

## **Guidelines for filling the Ethics Synopsis Format**

1. **Basic Data** should be filled accurately.
2. **Background information** -. Background information should include summaries of important, relevant research studies and therefore the need for research.
3. **Aim and Objectives** - Aim and Objectives should determine the scope, depth and overall direction of the research. There should be one aim and approximately 4-5 objectives.
4. **Study Design** - Study design should include materials used and methodology in detail, with appropriate inclusion and exclusion criteria and sample size with justification (Attach letter from Statistician). If a comparative study is done samples should be age matched.
5. **Assessment of efficacy** – Specification of the efficacy parameters, methods, timings/duration for assessing, recording and analyzing of efficacy parameters.
6. **Specifications of safety parameters** for the participants as well as the researchers to be mentioned in synopsis.
7. **Risks and Benefits** of the study to be mentioned in detail.
8. **Safety and other controls**- At all times the study participants and researchers should be safe. List the risks and safety measures taken for the same.
9. **Consent**- Written informed consent should be obtained from the study participants prior to beginning of the study.  
For In-Vitro studies please attach **Waiver of Consent**.
10. Explain the method of maintaining **confidentiality** of the participant.

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**Kindly note-**

1. Read the Undertaking by the Investigator **carefully**.
2. It is necessary to **submit the Informed written consent and the Subject Information Sheet** in all the **three languages**. (English, Marathi, Hindi)
3. After getting approval from Institutional Research Committee, submit synopsis in Ethics format within 10days.
4. Researcher should submit **08 hard copies (to the Office with a covering letter) and one soft copy in single PDF format ( by email: [iec.bvdudchpune@gmail.com](mailto:iec.bvdudchpune@gmail.com)) of the synopsis** to the Institutional Ethics committee on the said date and bring **14 copies of the Format of the Reviewer's comments** duly filled in detail, on the day of Ethics meeting.
5. During the meeting the Researcher should give a **brief power-point presentation** about the study with emphasis on the Ethics considerations pertaining to it.
6. The format of the consent form will be given to you of which Part A is common for all and Part B is subject specific, **Needs to be checked by the Post Graduate Guide thoroughly**.
7. The Investigators must **submit a periodic six monthly progress report of the study and a final report at the end of the study**.
8. **Email Id of Ethics Committee: [iec.bvdudchpune@gmail.com](mailto:iec.bvdudchpune@gmail.com)**

*Spwaelgaonkar*

**Dr. Shubhangi Wadgaonkar**  
**Member Secretary,**  
**Institutional Ethics Committee**