



**SIDCER-FERCAP Survey Form 08: Office Visit**  
Version 3.0, 30 April 2020

<b>EC Name</b>	
<b>City/State, Area/Country</b>	
<b>Group</b>	

<b>1. OFFICE</b>	<b>Comments</b>
<ul style="list-style-type: none"> <li>▪ Is the office easy to locate and accessible with proper signage?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Is the office space sufficient for the Staff to receive and file documents?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ How is the office secured?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Is there an organogram that locates the EC in the structure of the institution?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Are there charts or posters that help explain EC procedures?</li> </ul>	
<b>2. EQUIPMENT and FURNITURE</b>	<b>Comments</b>
Does the EC have sufficient equipment and furniture?	
<ul style="list-style-type: none"> <li>▪ Telephone</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Equipment for sending documents</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Photocopier</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Shredder</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Computer</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Internet connection</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Printer</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Cabinets with lock and key</li> </ul>	
<b>3. FILING SYSTEM: Administrative Documents</b>	<b>Comments</b>
Are the following available and filed in an orderly manner?	
<ul style="list-style-type: none"> <li>▪ SOPs and Forms</li> </ul>	
<ul style="list-style-type: none"> <li>▪ File of Members and Staff (<i>e.g.</i>, TOR, CV, Training Certificates, etc.)</li> </ul>	
<ul style="list-style-type: none"> <li>▪ File of Agendas and Meeting Minutes</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Communication Records (<i>e.g.</i>, submission documents, letters etc.)</li> </ul>	
Are the latest editions of the following references available?	
<ul style="list-style-type: none"> <li>▪ WMA Declaration of Helsinki</li> </ul>	
<ul style="list-style-type: none"> <li>▪ ICH-GCP</li> </ul>	
<ul style="list-style-type: none"> <li>▪ WHO Guidelines</li> </ul>	
<ul style="list-style-type: none"> <li>▪ CIOMS</li> </ul>	
<ul style="list-style-type: none"> <li>▪ National ethical guidelines</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Other reference resources</li> </ul>	

**SIDCER-FERCAP Survey Form 08: Office Visit**  
Version 3.0, 30 April 2020

Is there a log system for incoming and outgoing documents? What type (hard copy/electronic)?	
<b>4. FILING SYSTEM: Protocol Files</b>	<b>Comments</b>
<ul style="list-style-type: none"> <li>▪ Are the protocol file cabinets properly labeled?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Are the protocol files arranged in an orderly manner?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Is there a coding or numbering system for active/inactive protocol file folders?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ How is the security of the protocol files (paper and digital) maintained?</li> </ul>	
<b>5. DATABASE</b>	<b>Comments</b>
<ul style="list-style-type: none"> <li>▪ Is there an electronic database?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Are the fields in the database sufficient to enable EC to manage and track protocols from submission to archiving?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Is the database updated? How often is it updated?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Is there backed-up for the database? Where is back-up located?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ How is the confidentiality of database protected? Who has access?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ How is the database used? <ul style="list-style-type: none"> <li>– For showing the history of the protocols from submission to archiving</li> <li>– For tracking researcher reportorial obligations after approval?</li> <li>– For checking the list of projects of the researcher?</li> </ul> </li> </ul>	
<ul style="list-style-type: none"> <li>▪ Does the EC have other databases (e.g., Membership, SAEs, etc.)?</li> </ul>	
<b>6. WEBSITE</b>	<b>Comments</b>
<ul style="list-style-type: none"> <li>▪ Is there an EC website? If yes, provide link.</li> </ul>	
<ul style="list-style-type: none"> <li>▪ What EC information are available in the website?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Can the EC SOPs and forms be downloaded from the website?</li> </ul>	
<b>7. STAFFING</b>	<b>Comments</b>
<ul style="list-style-type: none"> <li>▪ Is there a regular full time EC Staff?</li> </ul>	
<ul style="list-style-type: none"> <li>▪ Is the number of Staff sufficient for efficient EC operation?</li> </ul>	
<b>8. BUDGET</b>	<b>Comments</b>
<ul style="list-style-type: none"> <li>▪ Does the EC have sufficient budget to support operational expenses? Is a copy of the approved budget for the year available?</li> </ul>	



**SIDCER-FERCAP Survey Form 08: Office Visit**  
Version 3.0, 30 April 2020

OTHER COMMENTS AND SUMMARY
<b>OTHER COMMENTS</b>
<b>GOOD PRACTICES</b>
<b>RECOMMENDATIONS</b>