

RESEARCH ETHICS COMMITTEE

List of Synopsis with observations

May 7, 2013

S#	Research Topic	Name of Researcher	Course	Supervisor	Status /remarks
1.	Surgical management of liver trauma at liaquat university of medical and health sciences jamshoro/Hyderabad	Dr. Khenpal Das	MS Gen Surg	Prof. A Razzak sheikh	The Research Ethics Committee has reviewed your Synopsis. The Committee suggests that the consent form needs major changes before your synopsis can be approved. You are advised to make the necessary changes before resubmitting your synopsis. For your convenience, a sample of proper consent form is available on the homepage of the Research Ethics Committee.
2.	The outcome of day case surgery and its acceptance at Liaquat University Hospital	Dr. Saba Gul	MS Gen Surg	Prof. Abdul Razaque Shaikh	Please specify the surgical procedures that will be included in your study.
3.	Biological characterization of colorectal cancers and correlation with the gender and age groups	Dr. Mashal Saeed Siddiqui	MS Gen Surg	Dr. Ahmed Khan Sangrasi	After reviewing your synopsis, the Research Ethics Committee finds it inappropriate for approval. You are directed to rectify/explain the following observation(s) and resubmit your synopsis. <ul style="list-style-type: none"> • The objective and rationale of the study are vague and do not match with the title of the study. Please rephrase these in clear terms. • Tumour markers are not part of “Biological Characteristics” of cancer; their assessment appears to be beyond the scope of this study • The cost of the tumour markers is very high. Please specify who will bear the cost of these tests.
4.	Diaphyseal femoral fractures in children treated conservative by spica cast versus rush nail fixation	Dr. Muhammad Ali Soomro	MS Ortho	Dr. Zulfiqar Ali Mastoi	Please be notified that the Committee finds your proposal inappropriate for review due the following shortcomings; <ul style="list-style-type: none"> • The consent form is not attached. • The criteriae for dividing participants into two groups are not explained. • The REC form; <ul style="list-style-type: none"> – Is hand written (must be typed) – Is incompletely filled – Does not highlight any ethical issues despite the fact that this is a comparative study involving vulnerable population (children 5-10 years)
5.	Surgical treatment of congenital talipes equinovarus (CTEV) presenting between the age of 2-4 years	Dr. Zulfiqar Ali Zaur	MS Ortho	Dr. Gulzar Saeed	After reviewing your synopsis, the Research Ethics Committee finds it inappropriate for approval due to the following shortcomings; <p style="text-align: center;">The consent form submitted;</p> <ol style="list-style-type: none"> 1. Is not written in simple language; it should be rewritten without using medical jargon 2. Does not explain the nature/procedure of the study and its likely impact on participants 3. Does not explain what the participants should reasonably expect to anticipate in the

					<p>research</p> <ol style="list-style-type: none"> 4. Does not specify clearly how the PI will ensure confidentiality of participants 5. Does not outline the benefits accrued by the participants
6.	Outcome of humeral shaft fracture treated by compression plate fixation	Dr. Shakeel Soomro	MS Orthopaedics	Dr. Gulzar Saeed	<p>After reviewing your synopsis, the Research Ethics Committee finds it inappropriate for approval due to the following shortcomings;</p> <p>The Consent form;</p> <ol style="list-style-type: none"> 1. Is not written in simple language; uses lot of medical jargon 2. Does not explain the nature/procedure of the study and its likely impact on participants 3. Does not explain what the participants should reasonably expect to anticipate in the research 4. Does not specify how PI will ensure confidentiality of the participants 5. Does not outline the benefits that will accrue to the participants
7.	Gustilo III A & III B open diaphyseal fracture of tibia treated by NA external fixator as definitive treatment	Dr. Rizwan Ali Jhatial	MS Orthopaedics	Dr. Gulzar Saeed	<p>After reviewing your synopsis, the Research Ethics Committee finds it inappropriate for approval due to the following shortcomings;</p> <p>The Consent form;</p> <ol style="list-style-type: none"> 1. Is not written in simple language; uses lot of medical jargon 2. Does not explain the nature/procedure of the study and its likely impact on participants 3. Does not explain what the participants should reasonably expect to anticipate in the research 4. Does not specify clearly how the PI will ensure confidentiality of the participants 5. Does not outline the benefits that will accrue to the participants. The statement that the "PI will be able to decide the benefit of the proposed treatment ONLY at the END OF THE STUDY" appears irrational 6. The side-effects of the surgical procedure have not been explained
8.	What is best for pediatric bladder stones?	Dr. Muhammad Sharif Alias Humayun	MS Urology	Dr. Shafique-ur-Rehman	<p>After reviewing your synopsis, the Research Ethics Committee finds it inappropriate for approval due to the following reason(s);</p> <ul style="list-style-type: none"> • The title is not properly phrased. It should be re-written keeping in view the objective and rationale of the study.
9.	Effects of chewing tobacco on coronary vessels of humans and animals	Dr. Shagufta Shaheen Qureshi	M.Phil Anatomy	Dr. Samreen Memon	Sent to reviewer
10.	Teratogenic effects of use of carbaryl (A pesticides) on lumbosacral junction in offspring of swiss albino MICE	Dr. Asadullah Yousfani Qalli	M.Phil Anatomy	Dr. Samreen Memon	Sent to reviewer

11.	To compare the efficacy and safety of glycopyrrolate and atropine in organophosphate poisoning	Dr. Aisha Khalid	MD Forensic Medicine	Prof. Afzal Memon	<p>The Research Ethics Committee has reviewed your research proposal. You are advised to resubmit your synopsis after providing following document(s) and/or making corrections.</p> <ul style="list-style-type: none"> • Permission letter from the in charge ICU. • Consent form should address the attendant of the patient, in view of the moribund state of the participants. • Identify the source of funding for the cost of medicines.
12.	Variability of optic disc damage in primary open angle	Dr. Naheed Abrejo	MS Ophthalmology	Prof. K. Iqbal Talpur	<p>The Research Ethics Committee has reviewed your Consent Form. The Committee is of the opinion that the consent form still needs few major changes before your synopsis can be approved. You are advised to make the necessary changes as identified below. For your convenience, a sample of proper consent form is available on the homepage of the Research Ethics Committee.</p> <ul style="list-style-type: none"> • The medical terms such as glaucoma either be replaced or explained in laymen's terms. • Proper methodology explaining the participants what they should reasonably expect during the study be described without using medical jargon. • If the study only involves review of the medical records of the patients, there seems no need for taking consent from the patients. • Explain to the patient the parameters for identifying the damage to optic nerve • The consent form has used the terms "optic nerve" and "optic disc" interchangeably.
13.	prevalence and risk factors of obesity among secondary school girls of Hyderabad	Dr. Samar Anwar Memon	MPH	Dr. khalil Kazi	<p>The Research Ethics Committee has reviewed your research proposal. You are advised to resubmit your synopsis after making the corrections advised as follows;</p> <ul style="list-style-type: none"> • The study involves minors (<16 years); the consent form, therefore, should to be addressed to the parents/guardians instead of the participants. • The informed consent uses phrases such as "your physical appearance suggest thatto assess the causes of obesity and overweight"; this tantamount to causing psychological stigma to young girls. It is suggested that it may be rephrased without hinting at physical appearance of the participants. • The informed consent should not use medical terms like BMI. • The methodology does not explain in simple terms what the participants should reasonably anticipate during the study. • Permission letter from the Principal(s) of schools where this study will be conducted, shall be provided.