**A Study to assess the Completeness of Informed Consent Documents for Biomedical Research on Human Participants submitted to the Institutional Ethics Committee of a Tertiary Care Hospital**

**Total number of boxes :** 2

**Total number of tables :** 4

**Total number of figures :** 1

**Box 1 : Checklist of the essential elements that are required to be mentioned in the Informed Consent Document**

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| --- |
| * Statement that the study is a research * Nature and purpose of the study * Expected duration of participation * Expected number of participants * Procedures to be followed in the study * Investigations, if any, to be performed * Foreseeable risks and discomforts adequately described * Benefits to participant, community or medical profession as may be applicable * Policy on compensation for trial related injury * Availability of medical treatment for trial related injuries or risk management * Disclosure of alternative procedures/treatments if available * Steps taken for ensuring confidentiality * No loss of benefits on withdrawal from the study * Benefit sharing in the event of commercialization * Contact details of Principal Investigator (containing the name, designation, department, affiliated institution, phone number and email ID) for asking more information related to the research or in case of injury * Contact details of Chairman of the IEC for appeal against violation of rights * Voluntary participation * If test for genetics and HIV is to be done, counseling for consent for testing must be given as per national guidelines * Storage period of biological sample and related data * Choice offered to participant regarding future use of sample, refusal for storage and receipt of its results |

**Box 2: Elements not mentioned in any of the Informed Consent Documents**

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| --- |
| * Contact details of Chairman of Ethics Committee (n=212) * Choice offered to participant regarding future use of sample, refusal for storage and receipt of its results (n=76) * Policy on compensation for trial related injury (n=28) * If test for genetics is to be done, counseling for consent for testing (n=2) |

n: indicates the number of Informed Consent Documents for which the essential element is applicable

**Table 1 : Baseline characteristics of the research proposals submitted to the Institutional Ethics Committee (N=212).**

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| --- | --- |
| **Characteristics** | **n (%)** |
| **Type of Principal Investigator** | |
| Postgraduates | 150 (70.8) |
| Faculties | 38 (17.9) |
| Undergraduates | 22 (10.4) |
| PhD scholars | 2 (0.9) |
| **Study design** | |
| Cross-sectional | 157 (74) |
| Interventional | 34 (16) |
| Mixed methods | 16 (7.5) |
| Cohort | 1 (0.5) |
| Case-control | 3 (1.5) |
| Qualitative | 1 (0.5) |

**Table 2 : Completeness of various elements of Informed Consent Documents (applicable for all studies) submitted to the Institutional Ethics Committee (N=212).**

|  |  |  |  |
| --- | --- | --- | --- |
| **Elements of Informed Consent Document** | **Clearly explained**  **n (%)** | **Vaguely explained**  **n (%)** | **Not mentioned**  **n (%)** |
| Statement that the study is a research | 2 (0.9) | 0 | 210 (99.1) |
| Nature and purpose of the study | 132 (62.3) | 80 (37.7) | 0 |
| Duration of participation | 67 (31.6) | 2 (0.9) | 143 (67.5) |
| Number of participants | 2 (0.9) | 1 (0.5) | 209 (98.6) |
| Procedures to be followed | 146 (68.9) | 66 (31.1) | 0 |
| Foreseeable risks and discomforts | 151 (71.2) | 47 (22.2) | 14 (6.6) |
| Benefits | 197 (92.9) | 2 (1) | 13 (6.1) |
| Steps taken for ensuring confidentiality | 210 (99.1) | 0 | 2 (0.9) |
| No loss of benefits on withdrawal from study | 186 (87.8) | 2 (0.9) | 24 (11.3) |
| Contact details of Principal Investigator | 211 (99.5) | 0 | 1 (0.5) |
| Voluntary participation | 209 (98.6) | 3 (1.4) | 0 |

**Table 3 : Completeness of additional elements of Informed Consent Documents (applicable for selected studies) submitted to the Institutional Ethics Committee.**

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| --- | --- | --- | --- |
| **Elements of Informed Consent Document** | **Clearly explained**  **n (%)** | **Vaguely explained**  **n (%)** | **Not mentioned**  **n (%)** |
| Investigations, if any (N=136) | 62 (45.6) | 69 (50.7) | 5 (3.7) |
| Availability of medical treatment for trial related injuries or risk management (N=28) | 6 (21.4) | 2 (7.2) | 20 (71.4) |
| Disclosure of alternative treatments if available (N=28) | 17 (60.7) | 2 (7.1) | 9 (32.2) |
| Storage period of biological sample and related data (N=76) | 1 (1.3) | 0 | 75 (98.7) |

**Table 4 : Analysis of other aspects of Informed Consent Documents submitted to the Institutional Ethics Committee. (N=212)**

|  |  |
| --- | --- |
| **Aspects of Informed Consent Documents** | **n (%)** |
| Provided space for date, signature of investigator and witness in PIS | 201 (94.8%) |
| Provided space for signature of participant in ICF | 212 (100%) |
| Provided space for date and signature of the witness in ICF | 205 (96.6%) |
| Presence of medical jargons in PIS | 120 (56.6%) |
| Presence of grammatical/spelling/typographical errors in ICDs | 29 (13.7%) |

PIS-Patient information sheet, ICF- Informed consent form, ICD-Informed consent document

