**Survey and Evaluation Report**

*Draft/Final* Report:

Month/Day/Year

This report contains the collective views of the FERCAP Surveyor Team and contains their findings and recommendations.

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**Section 1: General Information**

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| * 1. **EC Name**: |
| * 1. **EC Address**: |
| * 1. **Contact Person(s)** (Name/Position/E-mail): |
| * 1. **Survey Team**   **Lead Surveyor** (Name/Institution/E-mail):  **Foreign Surveyor** (Name/Institution/E-mail):  **Local Surveyor** (Name/Institution/E-mail):  **Survey Coordinator** (Name/Institution/E-mail): |
| * 1. **Survey Trainees** (Name/Institution/E-mail): |
| * 1. **List of Persons Interviewed** (Name/Position): |
| * 1. **Survey Visit Date**: |
| * 1. **Survey Report Date**: |

**Section 2: Executive Summary**

This Survey Report contains findings and suggestions for Corrective Actions prepared during the survey and evaluation done by the FERCAP Survey Team based on the SIDCER Recognition requirements.

The overall survey objective was to assist the Name of EC to improve the quality of its ethical review practices through an assessment of its performance based on the SIDCER criteria for recognition.

The reference documents that were used for assessment were the following:

* Applicable laws, regulations, guidelines, and organizational policies for the EC
* WMA Declaration of Helsinki, 2013
* CIOMS guidelines for ethics review, 2002, 2009, 2016
* WHO standards and operational guidance for ethics review of health-related research with human participants, 2011
* WHO surveying and evaluating ethical review practices, 2002
* ICH-GCP (E-6), 1996, 2016
* SIDCER-FERCAP Survey TOR, 2020
* SIDCER-FERCAP Survey SOPs, 2007, 2010, 2020
* SIDCER-FERCAP Survey Forms, 2009, 2013, 2020

Main Findings:

**Section 3: Objectives and Scope**

The objectives of the survey are:

* + To conduct an independent evaluation of the EC and to provide feedback on its practices and overall performance
* To review existing written Standard Operating Procedures (SOPs) and adherence to these procedures
* To observe compliance to international, national and local standards
  + To make recommendations as appropriate to ensure best standards of quality and transparency in ethical review for the EC

The Survey Team conducted this survey and evaluation for and on behalf of FERCAP:

* EC office visit date:
* EC Members and Staff interview dates:
* EC full board observation date:
* EC document review:
* Number of SOPs reviewed:
* Number of Agenda reviewed:
* Number of Minutes reviewed:
* Number of Protocols reviewed:
* Number of SAE Reports reviewed:

**Section 4: Methodology**

**4.1. EC Self-Assessment Form**

The Survey Team was furnished a copy of the accomplished/completed EC Self-Assessment Form for study and analysis. This was later compared with the observations of the Surveyors and the discrepancies were analyzed.

**4.2. Document Review**

The Survey Team identified the protocols for review. This list was forwarded to the EC Secretary and the Protocol Files were made available to the Survey Team.

The Survey Team prepared the lists of documents for review including the SOP Files, Membership and Staff Files, the selected Protocol Files, Meeting Agenda and Minutes, SAE Reports, and Communication Records that were made available for review by the Survey Team.

**4.3. Interview of EC Members and Staff**

The interviewees were identified and the interview schedules were set according to the availability and preferred time of the interviewees.

**4.4. EC Full Board Meeting Observation**

The EC Full Board Meeting was observed on Month/Day/Year. The Agenda and Protocol Files were provided to the Survey Team in preparation for observation of the meeting. The Local Surveyor(s) assisted the Foreign Surveyor(s) by translating the protocols to be reviewed during the meeting. The Survey Team reviewed the Agenda, Protocol Files, and the relevant SOPs for Full Board Meeting before the actual meeting. The number of new protocols discussed during the Full Board Meeting was number.

**4.5. Visit of EC Office, Document Storage, and Archiving Facilities**

The Survey Team visited the office of the EC located at address.

**Section 5: Findings and Suggestions for Corrective Actions**

This section describes the findings and recommendations of the FERCAP Survey Team.

**5.1. Structure and Composition**

|  |  |
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| 5.1.1. Membership Requirements | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.1.2. Administrative Requirements (Financial, Staff & Office Support) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.1.3. Membership Initial & Continuous Training | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.1.4. Management of Conflicts of Interest (Policy & Practice) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

**5.2. Adherence to Specific Policies**

|  |  |
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| 5.2.1. Availability of Guidelines & Regulations for EC Reference | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.2.2. Adherence to National & International Guidelines | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.2.3. Availability of SOPs (to the EC Members, Investigators & the Public) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.2.4. Areas & Functions Covered by the SOPs (Completeness & Consistency) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.2.5. Availability of Forms & Checklists (including the Use of SOP Forms & Checklists) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.2.6. Periodic Updating of SOPs (Frequency of Updates & SOP Versions) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

**5.3. Completeness of the Review Process**

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| 5.3.1. Assignment of Appropriate Reviewers | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.3.2. Availability of Comprehensive Reviewer Assessment ~~Form~~ | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.3.3. Review Process (Expedited & Full Board) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.3.4. Elements of Review/Quality of Review (Science, Ethics & Informed Consent) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.3.5. Decision-making Process (Types of Decision, Approval Letter & Communication to PI) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.3.6. Completeness of Meeting Agenda (Details in the Meeting Agenda) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

**5.4. After Approval Review Process**

|  |  |
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| 5.4.1. Meeting Minutes (Complete Sections to include Initial & Continuing Review, Discussion Points & Board Decision) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.4.2. Amendments | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.4.3. Progress Reports (Progress of Review & Decision-Making) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.4.4. SAE Reports (Proper Classification of Onsite/Offsite SAE, SUSAR & Appropriate EC Action) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.4.5. Site Visits (EC Procedures & Reporting to the Board for EC Action) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.4.6. Protocol Deviations/Violations (EC Procedures and Action) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.4.7. Final Reports (EC Procedures and Action) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

**5.5. Documentation and Archiving**

|  |  |
| --- | --- |
| 5.5.1. EC Office (Adequate Space, Equipment, Confidentiality & Security Protection) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.5.2. Comprehensive Documentation (in the Protocol Files, Membership Files & Other Files) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.5.3. Orderly Filing System | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.5.4. Separation of Active from Inactive Files (Protocol Files) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.5.5. Archiving | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

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| 5.5.6. Database for Tracking (Complete Details) | |
| ***Good Practices*** | |
| ***Weaknesses*** | ***Recommendations*** |

**Section 6: Conclusions and Recommendations**

**6.1. Over-all Assessment**

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| The overall assessment is that the Name of EC is/is not a functional EC, whose members are description and staff are description. The EC has essentially description SOPs. Generally, the EC review process is description and their after review process is description. Overall, EC documentation and archiving is description. |

**6.2. Follow-up Action**

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| The items identified for improvement should be properly addressed by following the recommendations of the Survey Team. The Name of EC should submit its Action Plan with some documentary evidence to indicate its compliance with the recommendations. |

**Section 7: Attachments**

**7.1. List of SOPs Reviewed**

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| **#** | **SOP Code/Number** | **SOP Title** |
| 01 |  |  |
| 02 |  |  |
| 03 |  |  |

**7.2. List of Protocols Reviewed**

|  |  |  |
| --- | --- | --- |
| **#** | **Protocol Code/Number** | **Protocol Title** |
| 01 |  |  |
| 02 |  |  |
| 03 |  |  |

**7.3. List of Meeting Minutes Reviewed**

|  |  |
| --- | --- |
| **#** | **Meeting Minutes Code/Date** |
| 01 |  |
| 02 |  |
| 03 |  |

**7.4. List of SAE Reports Reviewed**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **#** | **Protocol Code/Number** | **Onsite** | **Offsite** | **SAE** | **SUSAR** |
| 01 |  |  |  |  |  |
| 02 |  |  |  |  |  |
| 03 |  |  |  |  |  |

**7.5. Closing Meeting Presentation**

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| Closing meeting presentation prepared by the Survey Team was presented by the Local Surveyor to the Name of EC on Month/Day/Year. |

**7.6. Summary of Recommendations**

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| **Structure and Composition** |
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| **Adherence to Specific Policies** |
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| **Completeness of the Review Process** |
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| **After Approval Review Process** |
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| **Documentation and Archiving** |
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**7.7. Quality of Ethical Review**