**Tables:**

**Table.1 Evolution of title and pages of the ICMR guidelines from 1980 to 2017.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Title of guidelines** | | | |
| **1980** | **2000** | **2006** | **2017** |
| “Policy statement on ethical considerations involved in research on human subjects” | “Ethical Guidelines for Biomedical Research on Human Subjects” | “Ethical Guidelines for Biomedical Research on Human Participants” | “National Ethical Guidelines for biomedical and health research involving human participants”  “National Guidelines for Stem Cell Research”  “National ethical guidelines for Biomedical Research involving children” |
|  | The word Policy statement was changed as Guidelines | The word Human subjects was changed as Participants | Separate guidelines were issued for Stem cell research and Biomedical research involving children |
| **Pages of the guidelines**: | | | |
| **1980** | **2000** | **2006** | **2017** |
| **9 pages** | **77 pages** | **120 pages** | National Ethical Guidelines for biomedical and health research involving human participants – **187 pages.**  “National Guidelines for Stem Cell Research” – **84 pages**  “National ethical guidelines for Biomedical Research involving children” – **42 pages** |

**Table.2. Evolution of changes in the guidelines for Ethical review procedures in ICMR guidelines from 1980 to 2017**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1980** | | **2000** | | **2006** | **2017** |
| **Institutional Ethics committee or Ethical review procedures** | | | | | |
| * The need for an independent institutional ethics committee was recognized | * Insisted the need for institutional ethics committee in every institute involved in research. * Elaborated details of composition, quorum requirements, terms of reference, review procedures, submission of application, decision making process, interim review. * Record keeping – all records should be maintained for 15 years after study completion | | * The registration of ethics committee approving clinical trials with authority (bill was proposed) * Training of the ethics committee members. * Review procedures were classified into exempt, expedited and full board review. * An addition of study title with signature of investigators was insisted with regard to submission of application to IEC * Administration and management – requirement of full time secretariat was elaborated. * Record keeping was changed as 3 years after study completion. | | The following new headings were added.   * Composition, affiliations, qualifications, member specific roles and responsibilities of an Ethics Committee. * Ethical issues related to reviewing a protocol * Types of decisions by Ethics Committee * Review of multicentric research * On site monitoring * Registration and accreditation of Ethics committees * Types of document were classified into administrative related documents and proposals-related documents. |
| **Chairperson of the ethics committee** | | | | | |
| Need for Chairperson was felt | | Chairperson was recognized as the most responsible person | | Concept of **Alternate Chairperson** was felt in the absentia of the Chairperson | Concept of **Vice Chairperson** was introduced |
| Chairperson can be from the institute | | Chairperson **preferably** from outside the institute | | Chairperson **should be** from outside the institute | Chairperson **should be** from outside the institute |
|  | |  | |  | Concept of **Alternate Member Secretory** was introduced |
| **Members of the ethics committee:** | | | | | |
| 5-7 members | | 5-7 members | | 8-12 members | 7-15 members |