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**POLICY**  
**FOR ACCEPTING NON-COMMERCIAL STUDIES TO RUN ON THE**  
**SCOTTISH MENTAL HEALTH RESEARCH NETWORK**

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## 1. BACKGROUND

The Scottish Mental Health Research Network has two main aims:

- To facilitate the development of protocols for RCTs of relevance to mental health (including systematic reviews);
- To facilitate RCTs once they are funded. This assistance can cover authorisations, recruitment and data collection. These studies are called “adopted” studies.

In order for the Scottish Mental Health Research Network to make the best use of its resources, it is necessary to implement decision making procedures to determine which studies the Network will facilitate.

This policy covers the second aim, that is, the entry route for investigators who wish their study to be adopted. It specifically covers non commercial studies.

There is a separate policy “Policy for accepting Industry studies to run on the Scottish Mental Health Research Network version 1.0” to cover studies which are commercially funded.

There is a separate policy “Policy for accepting pre-protocol studies by the Scottish Mental Health Research Network version 1.0” to describe the entry route for investigators who would like assistance with developing RCTs for funding.

## 2. ACCEPTANCE CRITERIA

Studies must meet the following five criteria before they are submitted for adoptions:

- The study must be **topic specific**, that is directly relevant to mental health or using mental health interventions to improve health more generally. The network has not been funded to undertake studies in dementia;
- The study must be a **randomised controlled trial (RCT)** or a pilot study with the potential to become an RCT;
- The study must be **multi-centre**. Multi-centre studies with a single centre in Scotland meet this criterion. The reason for designing a multi-centre study must be because of a need for:
  - a large sample size, recruitment of participants with a rare condition, or recruitment of participants from a particular group or lifestyle;
  - multiple units of randomisation for cluster randomisation;
  - in order to establish that a finding or an intervention is generalisable across different settings or is applicable in specific settings;

- The study must be funded by <sup>1</sup>an **eligible funder** <sup>2</sup>. Studies will be accepted for adoption decision if they are funded by overseas governments or other organisations (e.g. US NIH) as long as funds to cover service costs are guaranteed to be covered by the grant.

### 3. ASSESSMENT CRITERIA

Studies which apply to the SMHRN will be assessed on the following criteria:

**Study Quality.** That is, the study must be designed adequately to answer the primary outcome.

**Study Feasibility.** That is, are clinicians / patients / service users / carers likely to participate in the study? Proof of clinician involvement, pilot studies and patient/ public involvement will be required for this to be assessed.

**Network Capacity.** That is, does the Network have the available staffing to facilitate the trial in the proposed geographical areas during the proposed recruitment and data collection periods?

**Added value of the Network.** That is, could the work be done more effectively by staff on the research grant?

These assessment criteria will require the investigator to complete an adoption form which will be formally reviewed by the Network.

### 4. PROCEDURE

Investigators are encouraged to apply to use the Network before funding is sought. Such applications (if successful) will be given conditional approval and if the investigator is also successful in getting funding, they will also be asked to update their adoption form to capture any changes to recruitment targets etc.

Investigators will be strongly encouraged to speak to either the Network Manager or the Senior Co-ordinator before applying to use the Network to ascertain whether, in principle, the study would be suitable for the Network and whether the Network can provide any useful benefits for the study.

Investigators wishing to use the Network must use the SMHRN Adoption form. This is available online at [www.smhrn.org.uk/apply](http://www.smhrn.org.uk/apply) . It can be

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<sup>1</sup> or an application must be being made to

<sup>2</sup> for details of eligible funders see

<http://www.sehd.scot.nhs.uk/cso/SuppScience/Eligible%20funders/ELIGIBLE%20FUNDERS.doc>

completed online, or copied and emailed direct to the Network. Hard copies will not be accepted. All applications must be accompanied by a study protocol (even those at a very early stage).

Applications to use the network will be considered every month at the Network's Implementation Group. The dates of these meetings are published on the Network's website [www.smhrn.org.uk/adoption\\_meeting\\_dates](http://www.smhrn.org.uk/adoption_meeting_dates). The deadlines for application will be 3 weeks before the implementation group meeting.

The Implementation Group consists of the Network Director, Professorial Statistician, Manager, Senior Statistician, Senior Co-ordinator and Lead Clinical Studies Officer. For each application, at least 2 members of the SMHRN reference group will also be asked to review the study.

Any member of the Implementation Group or Reference Group who has a conflict of interest with regard to any application will be asked to declare it and describe it.

All reviews will be captured using SMHRN feedback forms. Copies of these will be retained for all studies (whether successful or not)

For studies which are only applying to be run on the SMHRN, the outcome of the decision will be given to the Investigator in writing with reasons for the decision within 24 hours of the meeting. For studies which are applying to be run on both the SMHRN and at least 1 other network, the outcome of the meeting will be given within 1 week of the meeting date.

Four types of decision are possible:

- Accept
- Reject
- Suggest minor changes and resubmission which can be given expedited approval by Director
- Suggest major changes and resubmission for consideration by full Implementation Group

Reasons for the decision will always be given to the applicant.

## **5. COLLABORATING WITH UK MHRN AND MHRN C**

For cross border studies, the English MHRN (UK MHRN) and Welsh MHRN (MHRN C) will accept Scottish Adoptions forms and the SMHRN will accept English and Welsh ones.

The receiving administrator in any of the devolved nations who receives a potential cross border study will forward it immediately to the relevant administrator(s). Each devolved network shall have its own decision making

procedures which are timed to coincide with each other. Each collaborating network will then forward their decision to the originating administrator so that a single decision can be conveyed to the investigator.

## **6. COLLABORATING WITH SCOTTISH TOPIC SPECIFIC RESEARCH NETWORKS (TCRN)**

Some trials may require collaborative input from more than one Scottish TCRN. This is particularly likely with primary care but also possible with medicines for children, stroke, and diabetes. To prevent duplication of effort and to reduce bureaucracy for investigators it is essential that a streamlined adoptions and feasibility process exists between the networks. However, there currently exists variation in adoptions procedures between the Scottish networks so a simple reciprocal acceptance of adoptions is not available in the short term. Until reciprocal arrangements are agreed, the following steps should be taken.

If an approach (formal or informal) is made to one network which network staff believe could run collaboratively on another, the 2 Network managers will discuss how the work could be shared. The investigator is then asked to apply to both Networks who make separate decisions about adoptions. The network managers then share the decision with each other before the investigator is informed.

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