



**ADELAIDE
HEALTH
FOUNDATION**

RESEARCH SCOPING DOCUMENT

***Research Study of genetic testing
and genetic counselling services in Ireland***

INDEX

- Executive Summary Page 3
- Background Page 4
- Research Brief Page 6
- Project Stages Page 7
- Communications Page 7
- Assessment Page 7
- Award Page 7
- Reporting Page 7
- Outline Project Flow Page 8

APPENDIX

- Research Regulations Page 9

EXECUTIVE SUMMARY

The Adelaide Health Foundation [AHF] is a voluntary Foundation with a proud history of supporting and publishing leading-edge research in healthcare.

We aim to generate and promote the use of evidence-based research which informs health policy, influences change within the Irish healthcare system and improves the health and wellbeing of the population.

To date, the AHF have invested over €1m in funding for health services research which includes:

- Assessment of funding options and barriers to Universal Healthcare (UHC) and an evaluation of general public opinions on the introduction of UHC in Ireland.
- Clinician and patient stakeholder analysis of chronic disease management in Ireland.
- A Health Asset and Need Assessment (HANA) of Tallaght.
- Study and recommendation on how best to encourage patient and family involvement in the design and delivery of health services.

The AHF now seeks to commission research into genetic testing and counselling services in Ireland.

This theme has been selected as we understand genetic testing and counselling services in Ireland to be under-regulated, underfunded and fragmented. This leads to many issues around availability and access to quality services impacting Patients, Health Professionals and Doctors.

The aim of the research project is to:

- review genetic testing and counselling services available in Ireland and compare them against best international practice
- provide recommendations on improving service design and delivery together with a roadmap to improve the patients experience in finding answers to difficult questions.

The Foundation's desired outcomes from all of its research undertakings are sustainable improvement and positive change, including the influencing of health policy



ADELAIDE HEALTH FOUNDATION

AHF Mission

We are a voluntary Foundation committed to supporting education, policy and research to advance and promote equitable health & healthcare in Ireland, with a particular focus on Tallaght University Hospital and the community it serves.

AHF Values

- Equal access to quality healthcare for all.
- Respect for the patient's dignity, and their right to self-determination over their healthcare.
- Independence in opinion and action of the Foundation and Medical Practitioners, including but not confined to the fields of ethics and genetics.
- Support public and patient involvement in health and wellbeing.
- Support Tallaght University Hospital, as a voluntary hospital, and the community it serves.

Research Objectives

The AHF seeks to support high-quality research which:

- Aligns with our mission and values
- Is patient focussed
- Fulfils a pressing health service demand

PROJECT BACKGROUND

A sub-group of the Foundation was charged with development of this research project. We acknowledge the significant input of Dr Gerard O'Connor without whom the project would not have progressed. We are also grateful to Prof Maeve-Ann Wren for her support and guidance.

AHF Research sub-group

Rory Brownlee	Director [Chair]
Peter Fitzpatrick	Director
Niamh Gavin	CEO
Hugh Sullivan	Director

As the Research sub-group embarked on scoping out the project, it was agreed to consult with a panel of experts from the field of genetics, in order that we properly identify the issues and use the available resources most effectively.

In June 2020, the sub-group and panel convened to discuss:

- Genetic testing and counselling services available in Ireland.
- The positives and negatives of the Irish offering.
- The ideal outcome of this research project.

We are grateful to the following for their contribution:

Advisors

Ms Tara Clark	Genetic Counsellor, Our Lady's Children's Hospital Crumlin
Prof James Geraghty	Consultant Breast Surgeon, St Vincent's Hospital
Prof Andrew Green	Consultant Clinical Geneticist, Our Lady's Children's Hospital Crumlin
Dr Marion McAllister	Programme Director, MSc in Genetic & Genomic Counselling, Cardiff University
Prof David McConnell	Fellow Emeritus in Genetics, Trinity College Dublin
Dr Deirdre Ward	Consultant Cardiologist Specialist in Inherited Cardiac Conditions, Tallaght University Hospital

GENETIC TESTING AND COUNSELLING SERVICE IN IRELAND RESEARCH BRIEF

With a focus on gaining a full insight into the patient experience, the scope of the research project will address, but not be limited to, the following areas:

1. Patient pathways through the public and private Irish health services in relation to testing, prevention, diagnosis, treatment, counselling and other services for genetic medical conditions, including:
 - a. Genetic testing services
 - b. Referral patterns
 - c. Access to medical geneticists and genetic counselling services
 - d. Models of care
2. A review of regulatory frameworks and standards covering all areas from prevention and detection through to treatment and support for genetic medical conditions.
3. A benchmark analysis of current genetic counselling services against best international practice, including regulation and governance (with reference to no fewer than four suitable international comparators).
4. The organisation and availability of medical and other genetic reports and opinions within the context of the patient health record.
5. The professional relationships between genetic counsellors, medical geneticists and other medical specialists in Ireland.
6. Genetic counsellor access to research programmes and continuous development.
7. Requirements for wellbeing support framework(s) for genetic counsellors.
8. An indication of the general public's awareness, knowledge and perceptions of the role of genetic counsellors / genetic counselling in medical services.
9. Opportunities and needs for patient input in terms of:
 - a. Service design and delivery
 - b. Risk understanding & implementation
 - c. Ease of access to genetic counselling services [considering public vs. private]
 - d. Ethical guidelines that support the delivery of the service.

The selected research partner will be required to provide the foundation with a detailed report on their findings, supported by recommendations for service development and any proposed implementation plan.

As people with lived-experiences contribute additional expertise and give valuable insights, we expect that a level of Patient and Public Involvement (**PPI**) will be included in the project plan.

The grant amount available for this project is **€115,000** and the project duration is **18 months**.

Project stages [An outline flow for the project is shown in Fig 1]

The expected stages in the project are as follows:

1. Publication and call for submissions	12 th Nov 20 to 11 th Jan 21
2. Assessment and scoring of submitted proposals	Mid Jan-21 to late Feb-21
3. Signoff meeting with assessment panel	End Feb 2021
4. Research sub-group make recommendation to AHF board	Mar 2021
5. Board nominates preferred research partner	Mar 2021
6. Contract signoff /Research program commencement	May 2021
7. Implement managed liaison program with research partner	On commencement
8. Six monthly report to steering group	On-going
9. Project close and reporting	Nov 2022

COMMUNICATIONS

- Informal enquires are welcome in advance of proposal submission.
- Once a research organisation has submitted a proposal to the AHF, receipt will be acknowledged.
- When the close off date has passed, no amendments to the submitted proposal will be considered
- No communication will be entered into after the closing date.
- Unsuccessful applicants will be notified in writing.
- Unsuccessful applicants may request and will be provided with feedback on their application.

ASSESSMENT

- All submitted proposals will be included in the assessment exercise.
- An independent panel of assessors will review proposals against set criteria.
- Research sub-group will propose the recommended research partner to the Board of the Foundation.

AWARD

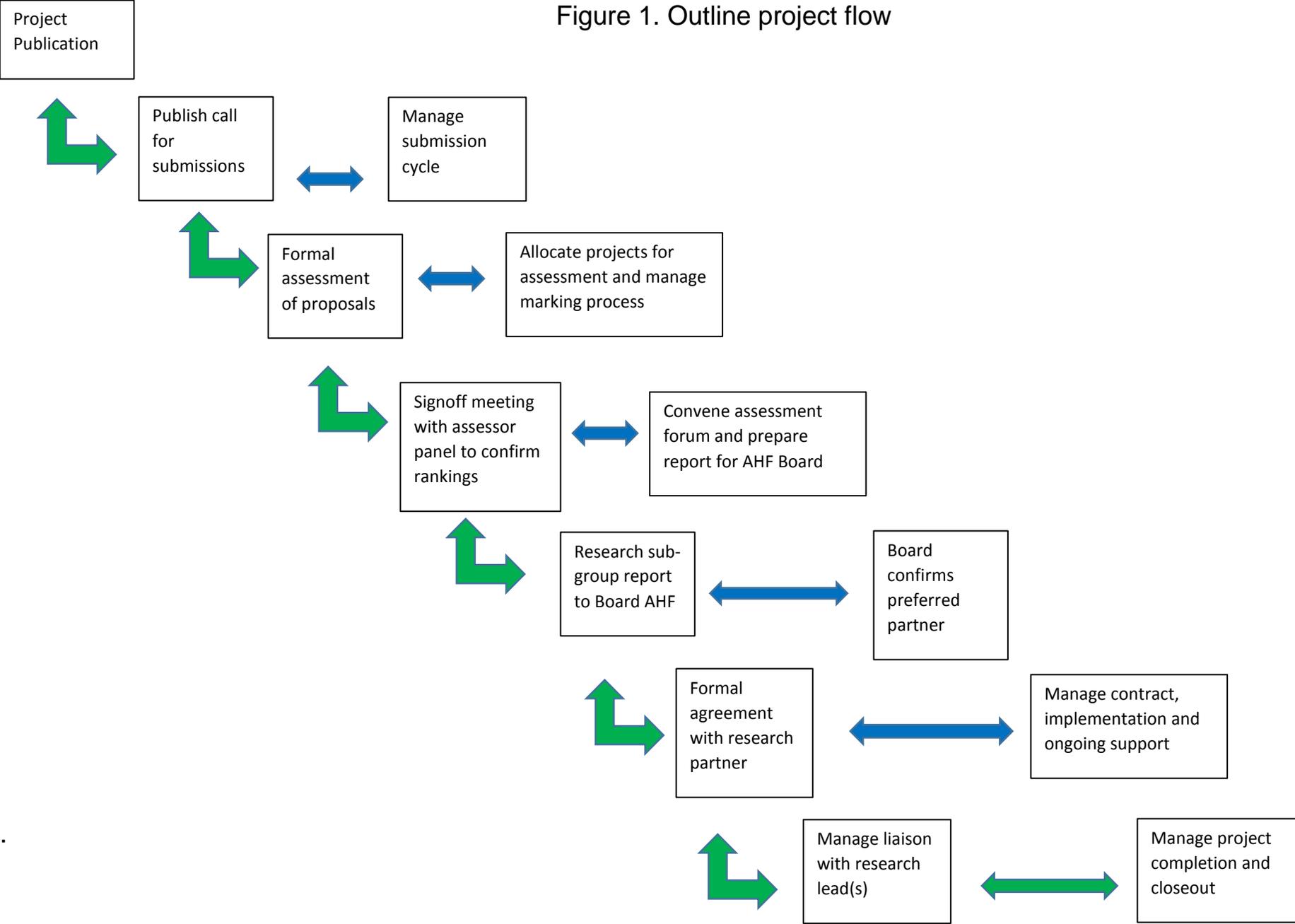
- The AHF Board will nominate the preferred research partner and their decision is final.
- The successful applicant will be notified and a contract of agreement for the research program will be finalised
- An agreed start date and end date will be identified, the former being within three months of agreement signoff.

REPORTING

- It is the view of the AHF that the research project will run independent of the foundation and liaison will be limited to project updates, contractual matters and final report.
- A Steering group will be convened which will have AHF representation.
- Following project commencement, reporting will be required at 6 monthly intervals.
- Clarifications and discussions will in so far as possible, be conducted in the spirit of partnership.
- In the rare circumstance where an unresolvable difference arises, this will be referred for mediation.

Project completion will take place when the final research report is submitted to the foundation. In advance of this, it is expected that a draft report will be available to ensure a fit with the mission and values of the foundation.

Figure 1. Outline project flow



APPENDIX

AHF RESEARCH REGULATIONS

These regulations are intended to ensure that:

- i. Grants are spent for the purpose for which they were approved.
- ii. The AHF is informed promptly of any intended changes in the research with permission being sought where necessary.
- iii. AHF receives a proper account of the outcomes of the project.

Conditions under which grants are awarded:

1. The grant holder must be employed in a defined capacity by a recognised Hospital or Health Institution/ Academic Institution within Ireland. If the grant holder is a qualified healthcare practitioner, the Clinical Indemnity Scheme must cover the position held by the healthcare practitioner in so far as any clinical risk that can arise associated with the research programme funded by the Foundation.
2. Grants will be approved for the agreed duration of the project.
3. Application forms and Regulations for Grants can be obtained through the Foundation's office or website.
4. Application forms must be completed in full. Incomplete forms will not be accepted.
5. Applicants should use plain English, avoid unnecessary jargon and use language that is accessible for non-medical reviewers.
6. Research must be in keeping with the Foundation philosophy.
7. Institutions in receipt of funding from the AHF have a duty to follow the highest ethical standards when conducting research. The grant holder shall confirm in writing as part of the application process that ethical approval has been obtained for any research project for which funding has been applied.
8. All researchers and Host Institutions must also ensure (before the research commences and during the full award period), that all legal and regulatory requirements in order to conduct the research are met, and all the necessary licences and approvals have been obtained.
9. Salaries should be stated and be in line with industry standards
10. Applicants must declare other funding applications/grants applied for/secured for the research project being applied for.
11. A grant payment schedule will be agreed with the successful applicant.
12. Unsuccessful applicants in any year are not prohibited from applying in the following years for funding for the same or different projects.
13. Once an application is passed by the AHF Research sub-group, it is submitted to the AHF Board.

14. All decisions of the Foundation on the awarding of Research Grants are final.
15. Successful applicants will be informed in writing of the decision after the approval of the AHF Board and must adhere to these Research Regulations.
16. A contract will be issued for signature by grant issuer and grant recipient.
17. The research must start within three months of notice of approval of such funding.
18. In the event there is a valid reason for a delay in the start of the research, an extension for a maximum of an additional three months must be requested in advance from the Research sub-group.
19. In the event the research does not commence within six months of approval, the approval will lapse and any funding provided must be returned to the AHF.
20. Should the PI become unavailable for longer than a four week period, a deputy [approved by the AHF] must be appointed to progress the project.
21. The Research sub-group will decide as to whether the applicant will be allowed to use some or part of the funds to cover registration costs of higher degree with the appropriate third level institutions.
22. The Foundation reserves the right, at any time during the period of the grant, to obtain from the grant holder a financial statement detailing disbursements from the grant and confirmation that the grant has been used for the purposes for which it was awarded.
23. The grant holder and all those associated with the grant shall participate in a review of the progress of the research, its organisation, financing and any other relevant issues at a date decided by the Foundation.
24. The Foundation reserves the right to withdraw funding at the end of six months if the research is not progressing satisfactorily based on submitted report.
25. The Foundation complies with the General Data Protection Regulation (the "GDPR") together with the Irish Data Protection Act 2018 in respect of its role as Data Controller. As part of the application process, all applicants must state compliance with GDPR in relation to their role as Data Controller in the research project being submitted.
26. The researcher will be required to give a presentation/paper based on his/her work to the AHF Board or Research sub-group after project completion which should comment on what the research activities have achieved in relation to the defined research objectives agreed with the Research sub-group.
27. The grant holder must ensure the dissemination, as widely as reasonably practicable the outputs of the Research Project in internationally peer-reviewed publications and the scientific press, and where appropriate, among the general public
28. The grant holder shall maintain separate Financial Records for the Grant identified by a reference code which is specific to the Grant and all costs and income properly relating to the Grant (including without limitation all disbursements of Grant monies) shall be accounted for through them. The Financial Records shall be maintained in accordance with good accounting practice.
29. The grant holder shall be wholly responsible for the conduct of the Grant Funded Activities and the AHF shall have no obligation, responsibility or any liability financial or otherwise of

any kind to the Host Institution, the Principal Investigator or any member of the Team or any third party arising directly or indirectly from the Grant or the Grant Funded Activities.

30. The views expressed in research findings are those of grant holder and do not necessarily reflect the views of the AHF.

Responsibilities of the Applicant:

1. Completed forms should be submitted to AHF by the stated deadline.
2. Research should be carried out in line with the Health Research Regulations 2018.
3. All approved research applications are subject to Ethics Committee review. Applicants should seek their institution's Ethics Committee approval prior to submitting an application.
4. A panel member or anyone associated with the AHF who is directly applying for funds [or is a collaborator on a grant application] will absent themselves from discussions about a grant.

Reports, Publications & IP:

1. The grant holder shall provide a final report to the AHF Board and Foundation within four months following the end of the period for which the grant has been awarded. Grant holders who do not comply with this requirement will be deemed ineligible to apply for future Foundation research grants and may be requested to return a portion of the funding already provided.
2. The format and layout of the final research report will be agreed with the Foundation Executive.
3. The grant holder shall provide the Foundation with signed copies of all publications and abstracts arising from research funded by the Foundation.
4. Any and all publications resulting from the grant must include reference to the research being conducted with the financial support of the AHF.
5. Any press releases relating to the research project should be jointly agreed. All media interviews and publicity should acknowledge the AHF's contribution.
6. The AHF Board reserves the right to publish a summary of research – only after the grant holder has published his/her research.
7. The Foundation recognises that the primary responsibility for research and research outcomes rests with the Researcher(s). The Researcher(s) has a duty to the Foundation to ensure that discoveries and advancements in knowledge arising from research funded by the Foundation are translated for public benefit e.g. by publication, by patenting or through securing Intellectual Property Rights.