

**PUBLIC CONSULTATION ON DRAFT ICMR GUIDELINES FOR COMMON ETHICS REVIEW OF  
MULTICENTRE RESEARCH**

**Format for receiving Feedback and Comments/suggestions**

Feedback and comments in the format given below may be sent by email to:

**Dr. Roli Mathur**

Scientist E and Head, ICMR Bioethics Unit  
National Center for Disease Informatics and Research,  
Indian Council of Medical Research  
Nirmal Bhawan, ICMR Complex (II Floor)  
Poojanhalli Road, NH-7,  
Kannamangala Post, Bengaluru - 562 110

Email: [icmr.bioethics@gmail.com](mailto:icmr.bioethics@gmail.com)

<b>These comments represent the views of (tick one box only):</b>	<input type="checkbox"/> <b>an Individual</b> <input type="checkbox"/> <b>Organisation/ Group</b>
<b>Name:</b>	
<b>Title/Role:</b>	
<b>Organization:</b>	
<b>Address:</b>	
<b>Contact Details (Email ID &amp; Phone/Mobile Number):</b>	

Give reference of page number and line number against each comment:

Guidelines Page No.	Guidelines Line No.	Original Sentence	Suggested Changes/ Comments

Format for General Comments/Suggestions:

Sections	Comments/ Suggestions
Section 1 - Introduction	
Section 2 - Purpose	
Section 3 - Scope	
Section 4 - Designated Ethics Committees (DEC)	
Section 5 – Participating Centre Ethics Committees (PECs)	
Section 6 – Coordinating Principal Investigator	
Section 7 – Principal Investigator	
Section 8 – Letter of Agreement/ Letter of Understanding	
Section 9 – Timelines for Review	

<b>Section 10 – Protocol Amendment</b>	
<b>Section 11 – Reporting of SAEs, AEs, Deviations, Suspension, Termination, etc.</b>	
<b>Section 12 – Record Keeping and Archiving</b>	
<b>Glossary</b>	
<b>Annexure 1 – Flow Chart for submission Process</b>	
<b>Annexure 2 – Flow Chart for Common Review Process</b>	
<b>Annexure 3 – Template for Letters (Loa/LoU)</b>	
<b>Annexure 4 – Suggested Governance Mechanism</b>	
<b>Annexure 5 – SOP and Application Form for Multicentre Research</b>	
<b>Any Other Specific Comments/ Suggestions</b>	