
	<b>Guideline</b>  <b>CHECKLIST FOR CLINICAL STUDIES</b>	REF NO.	: GD-FMHS-PGA-006
		REVISION NO.	: 01
<b>Universiti Tunku Abdul Rahman</b>		EFFECTIVE DATE	: 14/04/2021
		PAGE	: 1 of 4

### A. At the time of registering with UTAR as a graduate student


		Place a ✓ where relevant, if already complied/done/available	Date of Completion
Candidate	Fulfill UTAR admission requirements or its equivalent		
	Possess APC/practising certificate		
	Possess relevant GCP certification		
	Full cv		
	Final transcript of highest qualification		
	English proficiency <ul style="list-style-type: none"> <li>○ Oral</li> <li>○ Written</li> <li>○ Formal highest English qualification (State test taken and level of achievement)</li> </ul>		
Main supervisor (to be from UTAR)	Familiar with the disease/condition under study and has required expertise  GCP certified  *For interventional studies, the main or co-supervisor must be medically qualified		
Co-supervisor (UTAR)	Expertise in an area relevant to the research topic, GCP certified		
Co-supervisor (non-UTAR institution)	Medically qualified local co-supervisor, GCP certified		
On-site supervisors	GCP certified  *For interventional studies, the on-site supervisor must be medically qualified		
	Ethics approval has been obtained from recognised relevant authority of the study institution and UTAR.		

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		PAGE	: 2 of 4

Administrative/legal obligations	MOA: already signed with the institution of the candidate		
	Note: Unless it is not applicable in certain cases		
	Consider legal liability (both for UTAR and the institution of the clinical study)		
	<p>i. Insurance coverage for researchers (usual practice now for clinical trials); if the regulatory authority or ethics committee of the site of clinical study requires the institution/hospital where the candidate works to indemnify the investigator against claims arising from the trial.</p> <p>ii. Conform to the relevant regulatory authorities in the site of clinical study for drug trials/other forms of clinical trials</p>		
Facilities in site of clinical study	Laboratory: capacity and accredited for relevant biomarkers in monitoring progress of therapy		
	Hospital: accredited for conducting clinical trials		
	Availability of clinical trial monitors (or qualified site supervisors)		

## B. Post-registration at UTAR

		Place a ✓ where relevant, if already complied/done/available	Date of Completion
To develop clinical trial protocol (in addition to a proposal)	This to be developed after registration, with the supervisors		
Monitoring mechanisms	Submit safety reporting of the clinical study when it is required		

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<b>Universiti Tunku Abdul Rahman</b>		<b>EFFECTIVE DATE</b> : 14/04/2021
		<b>PAGE</b> : 3 of 4

### C. Acknowledgement by Main Supervisor

I \_\_\_\_\_(main supervisor) have read and understood the requirements of conducting clinical studies as set out in item A and B.

\_\_\_\_\_

Name:

Date:

### Important note:

After the checklist is signed by the supervisor, the signed document must be submitted to the FRDPC. A copy of the signed document should also be kept by the supervisor as a record.