

## Maratha Vidya Prasarak Samaj's Dr. Vasantrao Pawar Medical College, Hospital & Research Centre



Vasantdada nagar, Adgaon, Nashik, Maharashtra - 422 003

## (Annexure 1) Application Form for Expedited Review

(C Ref. No. \*(for office use):

	Title of study:			
	Principal Investigator (Name, Designation and Affiliation):			
1	<ol> <li>Choose reasons why expedited review from EC is requested<sup>12</sup>?</li> <li>i. Involve non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples</li> <li>ii. Involve clinical documentation materials that are non-identifiable (data, documents, records).</li> <li>iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s))</li> </ol>			f 🔲
	iv. Revised proposals previously approved through expedited review, full review or continuing review of approved proposals			
	<ul><li>v. Minor deviations from originally approved research causing no risk or minimal risk</li><li>vi. Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee.</li></ul>			
	<ul> <li>vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modification in the study proposal through full committee meeting/ expedited review depending on the importance of local consent related issues involved specific to the centre.</li> <li>viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017).</li> </ul>			ı —
	ix. Any other (please specify):			
2	. Is waiver of consent being requested ?		Yes	No 🗖
3. Does the research involve vulnerable person <sup>13</sup> ? Yes No If Yes give details:			No 🖵	
	Signature of PI:	Date:		
	Comments of EC Secretariat:			
	Signature of Member Secretary:	Date:		

<sup>&</sup>lt;sup>12</sup>Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2

<sup>&</sup>lt;sup>13</sup>For details, refer to application for initial review, Section-C, 5(b)

<sup>\*</sup>In case this is first submission, leave it blank