

# 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"> <li>• ADEPT Committee Members</li> <li>• Review fees</li> </ul>	
01.08.17	1.3	Update of: <ul style="list-style-type: none"> <li>• Review Fees</li> <li>• ADEPT Secretariat Contact Details</li> </ul>	
17.12.18	1.4	Update of: <ul style="list-style-type: none"> <li>• Added new databases</li> <li>• Currency/review change for fees</li> <li>• Change of wording for decision criteria</li> </ul>	

## Change History

19.11.2020	1.5	Update of: <ul style="list-style-type: none"><li>• Scope of projects that can be submitted</li><li>• Criteria for chairman &amp; committee review</li><li>• Application review process</li><li>• Review fees</li></ul>	
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## **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 since January 1<sup>st</sup> 2019 by Professor Todor (Ted) A. Popov (Professor, University Hospital Sv. Ivan Rilski, Sofia) and supported by the Vice Chair Dr Daryl Freeman (Associate Clinical Director Norfolk Community Health & Care, Chair Norfolk & Waveney Respiratory Working Group) and further supported by the full committee of clinical experts and senior researchers. The Vice Chair will cover for the Chair 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 as well as other pragmatic research methodologies. Individuals or research groups interested in conducting a study using data from one of the following databases must submit an application to the ADEPT committee for approval before commencing a research project.

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

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.

In addition, individuals or research groups interested in conducting a study using data from a database may approach the ADEPT committee for advice on methodology and standard of research to be conducted.

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

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.

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## **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 and other pragmatic research methodologies 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 the online application form or downloading and completing the application form and sending by email to [application@adeptcommittee.com](mailto:application@adeptcommittee.com). Listed below is the mandatory documentation that is required to be sent with the application:

- 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 released 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 1250 GBP
  - b. Non REG supporter rate 2500 GBP

2. Academic research organisation/group      550 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 20 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 20 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 a panel approval which will usually be the chair plus 2 members of the Committee chosen as their areas of expertise align with the protocol content. If the application has already received an institutional ethics committee approval, the approval can be reviewed and approved/rejected by the chair. If the application has no institutional ethics committee approval, the application will be reviewed by the chair and 2 members of the committee.

### **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 depending on whether an institutional ethics committee review has approved the application. In addition, 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:

- Already have institutional ethics committee approval

#### **4.2. Chairperson's actions**

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

- No institutional ethics committee approval
- Forward-looking / prospective studies involving an a priori defined follow-up (within the historical dataset) after a defined index date
- 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.

Following approval, if substantial changes to the protocol or changes to the study procedures that may affect the conduct of the study are to be made the amended protocol, with changes highlighted should be sent to the ADEPT secretariat along with the original ADEPT protocol approval number for review. The changes will be reviewed by the Chair within 15 working days.

## **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 Secretariat 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

## **7. Application submission**

To submit a protocol for review/approval by the ADEPT Committee,

1. Complete the online application form and upload your protocol  
<https://www.regresearchnetwork.org/adept-committee/>

Or

2. Download and complete the application form and send with the protocol by email to **[application@adeptcommittee.com](mailto:application@adeptcommittee.com)**