects, and other than as a result of the Study or Future Projects, comes into, the ownership or control of a party, and which such party is free to disclose;

Background Rights means Intellectual Property Rights arising out of, or existing in, Background Information (other than Project Rights);

Data means any data in relation to Participants that is collected pursuant to and in the course of the Study and Future Projects ;

Future Project means any programme of work relating to the Study utilising Data and or Samples, or adding to Data or Samples, identified by the parties and approved by the AG and for which one party or a collaboration of more than one party may seek or be offered external funding;

Information means (without limitation) drawings, specifications, photographs, models, processes, inventions, procedures, instructions, software, reports, papers, correspondence and any other technical or commercial information, data and documents of any kind, and including oral information if confirmed in writing within 30 days after the disclosure thereof;

Intellectual Property Rights means processes and procedures, patents, design rights, (both registered and unregistered), including semiconductor topography rights, trade secrets, know-how, copyrights, trade marks, database rights and any other form of intellectual property protection either arising automatically at law, or arising further to any statutory procedure and including any application for registration of the same;

Joint Project Rights means Project Rights owned by one then one party;

Participant means a healthy volunteer or NHS patient who has consented to provide, and has provided, Samples and/or Data to be used for the Study and any subsequent Future Projects;

Project Results means results arising directly from the use of Data, Information, and Samples, including but not limited to genetic analysis capability, informatics tools, educational tools, novel drug targets and novel diagnostic methods, arising as a direct result of the Study or Future Projects;

Project Rights means Intellectual Property Rights (other than Background Rights) in any Project Results;

Resource means Data, Samples, databases and general expertise generated by the Study collaborating parties as a result of the Study and Future Projects available for use by parties and in collaboration with external third parties;

Samples means human samples of body tissue or bodily secretions, or excretions of fluids, all taken from a Participant, and/or any material directly derived from or incorporating the Sample created and/or collected during the course of the Study or a Future Project.

Scientific Committee means the Committee responsible for managing and administering the Study, and any delegated sub-groups, as detailed in Appendix 3;

Study means the work programme outlined in the UK Type 2 Genetics Consortium Case Control Collection Proposal subsequently funded by the Wellcome Trust, attached hereto as Appendix 1;