EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK - TRANSNATIONAL WORKING GROUPS

ECRIN-TWG

FP6-2005-Life Sciences and Health LSH-2005-3-4
Contract # 037199

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Standard Operating Procedure
Development, review, approval and management of SOPs

Date of preparation: **29 October 2008**

Work package 6: **Transnational working group on standard operating procedures**

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ECRIN-GE-SOPØØ1

Development, review, approval and Management of Standard Operating Procedures

European Clinical Research ECRIN Infrastructures Network

Development, Review, Approval and Management of Standard Operating Procedures

Reference: ECRIN-GE-SOPØØ1-V1.Ø

Version number: Final V1. Ø

APPROVAL

Author: Sarah Bathers
Christine Kubiak
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Validated by Chair of the Network Committee: Christian Ohmann

Date: 19 May 2008 Signature: C. Ohmann

Validated by QA Unit: Jacques Demotes

Date: 19 May 2008 Signature:

Effective Date: 2 June 2008

Supersedes version number (*if applicable*):

REVISION

Version number: Not applicable

Date: Not applicable

Reason for change: Not applicable

Main modifications: Not applicable

COUNTRIES
The SOP is valid in all ECRIN countries

1. PURPOSE

Describe the preparation, review, approval, revision and management of ECRIN Standard Operating Procedures (SOPs).

2. SCOPE

The SOPs produced by ECRIN will cover the tasks for multinational studies, particularly interaction with ethics committees, interaction with competent authorities and regulation, adverse event reporting, monitoring and data management. This will be achieved for any category of clinical research, in any step of a clinical trial, in any medical field and in any patient population. The SOPs must be used in conjunction with national laws and regulation. This SOP will apply to all SOPs for ECRIN.

3. DEFINITIONS AND ABBREVIATIONS

ECRIN:	European Clinical Research Infrastructures Network
EFCGP:	European Forum for Good Clinical Practice
IC:	Individual Centre, specific site where clinical trial is conducted.
QA:	Quality Assurance
QA Unit:	Quality Assurance Unit. ECRIN unit in charge of the update, upgrade of the quality system and definition of quality management policy.
QCD:	Quality Controlled Document, i.e. instructions, forms and Templates
SOP:	Standard Operating Procedure. Detailed, written instructions to achieve uniformity of the performance of a specific function.
WP:	Working Party
WP Leader:	Person who Chairs a Working Party or work package

4. RESPONSIBILITY

Responsibility	Activity
WPs	- Write the SOPs related to their activity area - Submit SOP to QA Unit - Review the final version of the SOPs
Any ECRIN representative	- May request a revision of existing SOPs and creation of a new SOP

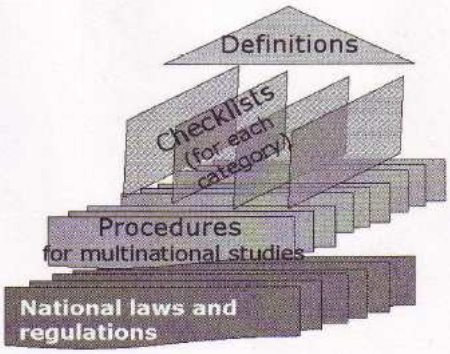
QA Unit Responsible for Standard Operating Procedures	- Establish the listing of required SOPs - Name and number the SOPs - Supervise the consistency of the set of SOPs - Write the checklists for each category of research - Review and approve the SOPs produced by the other WPs to ensure harmonisation and consistency - Maintenance of the website to ensure a consistent and up-to-date set of procedures. Inform users and distribute updated SOPs. Archive Superseded SOPs. - Establishing processes for QA/QC. - Maintain electronic copies of draft and finalised ECRIN SOPs in a version controlled Document Management System. - Maintain a hard signed copy in the Master File of all current SOPs. - Archive all Superseded.
WP on Education and Training (in collaboration with QA unit)	- Ensure Trainers are adequately trained. - Develop and maintain ongoing training requirements on use of SOPs and their updates.

5. DESCRIPTION

5.1 Background

The Standard Operating Procedures are detailed written instructions that describe policy and procedures for ECRIN. They focus on a stepwise description of each task, and are designed to reach uniform performance and best practice. They must clearly define "who does what". They should be clear, concise, using pictures and diagrams as far as possible. Effective management of SOPs is required to ensure that people have access to the SOPs, that they are using only the latest version, that they are appropriately informed and trained on relevant SOPs and updates in a timely fashion and that systems are in place to allow a cost effective audit to ensure adherence to SOPs.

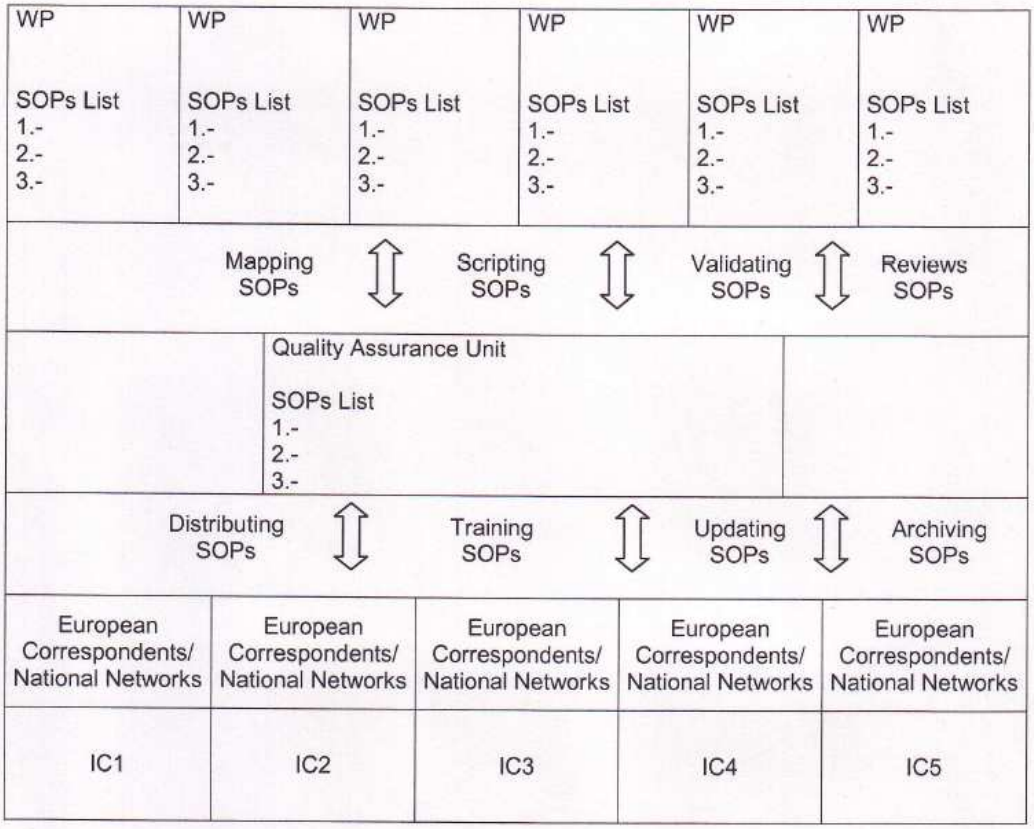
The documentation is organised as follows:



The definitions determine the relevant category of research. The checklists summarise the requirements for multinational support to sponsors and investigators, stratified by category of research. The ECRIN SOPs, stratified by task, provide detailed description of the specific requirements for each category of research. They are based on a core element valid throughout the EU, with adaptation to the particularities of each country.

All documents are based on the national laws and regulations.

5.2. SOPs Flowchart



5.3. Preparation

The SOPs will adhere to the standard format as defined in **appendix 1**.

The content of the SOPs will be as follows:

TITLE PAGE

- Title
- SOP identification number provided by the QA Unit according to the following rules. Each SOP will be issued with a unique code e.g. *ECRIN-GE-SOPØØ1*

- This categorisation identifies firstly the origin of the document [ECRIN], the topic of the SOP [GE for General, EC for Ethics Committees, CA for Competent Authority, MO for Monitoring, etc…], the SOP number in the topic [SOPØØ1] and the version number [eg VØ.1]. The first draft version will be numbered as Ø.1. Each successive draft will be altered accordingly i.e. Ø.2, Ø.3 etc. The finalised document will become version 1.Ø.

GE	General
EC	Ethics Committee
CA	Competent Authority
AE	Adverse Events
DM	Data Management
ED	Education
MO	Monitoring

Other quality controlled documents (i.e. instructions, forms and templates) will be numbered with the same rules substituting SOP with QCD and with two letters to identify the country e.g. ECRIN-GE-**QCD ØØ1- AT-** V Ø1.
The country identification abbreviations will be those used by the European Commission e.g for example AT- Austria, DK- Denmark, FI- Finland, FR- France, DE-Germany, HU- Hungary, IE- Ireland, IT- Italy, ES- Spain, SE- Sweden, UK- United Kingdom and CH- Switzerland.

- **Version Number**: the first version will be numbered as VØ.1. Each successive draft will be altered accordingly ie Ø.2, Ø.3 etc.
- **Approval**
  - Authors
  - Validated by
  - Validated by QA Unit
  - Effective date: date of implementation following validation
  - Supersedes version number
- **Revision**
  The first approved version is 1.Ø. Successive revisions will be altered accordingly ie 2.Ø, 3.Ø etc.
  - Version number
  - Date
  - Reason for change
  - Main modifications
- **Countries** where the SOP is applicable

SOP CONTENTS

- **1. Purpose**
- **2. Scope**
- **3. Definitions and Abbreviations**
- **4. Responsibility: specify responsibilities for each task/action**
- **5. Description**
- **6. Specific References:** references related to SOP
- **7. ECRIN references:** references related to ECRIN documents.
- **8. Appendices**

When a section is not needed it will be noted as "not applicable". When necessary, additional new sections can be added, then, revision point (page 1) should be updated to reflect these additions.

5.4. Mapping SOPs

Each WP will determine which activities require SOPs and will assign the responsibility for writing the initial version. The Individual Centers (ICs) and International Network will determine which specific activities of clinical phase require SOPs.

5.5. Scripting and validating the SOPs

The designated author will produce a first draft of a procedure. The author will circulate the draft SOP amongst the WP members for review and comment. The WP Leader will perform the final review and submit to QA Unit for authorisation. Final drafts will be authorised by signatures of WP Leader and QA Unit. The Network Committee will review and approve only the SOP "Development, Review, Approval and Management of Standard Operating Procedures".

5.6. Distributing SOPs

The approved SOP (pdf version) will be uploaded on the ECRIN website by the QA Unit. Information on the implementation of a SOP will be disseminated, via email, to the European Correspondent in each country. The European Correspondent will be in charge of the dissemination within the country. The authorized and current copy of SOPs are in the ECRIN website.

5.7. Training SOPs

To ensure that all members of the research team know the new SOP or the updates, they can fill the «training compliance form». Signed hard copies of this document will be archived at IC.

5.8. Review and Updating SOPs

The SOPs will be reviewed every two years, and revised when necessary. In the meantime, if a new SOP needs to be created or if a SOP requires a change (regulatory update, participation of a new country with particularities not covered in the SOP), any ECRIN representative should send a note to the QA Unit Lead who will be in charge of initiating the creation or the revision, in collaboration with the relevant working group.
SOPs requiring additional modifications will be revised by the author or a person designated by the WP Leader , the amended SOP will be circulated amongst the WP members for review and comment. The WP Leader will perform the final review and submit to QA Unit for authorisation. Final amended documents will be authorised by signatures WP Leader, QA Unit.

5.9. Archiving SOPs

QA Unit will maintain a complete collection of current ECRIN SOPs and all previous versions of ECRIN SOPs.

6. SPECIFIC REFERENCES

- International Conference on Harmonisation -ICH E6 Good Clinical Practices (1996)
- Handbook of SOPs for Good Clinical Practice. Second Edition. Celine M. Clive. Interpharm/CRC. 2004
- Good Clinical Practice. Standard Operating Procedures for Clinical Researchers. Edited by Josef Kolman, Paul Meng and Graeme Scott. Wiley. 1998

7. REFERENCED ECRIN DOCUMENTS

- Not applicable

8. APPENDICES

Appendix 1: SOPs Standard format

Appendix 2: Other Quality Controlled Document Standard Format

Appendix 1: SOPs Standard Format

"Title"
Reference:
Version number:

APPROVAL
Author (s):
Validated by WP Leader: Date: Signature:
Validated by QA representative: Date: Signature
Effective Date:
Supersedes version number (if applicable):
REVISION
Version number:
Date:
Reason for change:
Main modifications:
COUNTRIES List the countries where the SOP is applicable

1.- PURPOSE

2.- SCOPE

3.- DEFINITIONS AND ABBREVIATIONS

4.- RESPONSIBILITY

5.- DESCRIPTION

6.- SPECIFIC REFERENCES

7.- ECRIN REFERENCES

8.- APPENDICES

Appendix 2: Other Quality Controlled Documents Standard Format

	"Document" "Title" "Country" (if applicable)	Code
Approval	**Effective Date**	**Revision**

Description:	