



UK Mental Health Research Network

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Project Facilitation Policy

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1. Introduction

- 1.1 The UK Mental Health Research Network (MHRN) provides the infrastructure to support and coordinate high quality mental health and social care research throughout England. The Project Facilitation Policy is part of this infrastructure and is essential to ensure that the network is open, accountable, runs with the maximum efficiency and continually improves.
- 1.2 Appendix I outlines the research hub performance indicators as agreed between the coordinating centre and the research hubs to ensure the Mental Health Research Network (MHRN) maximises its ability to deliver MHRN adopted projects as efficiently and effectively as possible.
- 1.3 In having a project adopted onto the MHRN the Chief Investigator (CI) of that study must agree to work with the MHRN and abide by the MHRN Project Facilitation Policy.

2. Aims and objectives

- To provide an effective project monitoring system that will run throughout the MHRN.
- To develop an early warning system to detect avoidable delays in a timely manner.
- To aid the development of the research hubs by giving constructive feedback on performance and importantly, sharing good practice.
- To provide research project feedback to study teams and Chief Investigators.
- To ensure that the network runs efficiently, develops appropriately and gives value for money.

3. Why have a Project Facilitation Policy?

- 3.1 If a project mounted on the MHRN is failing to meet targets, it is important to understand why this is in order to try to rectify the problem and implement any improvements for future studies. The purpose of the project facilitation policy is to ensure systems are in place to monitor set-up and recruitment for each project, at each site within MHRN, thus ensuring that MHRN and its studies reach targets related to project set-up times and recruitment. Monitoring allows hubs to share good practice and improve the way they work by identifying where barriers occur and to learn through experience. Common reasons for project failure are included in Appendix II.



- 3.2 *Research Hubs:* Project facilitation monitoring will improve the way Hubs work by identifying where internal and external factors occur that could cause avoidable delays in the set-up of projects and recruitment to them. Monthly reports will provide an early warning system for identifying set-up and recruitment barriers. Future studies will benefit from shared Hub good practice and network experiences.
- 3.3 *Research Projects:* Project facilitation monitoring of individual MHRN adopted research projects is necessary to ensure that recruitment projections are on target and if problems occur will allow the early formulation of a recruitment recovery plan.
- 3.4 *MHRN Targets:* Project facilitation monitoring will assist in charting progress made towards the MHRN targets that relate to projects, set out in the MHRN business plan and will contribute information for the annual report to the Department of Health (DH).

4. What will be monitored?

All processes concerned with progress of research projects (see Appendix I):

- 4.1 *Core Administrative Functions*
- (i) Administrative functions undertaken starting with submission to the Adoptions Committee through to the recruitment of the first participant will be monitored thus identifying any factors that may cause avoidable delays.
 - (ii) Administrative services provided throughout the life of a project.
- 4.2 *Performance of the Research Hubs*
- (i) The administrative functions of the Research Hub related to project set-up, assistance provided during the life of a project, including monitoring of any facilitation plans in place.
 - (ii) Hub response to requests for information from the Coordinating Centres
- 4.3 *Recruitment*
- (i) Take up of projects by Hubs.
 - (ii) Recruitment rates for all adopted projects:
 - Cumulative project recruitment - minimum information recorded for all projects.
 - Recruitment by hub - when specific targets are set.
 - Recruitment by site within a hub - when specific targets are set.
 - Individual researchers -when specific targets are set.



5. How will monitoring take place?

- 5.1 MHRN personnel at the Coordinating Centres and Research Hub Centres have designated areas of responsibility for each step in the monitoring pathway (Appendix III).
- 5.2 Monitoring will commence when a completed adoption form is received by the MHRN and will end when the study results are disseminated (Appendix III).
- 5.3 Each Hub Lead and Coordinator is responsible for ensuring that information required to performance monitor the network is supplied to the Coordinating Centres.

6. Information Technology (IT)

- 6.1 The MHRN has developed an online secure data entry system (DES) to enter recruitment data and facilitate tracking of recruitment information. (The DES system being provided through Psygrid from April 07).
- 6.2 The MHRN Coordinating Centre will engage study teams to use DES whenever possible as only minimal additional recruitment information will be required from these projects thus reducing the burden on the research teams.

7. Project Set-up Stage

- 7.1 There are nine phases during the set-up stage that projects will pass through to prepare for recruitment (see Appendix IV for overview). Some phases can overlap.
- 7.2 The Research Manager (see Appendix V) is responsible for the collection and recording of set-up information and will be responsible for monitoring project set-up trajectories, producing reports and alerting the MHRN Director and MHRN Executive to any problems.
- 7.3 Research teams will supply set-up information when requested by the Research Manager.
- 7.4 Hub Coordinators will assist with the collection of set-up data when requested to do so by the Research Manager.
- 7.5 When a project is given approval to run on the Network the information supplied in the Adoptions Form will be used by the



Project Facilitation Manager to formulate a project trajectory: set-up timelines and recruitment start and end dates; sample size; number of hubs/sites and target set-up dates and recruitment targets for each site.

- 7.6 A meeting will be arranged between the CI/study team, MHRN Research Manager, Project Facilitation Manager and participating Hub Coordinators as soon as possible after final approval is granted. At the meeting the study set-up timeline and anticipated recruitment plan and trajectory will be discussed and agreed with the study team and a plan made for facilitating the study. Contacts for set-up and recruitment information liaison will be established both within the research team and at the MHRN. The MHRN contact will generally be the Research Manager for set-up issues and the Project Facilitation Manager for recruitment issues. However, for projects running in only one hub this can be the hub coordinator. When hub coordinators take on the role they will ensure that set-up information reaches the Research Manager and recruitment information reaches the Project Facilitation Manager.

8. Recruitment Stage

- 8.1 The CI of each project adopted by the MHRN will provide details to allow a project trajectory plan to be developed. The Project Facilitation Manager (Appendix V) in collaboration with the CI/ study team will agree the project trajectory plan (to include the number and geographic spread of sites and the recruitment target and period for each), a MHRN recruitment strategy and alerting plan.
- 8.2 The Project Facilitation Manager (Appendix V) is responsible for the collating and recording of recruitment information and will be responsible for monitoring project trajectories, producing reports and alerting the MHRN Director and MHRN Executive to any problems.
- 8.3 Research teams will supply recruitment information to the UKCRN database. Additional requests to the research team for recruitment information will be kept to a minimum. In most instances information submitted by the study team to the UKCRN database can be utilised. However, studies experiencing recruitment problems may be required to provide more frequent recruitment information to enable monitoring of recruitment recovery plan effectiveness.
- 8.4 Hub Coordinators will assist with the collection of recruitment data when requested to do so by the Project Facilitation Manager and will be asked to provide additional data on local recruiting activities and plans.



9. Alerting procedure and responses

The MHRN alerting procedure utilises a simple traffic light system to code the status of projects at each site and overall study recruitment.

- Recruitment on target.
- Recruitment has dropped below the project trajectory.
- Recruitment below project trajectory for a specific length of time; this is dependent on the type of project, recruitment period and sample size.

9.1 *Green Code*

When the recruitment nationally is on target but there is a problem at one or more site despite satisfactory national recruitment the Project Facilitation Manager informs the research hubs involved. These hubs will be asked to investigate why recruitment is lower than expected in their sites as compared to the others, report back to the Project Facilitation Manager with details of any planned actions.

9.2 *Amber Code*

The Project Facilitation Manager informs the MHRN Executive and MHRN Assistant Director that overall study recruitment for a project is amber. The research hubs involved will be asked to investigate why recruitment is lower than expected in their sites, report back to the Project Facilitation Manager with details of any planned actions. When the problem is in one hub responsibility for the production of a local improvement plan rests with the Hub Lead/Coordinator and the local PI. The Project Facilitation Manager will continue to monitor recruitment.

9.3 *Red Code*

If overall project recruitment does not improve and the study receives a red code the Project Facilitation Manager informs the MHRN Executive and MHRN Assistant Director and study CI when a project has a red code. If appropriate the research hubs involved will also be notified. All red code studies will be required to put in place a network wide recruitment recovery plan.



10. Recruitment recovery plans

10.1 *Who's involved?*

The MHRN Project Facilitation Manager and ultimately the Project Facilitation Team (Appendix V) will work with the CI/research team to identify the cause of the performance problem and will formulate a network wide recruitment recovery plan to be implemented throughout the Hubs, with approval of the Trial Steering Committee as appropriate.

10.2 *Hub Involvement*

The Hub Lead is ultimately responsible for the hub achieving performance targets and for making decisions regarding switching resources within a hub. The Hub Lead will ensure that the hub participates in the formation of recruitment recovery plans if requested to do so.

The Project Facilitation Team (Appendix V) may recommend certain actions to research hubs, for example, an increase in CSO allocation for a project with a recruitment recovery plan.

The MHRN Director has emergency authority to determine that a hub will no longer participate in a particular project and to switch funding elsewhere thus triggering an interim review of the hub by the Coordinating Centre. (See Appendix Ib: Procedures for Dealing with Hub Failure of Performance Indicators)

10.3 *MHRN Coordinating Centre Involvement*

The Project Facilitation Manager is responsible for monitoring recruitment recovery plans once they are in place until recruitment problems have been resolved and the recruitment recovery plan withdrawn.

10.4 *Research Team Involvement*

The CI is ultimately responsible for achieving target recruitment rates for his/her study. The CI is expected to participate in the formation of a recruitment recovery plan if requested by the MHRN.

If a recovery plan identifies a need for additional funding or a change to the protocol this remains the responsibility of the CI.

A policy for the suspension/withdrawal of MHRN support (policy number 02-08-05) outlines the exceptional circumstances when MHRN support for studies can be withdrawn or suspended (see website link:

<http://www.ukmhrn.info/dnn/ApplytoUKMHRN/Applytorunaproject/tabid/186/Default.aspx> for MHRN Policy on 'Suspension/ Withdrawal of Studies').



11. Reports

11.1 *MHRN Executive*

A monthly report containing information on all adopted projects in set-up and recruitment is produced with the Research Manager and Project Facilitation Manager for the MHRN Executive. This report includes updates on all current recruitment recovery plans.

11.2 *Hubs*

Hubs may request recruitment updates from the Project Facilitation Manager, for projects running in their hub, although it is expected these will be generated directly from the UKCRN portfolio database. Information on recruitment to projects running outside the hub will not be available unless a hub is asked to facilitate a study expansion into their hub; in these cases all available information will be provided including copies of recovery plans. NB If a hub is asked to take on a project with an existing recruitment recovery plan they will still need to provide recruitment information but hub performance will be assessed by the willingness to host the project and efforts made to increase recruitment.

Hub Coordinators will be asked to provide regular reports of their progress in set-up and recruitment to the Research Manager, Project Facilitation Manager and study team via study teleconferences, and internal hub updates.

11.3 *Study teams*

The CI and study team will receive progress reports for their project; set-up reports from the Research Manager and recruitment reports from the Project Facilitation Manager and individual progress reports from the Hubs via MHRN study teleconferences and local investigator meetings.

11.4 *UK MHRN Annual Report*

Non-contributable project recruitment information will be collated for the annual report to the Department of Health.

11.5 *Other Reports*

Other reports will be provided on request from the MHRN Executive or study CI. If an interim recruitment problem occurs the Project Facilitation Manager will produce an exception report for the MHRN Director and/or Executive.



Appendix Ia: Research Hub Performance Indicators

Hubs are expected to participate in all projects. Where the hub does not have the expertise or patient groups to participate in a study it will be expected to acquire these. There may be special circumstances whereby a hub cannot acquire the expertise or patients required in which case the hub may decline to participate in the project.

The following performance indicators are used by the MHRN executive to assess hub performance.

1. Quality of hub study portfolio

Performance indicator: Number, size and range of multi-centre MHRN-adopted studies

Measured by: Number of eligible MHRN-adopted projects not taken up by hub

Failure: Measure will be relative

A hub that has consistently much lower take up of eligible projects than the other hubs will fail the indicator.

2. Service User & Carer Involvement

Performance indicator: Involvement of service users and carers in hub activities.

Measured by: Adherence to the service user 'plan' developed for the hub with SURGE and the carer scoping group recommendations.

Reports to the coordinating centre which will include detail on service user & carer involvement.

Failure: Consistent failure to engage service users and carers in hub activities.

Failure to follow SURGE service user involvement plan for hub.

3. Set up times

Performance indicator: time taken to start a study from agreeing to participate in it.

Measured by: Time taken from agreeing to participate in study to the first patient being recruited.

Failure: Measure will be relative not absolute.

A hub that is consistently much slower than the others to recruit the first patient to studies will fail the indicator.

4. Research Governance

Performance indicator:

All research must be conducted in accordance with the Research Governance Framework for Health and Social Care.

Measured by:

Provision of research governance information including:

R&D approval from NHS Trusts involved in each project

Confirmation of substantive or honorary NHS contracts for staff with patient contact

Confirmation of MREC approval for those studies in which Hub is lead.

Failure: Failure to adhere to the Research Governance Framework for Health and Social Care

5. Recruitment rates

Performance indicator:

Rate at which hub recruits patients to studies

Measured by: Monthly recruitment of patients per hub to each study as entered onto a project data database.



Failure: Measure will be relative

A hub that has consistently much lower recruitment rates than the other hubs will fail the indicator.

6. Follow-up rates

Performance indicator:

The follow-up rates of hub recruits to studies

Measured by: Monthly follow-up of patients per hub to each study as entered onto a project data database.

Failure: Measure will be relative

A hub that has consistently much lower follow-up rates than the other hubs will fail the indicator. Positive rating will be given to hubs that are able to minimize missing data and encourage dataset completion.

7. Provision of information

Performance indicator:

The ability of research hubs to respond to information requests in a timely fashion.

Measured by:

The time taken for a hub to respond to specific information requests.

Failures to respond to information requests within a specified dead line.

Action:

Measure to be relative.

Measure not to be a 'make or break' indicator.

(Indicator included to ensure improved information flow across network.)

Appendix Ib: Procedures for Dealing with Hub Failure of Performance Indicators

Hubs that consistently fail to meet the minimum requirements of one or more of the performance indicators 1-7, as judged by the MHRN Executive will be subject to review.

Coordinating Centre Procedure:

1. MHRN Director to write to the Hub Lead to notify that the Hub is not fulfilling this requirement
2. Arrange meeting to discuss why hub is not fulfilling requirement
3. Report outcomes of meeting to MHRN Executive
4. Formulate action plan with time-scale for re-assessment
5. Continued failure – 90 days notice of contract termination given to Hub

The above procedure can be used for each of performance indicators 1-7.

Hubs failing to demonstrate financial probity and/or compliance with the Research Governance Framework:

1. Notify hub to stop recruiting and working on any MHRN trial
2. Meet with Coordinator to establish where and how the research governance procedures have not been adhered to
3. Notify the Executive of the scale of the problem. MHRN Executive to ascertain severity of the problem and whether trial can continue and/or whether hub contract can continue.

Appendix II: Types of project facilitation issues

Points where projects have failed historically:

- Implementation (ethics approval, sub-contracts, research staff employment, governance etc)
- Consent to trial entry
- Protocol violations
 - Wrong assessments
 - Entering inappropriate participants
 - Randomisation failure
- Data collection
 - missing data
- Data management
 - Late
 - Incomplete
 - Erroneous
- Recruitment to target
 - Unable to identify adequate numbers of eligible cases
 - Unable to secure consent in adequate proportion
 - Failure to ensure centres recruit equally
- Obtaining adequate follow up rates
 - Loss to follow up
 - Withdrawal of consent

Appendix III: Designated MHRN roles and responsibilities for project facilitation

1. Independent Adoptions committee

This independent committee, reporting to the UK MHRN Coordinating Centre, is responsible for advising the MHRN on study feasibility and network capability for all studies adopted onto the network.

2. Coordinating centre at Institute of Psychiatry (IoP)

MHRN Director:

- Overall responsibility of MHRN network performance as a whole
- Decides on any shift of resource from underperforming hubs.

MHRN Manager:

- manages the operation and future development of the network as directed by the MHRN Director and MHRN Executive
- takes the administrative lead for the national network as a whole
- oversees the set up and management of all research projects running on the Network
- ensures all areas of mental health research are fully engaged in the Network
- ensures introduction of streamlined procedures for setting up research projects on the Network

Research Manager:

- responsible for coordinating the feasibility, regulatory, governance and financial administration required for setting up MHRN-adopted projects as part of the overall project facilitation procedure
- works closely with the study teams for projects adopted on to the MHRN and provides a vital communication link for these teams and the 8 MHRN Hub Coordinators within the network, circulating all documentation necessary for hubs to carry out site feasibility and identify suitable recruitment sites and to progress R&D and LREC approval
- facilitates communications between lead investigator and Hubs including setting up meetings and monitoring requests for set-up information both from Hubs and study teams
- maps the impact of existing regulatory and governance issues for all projects adopted on to the network
- responsible for developing and implementing robust procedures to ensure that current and future MHRN adopted projects are set up efficiently and effectively
- publicises/promotes the use of DES to study teams
- reports to the MHRN executive and hubs on project set up
- agrees with the Lead Investigator a publication strategy for each project

3. Coordinating centre at Manchester (IoP)

Associate Director of Performance:

- develops and oversees performance monitoring strategy;
- decides on implementation of a recruitment recovery plan
- line management of Project Facilitation Manager

Project Facilitation Manager:

- oversees collection and recording of recruitment information
- produces recruitment reports for MHRN executive and hubs
- convenes / minutes study performance meetings
- monitors study information and ensuring that alerting procedure activated when necessary.
- Monitors patient recruitment throughout project life
- Oversees, monitors and advises on CSO input into studies
- Helps hubs solve problems of slow recruitment
- Produces recruitment facilitation evaluation and reports;
- develops improvement plans with the hub and CI;
- monitors requests for recruitment facilitation information.
- collates a report at study end for CI to inform MHRN involvement throughout study.

IT Associate Director:

- develops and oversees IT strategy;
- ensures that the Data Entry System (DES) is responsive to the needs of the network;
- ensures systems for reporting problems are put in place.

IT Manager:

- responsible for operating, maintaining and developing the MHRN Data Entry System for the MHRN
- works with study chief investigators to determine data requirements for new studies
- Implements and configures the data collection system for newly adopted studies
- provides support to end users of the system
- day to day system administration to ensure the data entry system is available
- operational management and planning of future upgrades of the data entry system
- liaises with NHS IT personnel to ensure integration of the data entry system with the NHS
- maintains the software code base fixing problems as they arise
- develops the data entry system to improve features and functionality



4. Hubs

Hub Leads

- ensure finance resources are allocated appropriately locally
- ensure that all projects running on the Hub have a Steering Committee involving relevant stakeholders and which will monitor progress of the project and solve any emerging problems in recruitment of participants
- facilitate the use of the Hub by Principal Investigators of adopted UK MHRN Projects
- engage clinicians within participating Trusts and associated clinical sites in the work of the Hub, augmenting capacity to recruit participants for adopted projects
- identify appropriate host services to accommodate projects adopted by the UK MHRN
- develop and strengthen links between the participating Trusts within the Hub (and associated clinical sites) and the UK MHRN
- facilitate user and carer involvement in the work of the Hub
- develop and sustain links between local academic institutions and the Hub

Hub Coordinators:

- support the Hub Leads, Hub Executive Committee and Hub Management Group in developing, implementing and managing the agreed strategy of Hub to meet the aims of the UK MHRN nationally
- develop and implement robust procedures to ensure that current and future research projects within Hub portfolio are set up and run efficiently and effectively
- Carry out thorough local feasibility assessments of potentially participating clinicians/teams, identifying local investigators responsible for study & notify the Research Manager
- progress R&D approval, LRECs and honorary contracts and notify the Research Manager when all approvals submitted and then obtained
- work with the Trusts within the Hub consortium to streamline R&D procedures and ensure good practice in study set-up
- establish project management groups
- oversee allocation of CSOs in hub Trusts
- assist with the collection of recruitment data when requested to do so by the Project Facilitation Manager
- work with the Project Facilitation Manager and local investigators to help solve problems of slow recruitment

5. Study teams

Chief Investigator:

- Study management to conform to MRC trial management structure standard, with independently chaired TSC and IDMEC
- at project start-up work with the MHRN coordinating centre to produce written agreement between the CI and the MHRN to document responsibilities.
- Sites which are outside the network will remain the responsibility of the CI though the MHRN will provide assistance where/when possible.
- The CI is responsible for populating the UKCRN Portfolio Database with general study information, or for designating a member of the research team to do this. A nominated accrual contact for each study will be responsible for uploading accrual on a monthly basis throughout the recruitment phase to the UKCRN.

Research Team:

- Research teams will supply the required information for project set-up when requested by the Research Manager
- Research teams will supply recruitment information when requested by the Project Facilitation Manager.
- Trial management will adhere to MRC recommendations about maximising recruitment.



Appendix IV: Project Facilitation Milestones & Timelines

Phase	Start Point	End point	Data Source	Person Responsible	Target
Pre Adoption	Adoption form received	Date letter sent to CI ¹ – preliminary approval	IoP ²	Research Manager	4 weeks
Funding Submission	Date of letter to CI	Letter confirming funding received	IoP	CI	No target
Service Support Costs	Date of letter to CI	Confirmation/agreement of service support costs	IoP	CI	No target
Adoption	Letter received confirming funding	Date letter sent to CI – final approval	IoP	Research Manager	4 weeks
Assignment	Date adoption approval letter	Confirmation of Hub participation received	IoP	Research Manager	4 weeks
Ethics	Date of submission to MREC	MREC confirmation letter received at IoP	IoP	CI	60 days ³
Local Ethics	Date last bit of required documentation sent to Hub Coordinators	LREC approval received for each site within the hub	IoP / Hubs	Hub Coordinators	35 days ⁴
R&D	Date last bit of required documentation sent to Hub Coordinators	R&D approval received for each site within the hub	IoP / Hubs	Hub Coordinators	35 days
Preparation	Date last bit of required documentation sent to Hubs	Project recruitment trajectory and recruitment plan in place	Man ⁵	Project Facilitation Manager	Study specific target set.
Recruitment	All required approvals obtained	First participant recruited	Man	Project Facilitation Manager	Proposed recruitment start date

¹ CI – Study Chief Investigator / Sponsor for industry-sponsored studies

² IoP – MHRN Institute of Psychiatry Coordinating Centre

³ Central Office for Research Ethics (COREC) (2004) *New Operational Procedures for NHS RECs London*

⁴ COREC (2004) *New Operational Procedures for NHS RECs London*

⁵ Man – MHRN Manchester Coordinating Centre



Appendix V: Project Facilitation Team

UK MHRN Director	Professor Til Wykes
UK MHRN Associate Director for Performance	Professor Max Marshall
UK MHRN Associate Director for IT	Professor Shôn Lewis
UK MHRN Assistant Director	Rachel Parker
UK MHRN Research Manager	Jacqueline Kraska
UK MHRN Project Facilitation Manager	Mrs Joanne Ashcroft
UK MHRN IT Manager	post vacant (formerly Austin Lockwood)