



QUERIES OR COMPLAINTS REPORT

To the IEC Member and Staff:

Please accomplish this Form to provide information on any queries or complaints concerning the conduct of an IEC-approved study and/or its investigators.

Please obtain an electronic copy of this Form, fill-out the requested information, and forward to the Secretariat both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

I. PROTOCOL INFORMATION	IEC Protocol Tracking No.
Study Protocol No.	Protocol Approval Date: <dd/mm/yy>
Study Initiation Date: <dd/mm/yy>	Expected End Date: <dd/mm/yy>
Title:	Version Number, Date
Name of Principal Investigator	Contact Nos.:
Sponsor/CRO	
Study Site	
Type of Review (To be determined by IEC) <input type="checkbox"/> Full Board <input type="checkbox"/> Expedited	

II. QUERY/COMPLAINT INFORMATION	RECEIVING DATE <dd/mm/yy>	
1. Query/Complaint received via: <input type="checkbox"/> Telephone/Fax () <input type="checkbox"/> Mailed letter () <input type="checkbox"/> E-mail () <input type="checkbox"/> Walk-in (and) <input type="checkbox"/> Others (<i>specify</i>)	2. Relation to Study Protocol <input type="checkbox"/> Study Participant <input type="checkbox"/> Participant's Parent <input type="checkbox"/> Participant's Legal Guardian/LAR <input type="checkbox"/> Others (<i>specify</i>)	
3. Information on Person Lodging the Query/Complaint		
3.1. Name	<Title, Name, Surname>	
3.2. Address		
3.3. Telephone	3.4. Mobile	3.5. E-mail.



4. What is raised?	
<input type="checkbox"/> Query (specify)	
<input type="checkbox"/> Complaint (specify)	
<input type="checkbox"/> Problem (specify)	
<input type="checkbox"/> Others (specify)	
<i>I declare that the above information/statements are true and correct to the best of my knowledge.</i>	
_____	_____
<i>Signature Over Printed Name of IEC Member/Staff</i>	<i>Date</i>

III. IEC RECOMMENDATION	Specifics
<input type="checkbox"/> UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION <input type="checkbox"/> REQUEST INFORMATION <input type="checkbox"/> RECOMMENDED FURTHER ACTION	
Reviewer <input type="checkbox"/> Primary <input type="checkbox"/> Secondary	_____ <i>Reviewer's Signature Over Printed Name</i> _____ <i>Date</i>