

Standard Operating Procedure 001

ADEPT Ethics Submissions

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Relevant regulations/legislation/guidelines	NHS Health Research Authority

Change History			
Date	Version Number	Reason for Change	Approved by
01.06.2015	1.0	Initial Document	
03.03.2016	1.1	Fast-track / Chairman's Actions addendum	
04/04.16	1.2	Update of: <ul style="list-style-type: none"> • ADEPT Committee Members • Review fees 	
01.08.17	1.3	Update of: <ul style="list-style-type: none"> • Review Fees • ADEPT Secretariat Contact Details 	
17.12.18	1.4	Update of: <ul style="list-style-type: none"> • Added new databases • Currency/review change for fees • Change of wording for decision criteria 	

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the standard procedures to be followed when obtaining and maintaining research governance approval for database research governed by the Anonymised Data Ethics & Protocol Transparency Committee (ADEPT).

INTRODUCTION

The (ADEPT) committee is an independent body of experts and regulators commissioned by the Respiratory Effectiveness Group (REG) to govern the standard of research conducted on internationally renowned databases. The ADEPT committee comprises scientists with statistical and epidemiological experience, members with specific database related expertise, independent clinical experts and also lay members adhering to UK standards.

The ADEPT committee has been chaired for the past 5 years by Dr Daryl Freeman, Clinical Director of the East of England Strategic Clinical Network (Respiratory Clinical Director NHS England- Midlands & East), further supported by the full committee of clinical experts and senior researchers. From 1st January 2019 Todor (Ted) Popov will take over as Chair. Dr Daryl Freeman will become Vice Chair and will cover for Ted in times of absence and in any cases where there may be a conflict of interest.

The ADEPT committee have been commissioned to govern research conducted on databases across the world including:

- Optimum Patient Care Research Database (OPCRD)
- Implementing Helping Asthma in Real Patients Database (iHARP)
- International Severe Asthma Registry (ISAR)
- Hospital Episode Statistics (HES)

Individuals or research groups interested in conducting a study using data from a database governed by the ADEPT committee must gain approval before commencing research analysis. The ADEPT committee may recommend that study-specific research ethics committee (REC) approval is sought if ethical issues arise in relation to any individual study. Following approval the investigator must advise the ADEPT committee of any substantial changes to the protocol or changes to the study procedures that may affect the conduct of the study. The decision will be based on a review of whether:

- Practice and patient confidentiality will be maintained
- The means by which confidentiality is maintained is clearly described
- There is a well-defined hypothesis or clear question to be addressed
- The database proposed are suitable for the research
- The methodology is considered appropriate and ensures patient confidentiality at all times
- There is scientific and academic rigor
- There are no sections of the protocol which would necessitate formal ethics approval where none has been sought.
- The team are experienced in real-life research, or are supported by experts

with relevant real-life expertise

In addition the ADEPT committee may be approached for advice on methodology and standard of research to be conducted on other international databases, prior to any further required ethical approval being sought.

SCOPE

This SOP describes the process of submitting a research project for ethical approval and the requirements post approval. This SOP does not cover specific requirements of ethics committees, which can be country specific. The requirements and procedure of ethics committees for database research are country specific, consequently, the relevant ethics committees in each country should be consulted to ensure that all the ethical, legal and regulatory requirements of that country are adhered to.

PROCEDURE

1. Submission of Application

The ADEPT application form should be completed in full and submitted to the ADEPT committee via its centralised email system at **application@adeptcommittee.com**. Listed below is the mandatory documentation that is required to be sent with the application:

- Covering letter on headed paper
- ADEPT Application Form
- Research/Study protocol
- C.V. for Chief Investigator (Or summary CV)

If an application is valid, the ADEPT secretariat will notify the Principal Investigator of receipt with a formal email. The acknowledgement email includes details of dates of the meeting/s at which the protocol will be discussed (if relevant), as well as the specific identifying number allocated to the protocol.

The protocol submitted will then be blinded by the ADEPT secretariat before release to the ADEPT chairman for processing.

2. Fees for Application

A fee is charged by REG to cover administrative cost of ADEPT applications as detailed below:

- | | |
|---|----------|
| 1. Commercial research organisation | |
| a. REG supporter preferential rate | 750 GBP |
| b. Non REG supporter rate | 1500 GBP |
| 2. Academic research organisation/group | 350 GBP |

Following receipt of application an invoice will be issued.

3. Processing Application

The ADEPT committee aim to provide timely, high-quality peer review of protocols; whilst recognising that the quality of the research ultimately remains the responsibility of the applicants. The committee have a period of up to 15 working days from receipt of a valid application to give their response to the applicant. The application is valid if the application form is complete and all of the required supporting documentation is enclosed. The ADEPT secretariat will notify the applicant if the application is valid or not. The ADEPT secretariat can send a single request for further information to be supplied. At this point the clock on the 15 working day time period is stopped until the supplementary information is supplied.

The application can be processed via two key streams either Chairman's or full panel approval this will usually be 3 members of the Committee chosen as their areas of expertise align with the protocol content. This decision will be made by the chairman based on its uniqueness and ADEPT opinion in previous applications of this kind,

4. Approval Opinion

Submissions can be reviewed and adjudicated by the Chairman, in isolate, under Chairman's actions, or circulated to Committee Members for wider review. The scope of the proposed study will inform the Chairman's decision to adjudicate on the proposal under Chairman's actions or to involve the Committee in its review.

4.1. Chairperson's actions

Submissions eligible for Chairman's actions (or "fast-track review") must meet the following scope criteria, they must be:

- Retrospective analysis of historical data
- Involve descriptive characterisation only

4.1. Chairperson's actions

Submissions that meet any of the following scope criteria must be reviewed by at least one member of the ADEPT Committee in addition to the Chairman:

- Forward-looking / prospective studies involving an a priori defined follow-up (within the historical dataset) after a defined index date
- Comparative effectiveness evaluations
- Involve statistical matching
- Or other studies which the Chair feels would require evaluation by the Committee

4.3. Committee / Chairman's Decision

The ADEPT committee can provide differing opinions of the application including:

- Full Approval
- Conditional Approval
- Resubmission with Amendments
- Rejection

If the application is not given a favourable ethical opinion and it is felt that the reasons given for this by the committee can be addressed, the research proposal should be revised accordingly and resubmitted to the ADEPT committee.

5. Publication

Applicants are required to include a statement in the manuscript indicating that it had been approved by the ADEPT committee (with the reference number). Applicants should submit a copy of all peer-reviewed publications based on ADEPT approved studies data to the ADEPT Secretariat. Please also notify the ADEPT should it become clear that an ADEPT-approved study will not be completed.

6. ADEPT Secretariat

ADEPT Secretariat
ESpace North
181 Wisbech Road
Littleport
ELY
Cambridgeshire
CB6 1RA

*Electronic submission of protocols to: **application@adeptcommittee.com***