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**Cairo University**

**Faculty of Medicine**

**Research Ethics Committee**

**Guide to preparation of research protocol submission for IRB approval**

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| **Document** | **Note** |
| **Protocol** | * All protocol sections must be completed
* Primary and secondary outcome parameters should be measurable and not overstated.
* Clearly mention eligibility criteria including gender and age range
* Clearly mention source of patients or samples.
* Sampling technique and sample size calculation are necessary
* Statistical analysis plan must be correctly stated and relevant to research objectives
* Describe how privacy and confidentiality of data will be maintained
* References must be correctly prepared and in a consistent reference style
* المدرس و الاستاذ المساعد لا يلقب "استاذ دكتور"
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| **Consent form** | * Guiding template is available
* Arabic title of the protocol must be stated in the consent form.
* Eight essential items mentioned in the consent guide must be clearly written to study participants in full details specially the procedure, risks and anticipated benefits
* Any human subject research that involves intervention or interaction with a human subject or prospective collection of data related to humans require a consent form.
* For research participants below 18 years: parental consent is needed, so consent document should be directed to parents and a field for parent or legally authorized representative signature will be required.
* Oral consent means no signature is needed “so the signature section is to be removed”. This is applicable in case the signature will bear the only identifier for data that will be collected anonymously. Example is a study involves data collection through a self-administered questionnaire.
* A waiver of consent could only be granted if the study entails retrospective data collection from hospital records that will be collected anonymously.
* For research participants (6-18 years): An assent is also required in addition to parental consent. This is a document directed to the child himself/herself and written in a more simple illustrative way.
* In case of patient lacking decision, making capacity (e.g. disturbed conscious level, or mental disability), Surrogate consent applies. That is a consent signed by patient surrogate or legally authorized representative.
* For clinical trials, a contact place accessible 24 hours in case of emergency must be stated. E.g. is Kasr Alainy emergency department.
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| **Data collection sheet** | * Questionnaire or -patient sheet or Case report form
* This depends on the study design, objectives, and outcome parameters.
* A unique identification number should be put instead of patient name.
* All variables to be collected should be clearly presented with units of measurements/ clear categories mentioned if applicable.
* Study tool should serve to achieve study objectives.
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| **Electronic Copy** | * Email should be sent to pg@kasralainy.edu.eg and a Carbon Copy (CC) torecsubcommittee@kasralainy.edu.eg
* Title of the email is the PG-REC code given to you by PG administration
* Email attachment must include all updated completed application documents
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