## NHS Health Education England

# **Educational Research**

### **Guidance for HEE Fellows**

#### Background.

HEE provides fellowship opportunities at national, regional and local levels for able medical and dental trainees, as well as clinicians from other professions. These are typically of up to 12 months in duration and usually include an element of project work; generally educational in scope. Previous fellows have found the governance associated with these complex and have often been given conflicting advice.

#### Project scope.

It is impossible to be comprehensive about the scope of every feasible project. However, it is important to note that **virtually all potential projects in education fall into the scope of a "service evaluation" rather than research per se.** As such their governance is simple and straightforward.

These do not normally require research ethics approval.

Whilst advice is often conflicting in this area, a broad indicator is that if a project has the potential to cause any significant adverse outcome to participants (usually to trainees or students) it should be discussed at an early stage with an expert as suggested below.

However, this is highly unlikely to be necessary for the vast majority of potential projects and can be managed through simple support by the trainee's fellowship supervisor.

A slight complexity is the requirement by most reputable journals and conferences to be satisfied that published work was undertaken appropriately. If publication or presentation is contemplated the fellow may wish to document that they have taken appropriate advice that their project does not require research ethics approval.

#### **Research ethics.**

Where there is risk of harm to a subject participant, or other, then careful advice should always be taken. An overview of this complex area of regulation can be accessed on the NHS health regulation authority (HRA) website at: <u>https://www.hra.nhs.uk</u>

The HRA provides a helpful on-line decision tool that can help decide if a project requires research ethics approval: <u>http://www.hra-decisiontools.org.uk/research/</u>

There are two further potential sources of help and advice for the type of small project likely to be in scope for HEE fellows:

 The Local Research Ethics Committee (LREC) chair. LRECs are based in all significantly sized trusts, and generally also support small associated NHS bodies such as nearby GP practices or hospices. This route is appropriate when the research is locally focussed. 2. A university ethics committee lead. These are often more appropriate for studies with a regional scope, where the fellow or his/her supervisor is associated with the university.

Such individuals are usually very helpful and will advise whether formal ethical approval is necessary, and if so the process for obtaining it.

Obtaining research ethics committee approval is very labour intensive, and the approval process rightly very thorough, and hence slow.

A further consideration for those contemplating projects categorised as "research", is the clear need to purchase a separate insurance policy against claims of negligence/personal injury.

# Generally, therefore projects for HEE fellows that require such approval are NOT usually viable in the context of a short fellowship.

#### Liability.

HEE has taken formal legal advice through its solicitors and NHS resolution (NHSR) Whilst inevitably somewhat complex, this can be summarised as:

- Cover is provided under NHSR scheme for these fellows undertaking service evaluations. This would normally be through the trainee's employer. Where however the project primarily benefits HEE rather than the employing NHS trust, such concerns should be addressed in an agreement between HEE and the employer in which HEE indemnifies the employer and agrees that HEE will take the lead in any litigation arising from the Fellow's work.
- As above If a fellow is engaged in research, the NHSR scheme <u>will not</u> provide cover and that is normally arranged by the research sponsor.

#### Further Advice.

HEE has no national oversight process of local projects undertaken by fellows. Advice should generally be obtained through the relevant local office and postgraduate dean.

#### **HEE Research Governance Group**

The aim of the Research Governance Group (RGG) is to provide strategic oversight of all health professions education research, evaluation and quality improvement activity across Health Education England (HEE). If further additional advice is required this group can be contacted at <u>ri@hee.nhs.uk</u>

More information can also be found at <u>https://www.hee.nhs.uk/our-work/research-governance</u>.

If, however additional informal input would be helpful Namita Kumar can be contacted by any Postgraduate Dean, as the Chair of this group.

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