Definitive Interventions and Feasibility Studies

The HRB funds ‘projects seeking to design and evaluate a trial or intervention’ specifically under the DIFA scheme. If your project is a trial, feasibility study, or pilot study, it may not be eligible for funding under any other scheme (e.g. ARPP, EIA, ILP, APA) – always check the ‘Scope’ section of the Guidance Notes for clarification on the scheme remit before beginning an application.

Definitive Interventions

An intervention is ‘the act or fact or a means of interfering with the outcome or course especially of a condition or process (as to prevent harm or improve functioning)’ (Merriam-Webster).

Examples:

- Preventative interventions e.g. vaccines
- Therapeutic interventions e.g. surgery, drug treatment, radiotherapy
- Health systems interventions e.g. policy, financing, personnel reform

Definitive interventions are trials which provide a definitive assessment of the proposed therapy or intervention, assessing its efficacy, cost, and broad impact.

Such trials may be:

- Randomised controlled trials
- Non-randomised trials
- Any other appropriate design

Examples of definitive interventions from past rounds of DIFA:

  
  ‘This trial will investigate whether those who have slightly more carbon dioxide in their blood do better after cardiac arrest than those who are treated normally. We can easily adjust the amount of carbon dioxide in the blood while on the ventilator in the intensive care unit using the equipment we use every day.’

- Colchicine for prevention of vascular inflammation in non-cardioembolic stroke (CONVINCE) - a randomised clinical trial of low-dose colchicine for secondary prevention of stroke (Peter J Kelly, UCD, 2017)
  
  ‘CONVINCE is a clinical trial, testing colchicine in low doses, a medicine used for many years to treat gout and other joint disorders. We will compare colchicine to usual care (eg. aspirin, cholesterol lowering medicines and blood pressure treatment) in a randomised fashion.’

Stand-Alone Feasibility Studies

A feasibility study is a study done in preparation for a main study or trial.

‘Feasibility Studies are pieces of research done before a main study in order to answer the question “Can this study be done?” They are used to estimate important parameters that are needed to design the main study. For instance:

- standard deviation of the outcome measure, which is needed in some cases to estimate sample size;
- willingness of participants to be randomised;
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- willingness of clinicians to recruit participants;
- number of eligible patients, carers or other appropriate participants
- characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure;
- follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc.
- availability of data needed or the usefulness and limitations of a particular database
- time needed to collect and analyse data.'

('Feasibility Study' in https://www.nihr.ac.uk/glossary

**Pilot studies** are a subset of feasibility studies (Eldridge 2016: 18). In a pilot, a future study, or part of a future study, is conducted on a smaller scale:

‘Pilot studies are a smaller version of the main study used to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure that recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It resembles the main study in many respects, including an assessment of the primary outcome. In some cases, this will be the first phase of the substantive study and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Or, at the end of the pilot study, the data may be analysed and set aside, a so-called external pilot.’

('Pilot Study' in https://www.nihr.ac.uk/glossary

**NB Stand-alone feasibility studies (including pilot studies) are eligible to be funded under DIFA, but clear progression to a future substantive study is required.**
Example of Feasibility Study and Pilot Scheme from past round of DIFA:

- **Improving outcomes for young adults with type 1 diabetes in Ireland: the D1 now feasibility and cluster randomised pilot study** (Sean Dinnen, NUIG, 2017):

  ‘To address these areas our new D1 now intervention will have a key worker that will guide the young adult through the adult diabetes service and identify their needs; an online service to help improve communication between health care professionals and young adults; and an agenda setting tool to help health care professionals and young adults to work together on making decisions about their diabetes care.

  We will test out these parts of our intervention separately and then together to see if they are acceptable to both young adults and health care professionals and make changes if needed. We will then test the D1 now intervention out in a pilot study by comparing young adults in 3 diabetes centres who receive the D1 now intervention with young adults in another 3 centres who receive the same care as normal. At the end of this study, D1 now will be ready to be tested in a full trial across Ireland.’

**Clinical Trial Sponsorship**

Studies meeting the definition of a ‘clinical trial’ must have a sponsor, defined as ‘an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial’ (EU Clinical Trials Directive 2001/20/EC). The HRB cannot take on the role of sponsor for clinical studies within the scope of the EU Clinical Trials Directive, so TCD investigators must secure sponsorship through the CRF at St James’s.

Prior to submitting a funding application, investigators conducting research involving human subjects, their data, and/or their biosamples should explore whether they require sponsorship support – contact Fergal Seeballuck, Quality and Regulatory Affairs Manager at the CRF at St James’s (fseeball@tcd.ie).

**Resources**

HRB website: ‘[Funding Awarded: DIFA](#)’


Hoffmann, Tammy c, et al. 2014. ‘**Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide**’, BMJ 348, doi: [https://doi.org/10.1136/bmj.g1687](https://doi.org/10.1136/bmj.g1687) (Published 07 March 2014)