



Guidance for Auditing Quality Systems of IECs in Europe

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GUIDANCE FOR AUDITING QUALITY SYSTEMS OF INDEPENDENT ETHICS COMMITTEES IN EUROPE

The European Forum for Good Clinical Practice



'where science and ethics meet'

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<http://www.efgcp.be/Publications>.

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Table of Contents



1. Introduction
2. Glossary
3. Assigning Auditors/Auditor Qualifications and Training
4. Audit Planning
5. The Conduct of an Audit
6. The Audit Report
7. Audit Follow Up

1. Introduction (1)



- Defines guidelines and recommendations to establish QA programme for IECs
- EFCGP Ethics Working Party research and discussion
- Review of 'The Procedure for Ethical Review of Protocols for Clinical Research Projects in the European Union' (2007); the question asked 'Is there an ongoing quality assurance process (e.g. audits, inspections, internal SOPs) for research ethics committees?'



1. Introduction (2)



- Introducing a quality system within an IEC assists in raising standards of the committee and thereby providing greater protection for human subjects.
- The document aims to act as guidance to identify the minimum requirements (as defined by EFGCP) for audits/quality systems. A complimentary guide to support '*Guidelines and Recommendations for European Ethics Committees*' (EFGCP 1997). The process for accreditation has not been defined.
- Types of internal audits for IECs include: documentation, processes and facilities.

2. Glossary



GUIDANCE FOR AUDITING QUALITY SYSTEMS OF INDEPENDENT ETHICS COMMITTEES IN EUROPE

2. Glossary

Accreditation

A system of accreditation or certification of Independent Ethics Committees by a suitable body that has the authority and appropriate procedures and qualifications to determine that a Committee qualifies for accreditation.

Applicant

A qualified researcher undertaking the scientific and ethical responsibility for a research project, either on his / her own behalf or on behalf of an organisation/ firm, seeking a decision from an Independent Ethics Committee through formal application.

Appointing Body

The organisation that appointed the Independent Ethics Committee such as a Health Authority, Institution or Governmental Authority.

Audit

A systematic and independent examination of clinical trial-related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). In the context of this document, an audit refers to a systematic and independent examination of the constitution and practices of an Independent Ethics Committee.

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Audit Plan

A plan setting out the specific practices, resources, activities, and time lines relevant to a particular audit or a group of related audits.

Audit Report

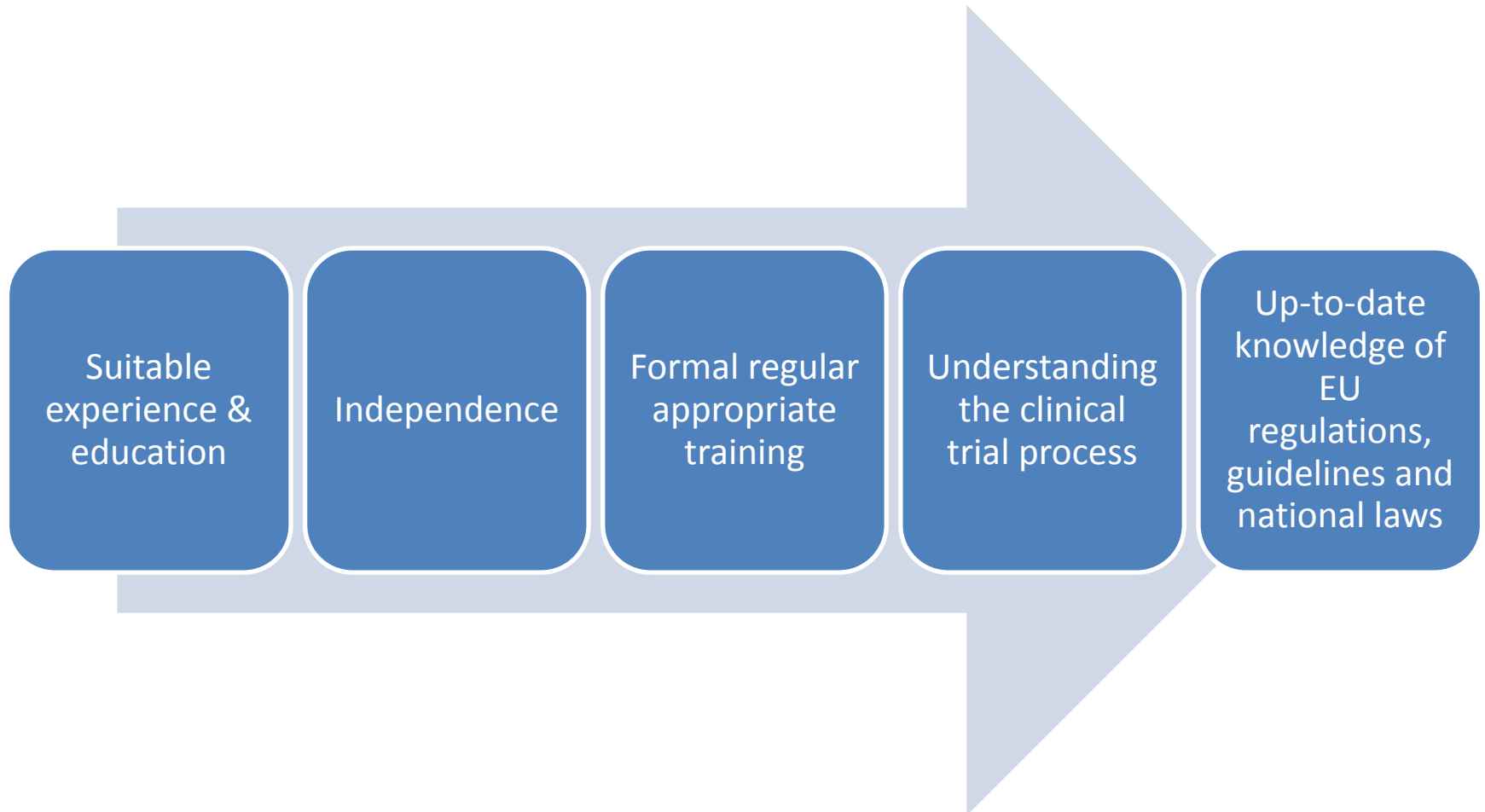
A written evaluation by the auditor of the results of the audit.

Conflict of Interest

A conflict of interest arises when a member (or members) of an Independent Ethics Committee hold(s) interests with respect to specific applications for review that may jeopardise his/her (their) ability to provide a free and independent evaluation of the research with a focus on the protection of the trial participants. Conflicts of Interests may arise when a member of an Independent Ethics Committee has financial, material, institutional, occupational or social ties to the research.

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3. Assigning Auditors/Auditor Qualifications and Training (1)

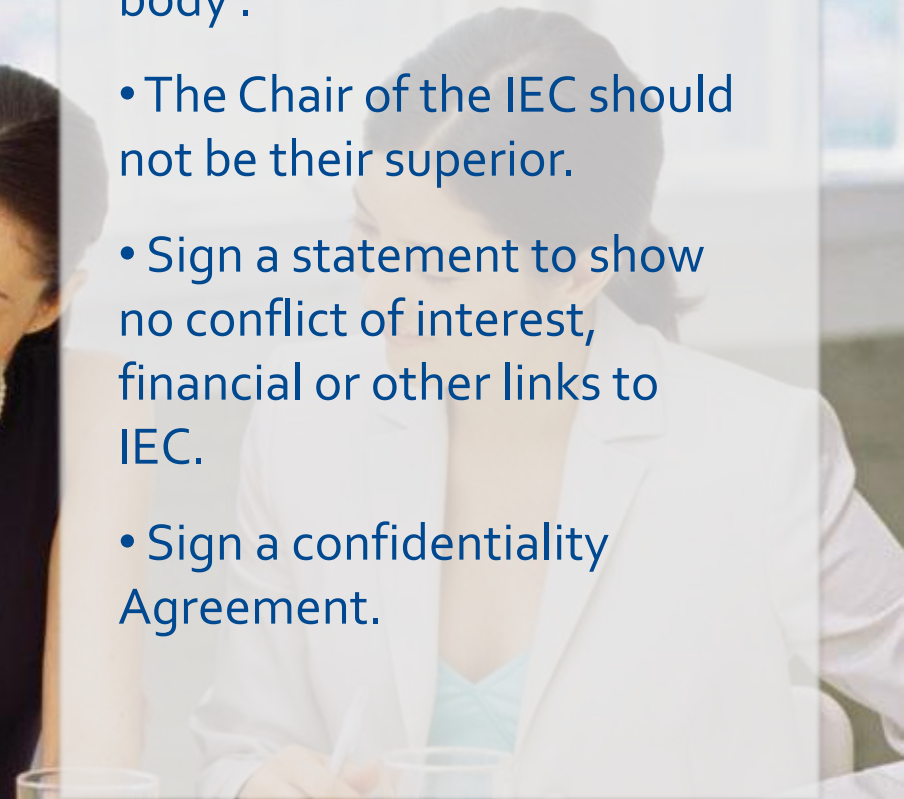


3. Assigning Auditors/Auditor Qualifications and Training (2)



'Independence'

- Report to the highest level usually the 'appointing body'.
- The Chair of the IEC should not be their superior.
- Sign a statement to show no conflict of interest, financial or other links to IEC.
- Sign a confidentiality Agreement.



4. Audit Planning



- To identify the intent, purpose, location, date (if known) of the audit activities and any relevant study identifiers



- To identify the key personnel involved in conducting the audit (both auditors and auditees)



- Outline of detailed activities e.g. facility tour, identification of interviewees



- To identify the documents to be available for review



- To outline the audit history as relevant to the auditor e.g. describes past interactions



- Auditees should receive a letter of introduction with a confirmation of the audit dates and brief synopsis of activities to be conducted



- Description of how responses are to be made (e.g. inclusion of action plan) and expected timelines

5. The Conduct of an Audit (1)



5. The Conduct of an Audit (2)



SOPs should include the following information:

- Authority under which the Independent Ethics Committee was established and relationships to institutions (i.e. hospitals)
- A statement (dependant upon national laws) that the Independent Ethics Committee follows ICH Good Clinical Practices Guidelines (requirement ICH GCP 5.11.1.b), relevant laws and regulatory requirements, and appropriate national and international guidelines
- Terms for the appointment of members (for example, duration, renewal procedure, disqualification, and resignation and replacement procedures) including reserve members and specialists identified to provide advice as needed
- Conditions of appointment (for example, withdrawal from the decision-making process if there is a conflict of interest); willingness to publicise his / her full name, profession, and gender; agreement to declare any financial reward or equivalent from Independent Ethics Committee work to officials of the committee, and the signing of confidentiality agreements)

5. The Conduct of an Audit (3)



- Procedure for making the appointment including the individual or party that makes the appointment, selection of candidates (for example, by consensus, by majority vote, or by direct appointment)
- Provisions and conditions for expedited Independent Ethics Committee review and approval, e.g. “chairman’s approval”
- Membership requirements, including the duties, responsibilities and training of members
- Quorum requirements, including the minimum number of members of Independent Ethics Committee to be present, the minimum distribution of professional requirements, and gender requirements; and back up arrangement to ensure that there are always enough members to take decisions
- Procedures for submitting an application for the review of the proposed clinical research
- Required documentation to be included in the application

5. The Conduct of an Audit (4)



- Meeting procedures, including the preparation of the agenda, the minuting of the meetings, invitations of guests to the meeting (including sponsors, investigators, and specialists that may provide advice on occasions or assist in the review of a particular protocol with consideration for possible conflicts of interests and confidentiality agreements as warranted)
- Actions necessary for the enrolment of trial participants in emergency treatments
- Decision-making procedure, including whether the decisions are by consensus or vote, the manner of specifying conditional decisions, management of ambiguous decisions and the manner of documenting the reasons for negative decisions. The procedure for documenting the appeals and the outcome of the appeal
- Procedures to assess safety of a study (whether industry sponsored or non-commercial sponsored study), e.g. how safety reports are handled (SAEs / SUSARs / annual safety reports), how they are received from the investigator / sponsor and if there are any requirements for reports from other sites / countries
- Procedure for communicating with other Independent Ethics Committees and Regulatory Authority(ies)
- Procedure for communicating a decision which should include a dated and version controlled document stating the name of the Independent Ethics Committee (including if it is a central or local Independent Ethics Committee); the exact title of the research project / clinical trial; a list of the documents reviewed, their date and version number; the name and title of the applicant; the date and place of the Independent Ethics Committees decision; a list of members present during the vote (can be listed by role); a clear statement of the decision made with any advice or comment; and the signature and date of the chairperson of the Independent Ethics Committee or in his / her absence by another official of the Independent Ethics Committee but never a non-voting member of the ethics committee. In the case of a positive decision, confirmation that all amendments have been duly regarded and brought to the attention of the full committee by the chairperson. In the case of a negative decision, the reasons for a negative decision are clearly stated. [A full committee should review all individual amendments submitted to the committee involving patient safety and welfare.] Additionally, cycle times should be considered

5. The Conduct of an Audit (5)



- Procedures for the notifications of completion or premature study terminations
- Continuing review (including frequency, determined by the nature of the study) but recommended to be at least annually
- If procedures exist for Independent Ethics Committee visits to sites for monitoring purposes
- Processes for the development, maintenance and revisions of procedures
- Documentation and archiving procedures, including an inventory of all documents archived and the length of storage of the documents based on their SOPs and on the national legislation. These documents should identify the author, authorisation, date of release, and the date of future review of the documents. In addition, earlier editions of these documents should be available to the auditor when relevant

5. The Conduct of an Audit (6)



Documents to be Reviewed
Standard Operating Procedures
List of current and previous members of the IEC
CV of current members
A description of the requirements for holding office of Chairperson/ deputy, secretary and treasurer
Record of all incomes and expenses of the IEC
Description of the responsibilities and duties of members of IEC
Structure of IEC
Registration of applications, members informed of review date
Maintenance and tracking of records of all communications
Review procedures, timelines and frequency
Meeting agendas (relevant to audit plan)
Review of applications (relevant to audit plan), including correspondence regarding decisions and follow up
Process for determining the suitability of investigators and support staff
Process for determining the suitability and quality of site facilities
Procedure for review of rewards/compensation to investigators
Minutes of IEC meeting (relevant to audit plan)
Registration process for public availability, if applicable
Sources: IFGCP Ethics Working Party.
Table 2. A summarized list of the types of documents that can be reviewed during an audit.

Copyright: Table from Applied Clinical Trials article, June 2010

5. The Conduct of an Audit (7)



Storage & Archiving of Audit Documents:

- Consider the archive facility
- Retention of materials
- Destruction
- Electronic records
- Contract Archive Services
- Business Continuity and disaster recovery



6. The Audit Report



6. The Audit Report

The audit report should reflect the execution of the audit. It should be dated and signed by the auditor and contain, at the minimum, the following items:

- Scope and objectives of the audit (these should include that the conduct of the Independent Ethics Committee meets those aspects of ICH GCP and local regulations relating to Independent Ethics Committee)
- Identification of the auditor (s)
- Identification of the auditee(s) and the representative(s) of the auditee
- Audit plan
- Identification of the facilities, persons interviewed, and the documents reviewed
- Audit methodology
- Findings of the audit
- Recommendations for corrective actions or areas of suggested revisions in practice
- Timeframe for responses
- Audit report distribution list
- Signature and date of the auditor.

The audit report is strictly confidential and should be retained securely and only shared with the auditor(s), auditee(s) and the Appointing Body. Due to the sensitive nature of the audit report, some Independent Ethics Committees Standard Operating Procedures require that the audit report is destroyed (by confidential waste means) after the corrective and preventative actions have been put in place. The documentation of the completion of the corrective and preventative actions should be retained securely by the auditees for the period required by their local procedures for retention of other Independent Ethics Committee documentation.

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7. Audit Follow Up



- **Corrective and Preventive Actions**

Who is the most appropriate person to respond to a CAPA?

- **Follow-up**

Implementation of a CAPA will increase the quality of the operations of an IEC and will provide assurance to CAs. The responses are reviewed for acceptability.

- **Audit Certificate**

The purpose of the Audit Certificate is to confirm an audit was performed and completed. It does not reflect the outcome of the audit.

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