POEM
Pediatric Oncology
East & Mediterranean

IRB Application Guidelines

The following is a brief outline mentioning the main points that are included in the IRB application, extracted from the American University of Beirut IRB Application to Conduct Research on Human Subjects (For proposals submitted for expedited or full committee review only). However, please make sure to follow your institution's IRB guidelines.

Title of proposal:

A. Principal Investigator Information: Full name, degree, title, and contact information

B. Study Coordinator Information: Full name, degree, title, and contact information

C. Key Study Personnel – include all people responsible for the design and conduct of the study (if collaborators at other institutions go to "D"): Name, Department/Affiliation, Role in Study, and if CITI course completed

D. Collaborators and IRB involvement at other institutions: Name, Department/Affiliation, Role in Study, and if IRB approved
Provide information on how samples, information and data among the various collaborators will be handled. Provide copies of IRB reviews, approvals and consent forms.

E. Funding: If the research is funded or not, proposed annual budget, source of funding/sponsor name, starting date of study, expected date of study completion and site where the study will be conducted.

F. Requested review: Expedited or Full Committee

H. Specify the categories that applies to the study: Placebo controlled trial, randomized study, blinded study (describe), investigational drug or device (non-approval for use)

I. Provide an abstract of the study not exceeding 500 words written in language understood by LAY PEOPLE. This abstract which is different from that provided in the scientific proposal should include:

1. Scientific context
2 Hypothesis/aims
3. Experimental design, subject selection/recruitment, procedures involving human subjects
4. Justify involvement of human subjects
5. Describe risks and benefits, and risk/benefit ratio
6. Discuss privacy and confidentiality issues

J. Informed Consent: Specify all languages to be used for the informed consent form, describe the setting in which an informed consent will be obtained, provide the names of those who will obtain informed consent

from the subjects, specify if the person obtaining consent have any relationship with the patient and if yes, describe the relationship and indicate ways of protecting against undue influence or coercion.
In addition, justify the need for waiver or non-disclosure in case you will request a waiver of written informed consent or omission of any requirements, and provide the IRB with the script that will be used and describe means to document oral consent.

K. Subject Selection and Recruitment: List the number of subjects to be recruited, identification and recruitment of subjects: describe the procedure, the location/setting and the time frame. Indicate if there is a use advertisement to solicit participants and provide a copy of the advertisement.
In addition, describe the subject population, specify the vulnerable groups describing why it is necessary to include these groups in the study (if any), include criteria for inclusion/exclusion of potential subjects and justify the exclusion of any group based on age, sex, ethnicity, and social or economic factors.

L. Specimen Collection

M. Risks: Describe the potential risks associated with the study, the frequency and magnitude of the risks. Describe the tools to be utilized in collection and storage of data, describe your plan for data safety monitoring and for reporting adverse effects to the IRB.

N. Benefits: Describe the anticipated benefits to the subject, if no direct benefits are expected – state so and include in the consent form. Describe any anticipated benefits to the group or class to which the subjects belong and benefits to society or to science/medicine as a whole.

O. Risk/Benefit Ratio: Assess the relative weights of the study's risks and benefits. Where appropriate, discuss provisions for ensuring medical or professional intervention in the event of adverse effects to the subject.

P. Compensation or Costs to Subjects

Q. Personal/Financial Interest: Disclose any personal or financial interests in the research and the extent of such interest in the sponsor of the study if applicable.

R. Bibliography and References: List up to five relevant publications that, in your opinion, would be helpful to the IRB in reviewing this study.

For the full application please visit the below link,
https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx and click on Biomedical Applications Forms - "Application to Conduct Research on Human Subjects (Expedited and Full Committee Review)".