RD SOP 02 R & I Research Governance Annual, Monthly and Quarterly Monitoring

Greater Manchester Mental Health NHS Foundation Trust
RDSOP02 Research Governance Annual, Monthly & Quarterly Monitoring

Title of Standard Operating Procedure: RDSOP02 Research Governance Annual, Monthly & Quarterly Monitoring

Document Summary: To describe the processes for routine annual, monthly and quarterly monitoring of research activity within the Trust and actions to be taken.

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Target Audience: Trust-wide, Research Community, Internal and External Researchers

Consultation: R & I Office, research community and R & I Committee members

Approval Committee: R & I Committee

Cross Reference Document(s): Research Approval Policy
All Trust R & I SOPs

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Ref: RDSOP02  Issue date: 13/08/2018  Version number: 1.0
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1. Introduction

Under the Research Governance Framework for Health & Social Care (2005) (RGF), NHS organisations must have a system for monitoring research involving their staff, patients, organs, data or premises. The Trust therefore conducts routine onsite monitoring visits, involving checks on documents and procedures at project level to ensure that research governance and Good Clinical Practice (GCP) requirements are being adhered to.

Additionally, NHS organisations must have arrangements in place for ongoing monitoring of all research projects at Trust level to meet research governance requirements. The Trust achieves this through:

- **Annual Project Audits** which involve the annual collection of information by the Research Office and is a self-report audit.
- **Monthly audits** to identify studies that are about to end and audit these immediately after ending.
- **Monthly audits** to identify and renew as necessary researcher contracts that are about to expire.
- **Quarterly audits** to monitor changes to study end dates, changes in the research team, any new amendments, any unreported adverse events and research related incidents.

2. Purpose

2.1 By conducting these audits on all active studies conducted at the Trust, the R & I Office is able to ensure:

- the quality of the data it holds on its Research Manager Database
- awareness of all adverse events
- knowledge of all researchers working on projects
- all researchers possess the necessary honorary contracts or letters of access to enable them to conduct the research and these have not expired
- all researchers are adequately trained – in information governance, GCP, consent procedures, etc. as appropriate and proportionate to the type of study
- compliance with the protocol, data protection requirements and procedures for obtaining informed consent.

Details of recruitment to studies is collated and reported in the Trust annual Quality Accounts.

Monitoring also identifies arrangements for storage and disposal of research data following study completion.
Service user involvement in studies is monitored. The nature and extent of service user involvement in design, implementation and dissemination of studies is identified.

3. Roles and Responsibilities

3.1 Duties within the organisation

It is the responsibility of the Research & Innovation Office to make Trust R & I SOPs available to all research active staff working on Trust-approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R & I SOPs are available to research staff.

It is the responsibility of the study Chief Investigator or local Principal Investigator to ensure up-to-date SOPs are filed in the Investigator Site File and are available to research staff, and to inform the Research Support Co-ordinator of the names of all research staff involved on a study so that copies of SOPs can be distributed appropriately.

It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are too followed for a study. For example, those of a Clinical Research Network or commercial sponsor. If there is significant conflict between the external SOP and the Trust R & I SOP it is the responsibility of the CI or PI to resolve these with the Research Office prior to starting the study.

It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

The Research & Innovation Office is responsible for managing Trust R & I SOPs including their approval, dissemination and archiving. All Trust R & I SOPs must be made available via Q-Pulse and published on the Trust website.

3.2 Specific to this SOP

The Research Support Co-ordinator is responsible for arranging, conducting and reporting on the monthly, quarterly and annual project audits.
The local Principal Investigator (PI) and his/her team are responsible for cooperating with the monitoring process: responding to email requests for information; completing and returning annual audit forms.

The R & I Committee is responsible for overseeing the Research Monitoring Programme. The Research Support Co-ordinator provides annual reports to the Committee. Additionally, specific issues arising from monitoring activities are included on the Committee meeting agenda as required.

4. Procedure

4.1 Procedure for Annual Project Audits

These audits are conducted in February each year by the Research Support Co-ordinator and include ALL studies which are active on the Research Manager Database at the time of the audit.

Principal Investigators or Day to Day Contacts for a study receive an Annual Project Audit self-assessment form (see Appendix 1) by email for completion for each of their studies listed as active in the Research Manager Database.

Throughout the year as part of the monthly monitoring, PIs of closed studies will have received an End of Study Audit form to complete which has the same content as the Annual Project Audit form. This ensures all studies open throughout the year are captured in the annual audit.

The Annual Project Audit form is partially completed to reduce the burden on investigators before being sent out.

The form provides columns to enable provision of data for other NW NHS Trusts in order to remove the need to complete multiple forms.

A timeframe of approximately one month is given to complete the questionnaires; this task may be delegated by the PI to another member of the research team.

Following the initial contact, if a reply is not received, a further e-mail will be sent as a reminder to the researcher or other members of the research team, followed by a phone call. A request is made for partial information if the research team are unable to complete the form. If after all methods to try to obtain a completed form fail the researcher, local PI and CI are informed the study will be prematurely closed down.
The information provided via the Annual Project Audit self-assessment form is used to update the Research Manager Database, the Researcher Register and collated for production of the final Report.

Responses to both the Annual Project Audit and the End of Study Audits are collated for GMMH and recorded in Excel for analysis.

The Report on findings and recommendations is produced from the results of the project audits by the Research Support Co-ordinator and presented to the Trust’s Research & Innovation Committee in June/July each year.

Completed forms for multi-site studies containing details for other NW Trusts are forwarded electronically to those Trusts.

The fields within the Annual Project Audit self-assessment form are reviewed annually by the Research Office to ensure that the exercise generates meaningful data and to take account of any feedback received from the R & I team, researchers and their teams.

### 4.2 Procedure for Monthly end of Study Audit

An End of Study audit is performed on a monthly basis to monitor and capture information in relation to studies that are scheduled to end within the next calendar month. This enables the R & I Office to maintain current and accurate records for all research studies that are taking place in the Trust.

A list is extracted from the Research Manager Database, together with details of Principal Investigators, to identify which studies are scheduled to end in the next calendar month.

The End of Study Audit tool (based on the Annual Project Audit tool – see Appendix 2) is emailed individually to PIs of the projects asking for full completion electronically and return by email as soon as possible.

If the research study is to be extended beyond the current end date, the researcher is asked to provide a new proposed end date. The new end date is recorded on the Research Manager Database and the End of Study form does not need to be completed at this time.

For studies that have ended, on receiving completed audit forms, the details are entered onto the Research Manager Database and the study closed.

Responses for completed studies are extracted from the End of Study audit form to Excel and collated with the Annual Audit of Projects data for analysis for the final Report (see 4.1.9).

The End of Study audit data is included with the data from the Annual Project Audit and the Report on Findings produced and submitted to the Trust’s Research & Innovation Committee.
Completed End of Study audit forms for multi-site studies that include details for other NW Trusts are forwarded electronically to that Trust.

### 4.3 Procedure for Monthly Researcher Contract Audit

Research is an integral part of NHS activity, and is often undertaken in partnership with Higher Education Institutions (HEIs) and others. As a result of the partnership arrangements that characterise research, this activity raises a number of HR management issues for NHS organisations. Research within the NHS is often undertaken by NHS staff not directly employed by the host NHS organisation, or by non-NHS staff, particularly researchers employed by universities. This raises issues about responsibility, accountability, patient safety and duty of care. Research is also frequently undertaken across a number of NHS organisations and requires arrangements for both NHS and non-NHS staff to work across those organisations.

The Research Governance Frameworks published by the UK Health Departments require all parties undertaking research within the NHS to be clear about responsibilities and liabilities. One of the ways this is achieved is through using HR procedures appropriately.

The NHS and HEIs have responsibilities as employers of researchers. Only the employer can be accountable for the suitability of the individual in terms of training, experience and conduct. The substantive employer retains the primary accountability and liability for the actions of their researchers. Once NHS organisations have confirmed capacity and capability for research to take place at their sites that affects their legal duty of quality and common law duty of care, they then accept vicarious liability for harm due to clinical negligence.

An audit is performed on a monthly basis to monitor the Honorary Research Contract (HRC) and Letter of Access (LoA) status of those researchers who are performing research at the Trust. The audit ensures that all active researchers hold current and valid HRCs or LoAs by identifying those contracts that are scheduled to expire within the next calendar month. This enables the R&D Office to make sure that appropriate HR arrangements are in place for all external researchers, and to maintain accurate records for all researchers working on active studies at the Trust.

As part of the monthly monitoring performed by the R & I Office, a list is extracted from the Researcher Register to identify which Honorary Research Contracts (HRC) and Letters of Access (LoA) are scheduled to end in the following calendar month.

The researcher is emailed using the email at Appendix 3 and asked whether they require an extension to their HRC or a new LoA.

If an extension is required, a HRC extension letter or a new Letter of Access is issued. (Refer also to RDSOP12 Research Passports)
The Research Manager Database is updated with details of the new contract as is the Researcher Register.

If the researcher does not require an extension to their HRC or a new LoA, their entry is removed from the 'Active Contract' worksheets of the Researcher Register and moved to ‘Expired Contracts’ worksheet of the register.

The Research Manager Database is updated indicating the researcher no longer works on the study or studies.

4.4 Procedure for Quarterly Study Checks

Greater Manchester Mental Health NHS Foundation Trust strives to maintain accurate records of the research studies active at the Trust.

Checks should be performed quarterly commencing at least three months after the date of the annual project audit.

A list of open projects is extracted from Research Manager Database.

The Research Support Co-ordinator sends an email quarterly (Appendix 4) to the Day-to-Day Contact of all active studies to ask them for the following study updates:

- Change to the study end date
- Changes to the research team
- Amendments
- Adverse events
- Research-related Incidents

The email also provides a reminder about:

- Publication citations
- Data Protection arrangements.

When a response is received, and depending on what has changed, it should be actioned accordingly and in line with R & I Office Procedures:

Adverse events should be logged, considered by the Head of R & I Office where necessary, forwarded to the R & I Operations Group if deemed to be research related.

Changes to study end date should be entered in the Research Manager Database.
Changes to research team – update the Research Manager Database, enter on the Researcher Register; issue extended Honorary Research Contract or Letter of Access as required.

Amendments – enter in Ethics section of Research Manager Database, review by R & I Office and/or Head of R & I Office if necessary.

Incidents notified - record on Incident Log, add details to Research Manager Database, request outcomes of reviews, follow up as required, forward to Head of R & I Office for review.

If no response to the quarterly email is received within 14 days a reminder email is sent and followed up with a phone call.

It is a requirement of Trust ‘approval’ that Researchers respond to monitoring requests for information. If a response is not received the R & I Office may terminate access and close down the study.

End of Procedure
Appendix 1 – Annual Project Audit

The Annual Project Audit is now taken from an online survey provided by Survey Monkey. Details can be found via the research office email address:-

Researchoffice@gmmh.nhs.uk

A link will be provided to take part in the survey at the appropriate time.

Here are the questions that are asked on the survey:-

1. Study Title:
2. Trust Project No:
3. IRAS No:
4. Principal Investigator:
5. Actual Project Start Date:
6. Has the Study finished? Yes - provide project end date - No - provide proposed project end date
7. At what stage is the study now?
   Open - Actively recruiting participants -
   In follow up - No longer recruiting - Participants attending clinics etc.
   Complete - Closed - Study ended
8. GMMH Participant Recruitment in Current Financial Year -
   Please state how many of each have been recruited. Please use N/A if not applicable
   Service users
   Staff
   Relatives/Carers
   Other
9. GMMH Participant Recruitment - Total to date
   (Please use N/A if participant type not applicable)
   Service Users
   Staff
   Relatives/Carers
   Other
10. Please give date of First GMMH participant consent obtained
Date

11. Do you have any comments on your experience of recruitment? Please provide positive feedback if you were supported by any particular professionals working in the area.

12. You are required to provide a list of all the researchers actively involved in this study in spreadsheet format which will be sent by email for completion by the deadline specified.

Please confirm you have actioned this request here.

13. Have there been any Serious Adverse Events (SAE’s) associated with this study?

Yes/No If yes, has the Research Office been informed? If Research office has not been informed of any SAE’s please provide details here

14. for GMMH Employees only -

Have any incidents been reported on DATIX?

E.g. confidentiality breaches

Yes/No

If yes, has the Research Office been informed?

If Research office has not been informed please provide DATIX incident numbers here

15. Please confirm that all the researchers working on this study have complied with the procedure for obtaining informed consent as set out in the approved Protocol?

Yes/ No

16. Can you confirm that the research to date has been carried out in accordance with the Protocol or any subsequent amendments approved by Trusts and Ethics Committees?

Yes (Type Yes in box)

No (Type No in box)

If no please provide an explanation here

17. Have all researchers associated with the study complied with data protection /GDPR requirements and the information given in the Confidentiality section of the IRAS form?

Yes (Type Yes in box)

No (Type No in box)

If no, please provide an explanation here
18. Have service users been involved in the design, implementation or dissemination stages of the study?
   (this question does NOT refer to service users as participants in the study)
   Yes
   If yes, please provide details of their involvement here
   No

19. Please use this space for any additional information you think may clarify any of your responses in the previous questions

20. Do you plan to publish the findings from this research study?
   Yes/ No

21. Have any publications already arisen from this research study?
   Yes (Type Yes in the box)
   If yes, please give details of the publications
   No (Type No in the box)

22. Have publications included affiliation to GMMH?
   Yes (Type Yes in the box)
   No (Type No in the box)
   If no, please provide an explanation why not

23. Do you envisage there will be any impact on clinical services as a result of this research?
   Yes/No

24. Would you be prepared to present your findings at research events hosted by GMMH?
   Yes/No
Appendix 2 – Content of Email for End of Study Audit

Subject: GMMH Project – End of Study Audit

Dear

Trust project no: XXX

IRAS NO:

Full Title:

(All above required for completion of study survey)

In line with the national clinical research governance and applicable UK law and regulations, the Trust has to demonstrate local researchers’ governance compliance.

To achieve this you are required to complete the end of year R & I Audit survey to report the progress of the study you are leading on as the Principal Investigator in this financial year.

We have designed a web based survey to collect the data.

Completion of the survey can be delegated to study admin support staff however the overall responsibility for data accuracy stays with the study PI.

Please use the link here to complete the survey.

https://www.surveymonkey.co.uk/r/9WS6CCF

If you encounter any difficulties with the form and would like to feed this back to the team please email:

researchoffice@gmmh.nhs.uk

We will endeavour to rectify your concerns and amend the survey accordingly. This is a work in progress and will evolve as we learn from the experience.

Thanks for your support

R & I Team
Appendix 3 – Content of Email for Researcher Contract Audit


Dear [Researcher Name]

Your [Letter of Access] or [Honorary Research Contract] with Greater Manchester Mental Health NHS Foundation Trust is due to expire on [Expiry Date]. Please could you let me know whether you will be continuing to work on this study at the Trust beyond this date and if you require an extension of your [Letter of Access] or [Honorary Research Contract].

Kind Regards

[Email Signature]
Appendix 4 – Content of Quarterly Email

Dear

Our records in the R & I Office at Greater Manchester Mental Health NHS Foundation Trust (GMMH) show that you have the following active research study at this Trust.

GMMH Project Number:  
Study Title:

To help maintain accurate records, please could you provide an update about the following, ensuring that you include the GMMH Project Number (e.g. 123) and full study title in your email:

- **Adverse Events**

  Please notify us of any adverse events not previously reported to the R & I Office.

  For guidance about safety reporting in relation to CTIMPS and other studies follow the link:  
  [https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/](https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/)

- **Change to the Study End Date**

  If the study has ended early or the end date has been extended, please inform the R & I Office.

- **Changes to the Research Team**

  Please notify the R & I Office if any new researchers have joined the study team. A Letter of Access or Honorary Research Contract may need to be issued so that they can access GMMH as a research site. If researchers have left the study, please let us know so that we can update our records.

- **Amendments**
Please notify the R & I Office, NHS REC and the HRA of any minor or substantial amendments throughout the duration of your study.

For guidance about amendment notifications, please visit: https://www.hra.nhs.uk/approvals-amendments/amending-approval/

- Research Related Incidents

Have there been any incidents relating to the research or research team, e.g.