



# Standard Operating Procedures for Supporting Research Studies



February 2011

## Document Revision History

<b>Date</b>	<b>Version</b>	<b>Description</b>	<b>Compiled by</b>
31/01/11	0.1	First draft – reviewed by RM&G Manager	Kay Wright
08/02/2011	0.2	2 <sup>nd</sup> draft – revised after RM&G Manager review	Kay Wright

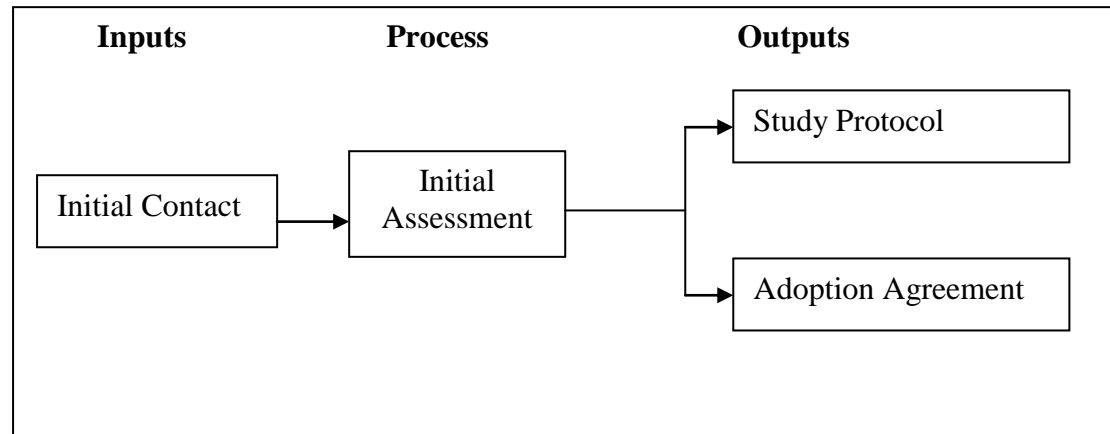
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## **1. INTRODUCTION**

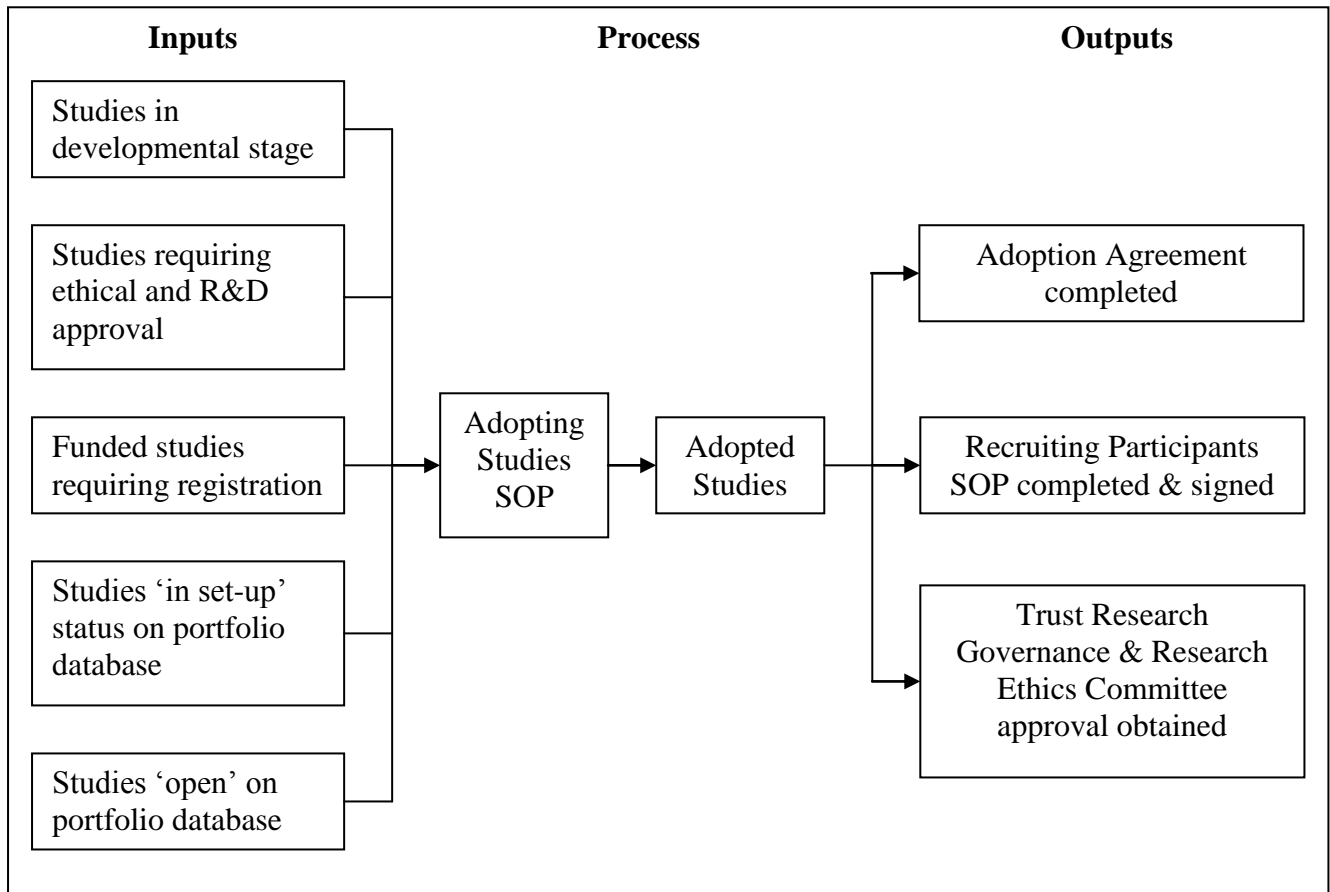
- 1.1 These procedures highlight the IAPT-RR processes that support National Institute for Health Research Clinical Research Network (NIHRCRN) Portfolio Studies.
- 1.2 IAPT-RR is funded by West Midlands (South) Comprehensive Local Research Network (CLRN). The CLRN forms part of the NIHRCRN.
- 1.3 IAPT-RR operates in partnership with the Coventry and Warwickshire Partnership Trust (CWPT) IAPT Service and Coventry and Warwickshire Mind, both funded by Coventry NHS and Warwickshire NHS.
- 1.4 The IAPT-RR Steering Group are specialists in research, public health, IAPT Services and clinical practice.
- 1.5 IAPT-RR has strong links with the local CLRN and can therefore provide a wide range of support to researchers at the planning, set-up and delivery phases of a study.
- 1.6 Full details of IAPT-RR services are available in our booklet that can be downloaded from our website: [www.covwarkpt.nhs.uk/IAPTRR](http://www.covwarkpt.nhs.uk/IAPTRR)

## 2. ADOPTING STUDIES



- 2.1 Initial contact will be made: i) directly from researchers who have responded to IAPT-RR marketing and have contacted a member of the IAPT-RR team, and ii) by a member of the IAPT-RR team contacting researchers who are, or are thinking of becoming, holders of NIHR Portfolio Studies. These will be identified from the Portfolio Database and regular contact with CLRN staff by the IAPT-RR contact.
- 2.2 IAPT-RR can support researchers who:
- Are thinking of developing a research project and want support with the design.
  - Have already designed a study and want support obtaining ethical and R&D governance approval.
  - Have already obtained funding for a study and want support registering it with the NIHR CRN Study Portfolio Database.
  - Have a study with ‘in set-up’ status on the NIHR CRN Study Portfolio Database and want support with recruiting participants.
  - Have a study ‘open’ on the NIHR CRN Study Portfolio Database and want additional support with recruiting participants.
- 2.3 The study will be discussed with a member of the IAPT-RR team who will make an initial assessment regarding suitability for IAPT-RR support based on whether or not researchers have, or are willing to obtain, NIHR CRN registration. Researchers who are not willing to register the study with the NIHR CRN will not be adopted.
- 2.4 Where available the study protocol of eligible studies will be obtained and details shared with the IAPT-RR Steering Group via emails and meetings.
- 2.5 An Adoption Agreement will be completed and signed by the Chief or Principal Investigator and an IAPT-RR contact (Appendix A).

### 3. REFERRALS AND MANAGING STUDIES



- 3.1 The IAPT-RR service offers support to researchers at all stages of the study development and studies will be adopted in accordance with the procedures outlined in Section 2.
- 3.2 Recruitment targets will be agreed by an IAPT-RR contact and the Chief/Principal Investigator. Targets will be determined in accordance with the study protocol and by preliminary analysis of the IAPTus data to establish the approximate number of IAPT clients who fit the study inclusion criteria.
- 3.3 Timescales will be dependent on the study protocol. The Chief/Principal Investigator will be responsible for informing R&D of any extensions to the recruitment period.
- 3.4 The Recruitment Methods form (Appendix B) will be completed by an IAPT-RR contact and signed by the Chief/Principal Investigator and the IAPT-RR contact.

- 3.5 The Chief/Principal Investigator will be responsible for obtaining Trust Research Governance and Ethics Committee approval and IAPT-RR will not undertake any research activities until the study has been approved.
- 3.6 At this stage the research activity will be covered by NHS indemnity as set out in guidance document HSG (96) 48: NHS 'Indemnity – Arrangements for Handling Clinical Negligence Claims Against NHS (see Appendix C).
- 3.7 The reporting of accruals to the NIHR CRN will be the responsibility of the Chief/Principal Investigator.
- 3.8 The study researcher will liaise with the IAPT-RR contact on at least a monthly basis to provide an update on recruitment.
- 3.9 IAPT-RR contacts will liaise with the Chief/Principal Investigator if any recruitment problems are encountered. It is the responsibility of the Chief/Principal Investigator to inform R&D of any changes made to recruitment procedures. IAPT-RR and its partners will not be responsible for non-achievement of targets within the agreed timescale.
- 3.10 It is the responsibility of the IAPT-RR contact to edit the IAPT-RR Recruitment Methods form (Appendix B) in accordance with any agreed changes and for this form to be signed by the Chief/Principal Investigator.

**6. DISCLOSING DATA**

- 6.1 Access to IAPTus is restricted to IAPT staff and IAPT-RR contacts.
- 6.2 All client identification and accompanying data received by the Chief/Principle Investigator and their research team from an IAPT-RR contact must adhere to the Data Protection Act 1998 and the Coventry and Warwickshire Partnership Trust Data Protection Policy and the Confidentiality, Security and Sharing of Personal Data Policy and Procedures. Information is available at:

[www.covwarkpt.nhs.uk/AboutUs/Policies/Pages/default.aspx](http://www.covwarkpt.nhs.uk/AboutUs/Policies/Pages/default.aspx)



## Appendix A

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### Adoption Agreement

	<b>Chief/Principle Investigator</b>	<b>IAPT-RR Contact</b>
<b>Name</b>		
<b>Title</b>		
<b>Address</b>		
<b>Telephone Number(s)</b>		
<b>Email address</b>		
<b>Signature</b>		

<b>Targets</b>	<p>The total target number of accruals to the study is</p> <p>The agreed target number of accruals from the IAPT Service is</p>
<b>Timescales</b>	<p>The proposed end date of the study is</p> <p>The proposed end date for recruitment from the IAPT Service is</p>

IAPT-RR and its partners will not be responsible for non-achievement of targets within the agreed timescale.

## Appendix B

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### Recruitment Methods

	<b>Principle Investigator</b>	<b>RM&amp;G Manager</b>	<b>IAPT-RR Contact</b>	<b>Study Researcher</b>
<b>Name</b>				
<b>Title</b>				
<b>Address</b>				
<b>Telephone No.</b>				
<b>Mobile Phone No.</b>				
<b>Email address</b>				
<b>Signature</b>				

#### **Clients who have already given consent to be contacted by researchers.**

[Name 1 & Designation e.g. Kay Wright, IAPT-RR Contact] will identify clients who have already consented to be contacted by researchers and who fit the study inclusion criteria.

[Name 1] will provide [Name2 & Designation 2 e.g. John Smith, Study Researcher] with client contact details and brief client information relevant to the study.

A client invitation letter from [Name 1] on IAPT Service letterhead will be countersigned and sent by [Name 2] with a study information sheet enclosed. The information sheet will ask the client to contact [Name 2] if they are interested in taking part in the study.

[Name 2] will make telephone contact with the client following a negative or a positive response to the letter.

#### **Clients who receive an IAPT Service Information Pack.**

IAPT Service staff will attach a study information sheet to the information packs that are routinely sent out to new clients.

The information sheet will ask the client to contact [Name 2] if they are interested in taking part in the study.

### **Telephone and Referral Centre (TaRC)**

IAPT Service clinicians will identify clients presenting with symptoms of [ ] during the initial telephone assessment at the TaRC.

IAPT Service clinicians will give a brief description of the study and will ask clients if they would be willing to provide verbal consent to be contacted by [Name 2].

The IAPT Service clinician will record the verbal consent in the patient's notes using IAPTus.

IAPT Service clinicians will give the IAPTus ID numbers of clients who have consented to be contacted by [Name 2] to the TaRC Operational Manager.

The TaRC Operational Manager will email the ID numbers to [Name 1] who will extract the contact details from the IAPTus database.

[Name 1] will forward the client contact details and information relevant to the study to [Name 2] by i) telephone; ii) email via a secure NHS net site and iii) fax.

### **Clients currently in treatment.**

[Name 1] will send an all user email to IAPT Service clinicians requesting them to identify clients currently in treatment for [ ].

IAPT Service clinicians will give a brief description of the study to all identified clients and will ask them if they would be willing to give their verbal consent to be contacted by [Name 2].

The IAPT Service clinician will record the verbal consent in the patient's notes using IAPTus.

IAPT Service clinicians will pass the clients details on to [Name 1].  
[Name 1] will forward the client contact details and relevant information to [Name 2].

### **All clients in the IAPTus database.**

[Name 1] will identify clients from the IAPTus database that fit the study inclusion criteria.

[Name 1] will ask an IAPT Service clinician who has had contact with the client before to contact them again and give a brief description of the study and ask them if they would be willing to give their consent to be contacted by [Name 2].

IAPT Service clinicians will pass the willing clients details on to [Name 1].  
[Name 1] will forward the client contact details and relevant information to [Name 2].

## Appendix C

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### Research in the NHS: Indemnity arrangements

**Gateway reference: 5957**  
**December 2005**

#### **RESEARCH IN THE NHS: INDEMNITY ARRANGEMENTS**

This note summarises the current position on NHS indemnity for NHS bodies involved in research. It is a guide to managing the risks associated with research that involves NHS staff and/or NHS patients, including their organs, tissues or data.

#### **General**

- NHS indemnity covers clinical negligence. It does not cover indemnity for any other liability such as product liability or employers' liability.
- NHS indemnity is Government policy: it is not a statutory obligation.
- NHS indemnity covers negligent harm to patients and volunteers.
- NHS indemnity means that NHS organisations forgo the right to recover costs and damages from their staff in respect of liabilities arising out of clinical negligence (except where that involves criminal or wilfully negligent behaviour).
- The Department of Health recommends that all NHS organisations in England with potential liabilities for clinical negligence join the Clinical Negligence Scheme for Trusts (CNST). This is a pooling arrangement for trusts run by the NHS Litigation Authority (NHSLA).
- Primary Care Trusts (PCTs) may find that some of the liabilities they have inherited from health authorities are met through the existing liabilities scheme. This too is a pooling arrangement that the NHSLA runs. It is funded centrally.

#### **Research**

- Research is a core NHS activity. It is therefore treated in the same way as any other NHS activity in relation to potential liabilities for clinical negligence.
- For all NHS research activity, whether commercial or non-commercial, liability for clinical negligence on the part of NHS staff lies with the health-care professional's NHS or honorary NHS employer.
- Being a research sponsor does not increase potential liability. However, the sponsorship agreement should clarify where liability lies.

#### **Non-negligent harm**

- Non-negligent harm carries no legal liability.
- It is *ultra vires* for NHS organisations to give indemnity for compensation in the event of non-negligent harm.

- NHS bodies may not offer advance indemnities or take out commercial insurance for non-negligent harm.
- An NHS organisation may consider making an ex-gratia payment in respect of non-negligent harm. This is possible if the participant in the research has sustained harm and the sponsor is an NHS organisation.
- NHS bodies should not make ex-gratia payments for non-negligent harm where research is sponsored by a non-NHS body.
- A research ethics committee may decide that a study cannot go ahead unless participants are assured of compensation for non-negligent harm. In that case the research can proceed, only if a non-NHS body is willing to make the required arrangements for compensation.

### **Primary Care**

- Most GPs are independent contractors. NHS indemnity does not cover them, or the staff they employ.
- Medical defence organisations (MDOs) provide cover for clinical negligence to GP practices. This is for the services they are contracted to provide to the NHS.
- This cover may extend to research activity that comes within the scope of these services but practitioners must check this with their MDO before starting the research.
- GP practices undertaking research outside this contractual arrangement will need to make separate arrangements.

### **Honorary Contracts**

- *Where appropriate*, honorary contracts may be used for those involved in research. They provide the opportunity under the NHS organisation's vicarious liability to define the legal arrangements for non-NHS personnel undertaking research.
- An honorary contract extends an NHS employer's responsibilities, but not beyond its existing legal duty of quality (see [Section 45 of the Health and Social Care \(Community Health and Standards\) Act 2003](#)) and its common-law duty of care.

### **Useful links**

- [NHSLA](#)
- [NHS R&D Forum \(see \*Indemnity Arrangements within Primary Care\*\)](#)

In case of any query about this document, please e-mail [stella.barclay@dh.gsi.gov.uk](mailto:stella.barclay@dh.gsi.gov.uk)