

Standard Operating Procedure 001

ADEPT Ethics Submissions

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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 	

PURPOSE

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

INTRODUCTION

The Anonymous Data Ethics Protocols and Transparency (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, and will continue to be, 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. Todor (Ted) Popov is Vice Chair and will cover for Daryl in times of absence and in any cases where there may be a conflict of interest.

The ADEPT committee formally govern the following databases:

- Optimum Patient Care Research Database (OPCRD)
- Implementing Helping Asthma in Real Patients Database (iHARP)

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 robust
- There is scientific and academic rigor
- 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 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 letter sent via email. The acknowledgement letter 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 500 USD
 - b. Non REG supporter rate 1000 USD
2. Academic research organisation/group
 - a. REG published research need* 200 USD
 - b. Non REG published research need 350 USD

*REG research needs are published on the REG website after the annual research review

Following receipt of application the REG Finance Officer will initiate the appropriate payment process.

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 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 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:

- Approved
- Approved with minor revisions
- Approved with major revisions
- 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

For protocols approved from 01 July 2015 onwards, 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
PO Box 75
Cromer
NR27 7BS

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