



## CM-REC

### Documents required for the submission of a study application to the Taibah University, College of Medicine Research Ethics Committee

	<b><u>Items Required</u></b>
1.	Application form “form 2”
2.	Study Protocol *
3.	Authorship form “form 3”
4.	Informed Consent Form (ICF).
5.	Case report form (CRF). <i>(If applicable)</i>
6.	Questionnaire/ Patient diary etc. <i>(If applicable)</i>
7.	Any materials to be used by the study Subjects (Video tapes, educational materials, brochures etc...).
8.	Any advertisement material to be used for recruiting subjects.
9.	An updated, signed and dated CV of the Principal Investigator and Co-Principal Investigator/s.
10	Proof of passing a valid research ethics course
11.	In case of Multinational Multicenter studies: <ul style="list-style-type: none"><li>• List of participating Centers inside or outside Saudi Arabia</li><li>• Previous Approval letters obtained from any other REC/IRB inside Saudi Arabia</li></ul>
12	Safety reports <i>(If applicable)</i>
13.	Investigational Brochure (IB). <i>(If applicable)</i>

#### **\*Protocol of the study must include the following:**

- An abstract of the research within one page
- Introduction or background and Rationale
- Aim and Objectives
- Type of the study
- Sample size with clear and scientific way of calculation included
- Subjects (patients) & Methods
- Statistical analysis plan
- Ethical consideration
- Sponsors
- References