Successful IRB Submission

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Mar 2021

Learning Objectives

At the end of this session, you will be able to:

- ✓**Identify** what is IRB
- ✓**Understand** the structure of IRB
- ✓**Complete** KSU IRB forms

What is IRB?

- An Institutional Review Board (IRB) is an independent body established to protect the rights and welfare of human research participants.

- Also known;
  - An independent ethics committee
  - Ethical review board

What is IRB?

- It is a committee that has been formally designated to approve, monitor and review the ethicality of biomedical and behavioral research, in protecting the rights of participants in a research project.

What is IRB?

- Any clinical investigation must be reviewed and approved by an IRB

- No clinical study may begin enrolling participants until it has received IRB approval

Principles

- Respect for Persons
- Beneficence
- Justice

Principles
Respect for Persons

- The principle of respect requires that subjects participating in the research should be fully aware of the nature of such research and assured that such participation is voluntary, with no pressure or coercion.
- They should also be aware of the physical, psychological, and socio-economic risks that such participation might bring to the subject immediately or in the future.
- This requirement is essential, even if the risks were described as minimal or insubstantial.

Principles
Beneficence

- Beneficence requires researchers to maximize the potential benefits to the subjects and minimize the potential risks.

Principles
Justice

- The principle of justice requires an equitable and fair selection of subjects and a fair and equitable distribution of risks and benefits of research.

Main Purpose of IRB

The purpose of an IRB is to safeguard the rights, safety, and well–being of all human research participants.

HOW??

Main Purpose of IRB

- Reviewing the full study plan for a research study to ensure that the research meets pre-defined criteria.
- Confirming that the research plans do not expose participants to unreasonable risks
- Reviewing and approving proposed payments or other compensation to study participants.
- Ensuring that human participant protections remain in force throughout the research by conducting continuing review of approved research. This continuing review is conducted at intervals appropriate to the degree of risk posed by each study, but not less frequently than once a year.

Main Purpose of IRB

- Considering adverse events, interim findings, and any recent literature that may be relevant to the research
- Assessing suspected protocol violations, complaints expressed by research participants, or violations of institutional policies
- Reviewing proposed changes to previously approved studies

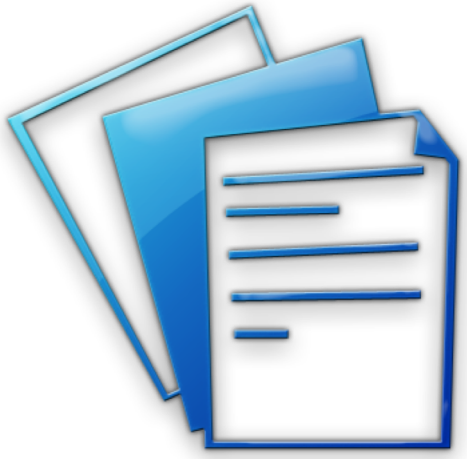
The IRB has the authority to:

- Approve, disapprove, or terminate all research activities
- Require modifications in protocols, including protocols of previously approved research.
- Require that participants be given any additional information that will assist them in making an informed decision to take part in research.
- Require documentation of informed consent or allow a waiver of documentation.

IRB structure

- IRBs are formed by
  - academic, research, and other institutions,
- They include at least five members of different professions
- Having enough expertise to make an informed decision on whether the research is ethical, informed consent is sufficient, and appropriate safeguards have been put in place

KSU IRB Forms



KSU IRB Meeting Schedule (2020 - 2021)

Meeting No.	Gregorian		Hijra		Submission Deadline (by 12:00 pm)
	Month/ Year	Date	Month/ Year	Date	
1	October 2020	01	Safar 1442	14	Sept. 03, 2020
2	October 2020	29	Rabi-I 1442	12	Oct. 08, 2020
3	November 2020	26	Rabi-II 1442	11	Nov. 05, 2020
4	December 2020	24	Jumaada-I 1442	09	Dec. 03, 2020
5	January 2021	28	Jumaada-II 1442	15	Jan. 07, 2021
6	February 2021	25	Rajab 1442	13	Feb. 04, 2021
7	March 2021	25	Shaaban 1442	12	March 04, 2021
8	May 2021	27	Shawwal 1442	15	May 06, 2021
9	June 2021	24	Dhul'qadah	14	June 03, 2021

Contact Details

For submission and inquiries, please email the following IRB Staff:

- IRB Application – Dr. Taha Inam – dr_taha_inam@hotmail.com (469-1530)
- IRB Application – Ms. Rubie de Ocampo – rdeocampo@ksu.edu.sa (469-1531)
- Renewal & Progress report – Ms. Ofela Lebanto – olebanto@ksu.edu.sa (469-1529)
- For approval letter before pandemic – Ms. Jawaher Alsuwelih – jsuwelih@ksu.edu.sa

Contact Details

Required Documents for IRB Application:

Non-Interventional Studies:	**Interventional/Clinical Trials:**
KSU-IRB Form-019 Signed Application Checklist Signed Conflict of Interest Form Certificate of Confidentiality CV of the PI/Inv. in KSU-IRB Template Informed Consent (for surveys and questionnaire-based studies) Copyright or permission to use the study tool (if necessary) Study Tool (data collection sheet, survey form, questionnaire sheet) Certificate from Bioethics (mandated by KACST)	KSU- IRB 001 Application Checklist KSU IRB 002_003 Research Proposal Form KSU-IRB 004 Informed Consent Checklist KSU-IRB 005 Informed Consent for Clinical Trial (Arabic and English versions) Curriculum Vitae of the PI/Investigators in KSU-IRB Template Certificate from Bioethics (mandated by KACST) GCP Certificate *sponsored trials need to be submitted thru CTU

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King Saud University
Institutional Review Board (IRB)

Checklists for Submission of a Research Protocol for Review

Research Project Title:

Primary Investigator: _____

FULL PROTOCOL REVIEW CHECKLIST

- ❑ The submitted proposal should be detailed as per IRB requirements.
- ❑ All co-investigators should sign the proposal (investigator's page) and make sure that their names and titles are correct.
- ❑ Informed Consent Form (in accordance with the enclosed Sample Consent Form).
- ❑ Signed and dated IRB Declaration of Conflict of Interest (enclosed)
- ❑ Signed and dated IRB Certificate of Confidentiality
- ❑ Signed and dated CV of Principal Investigator (PI) in IRB CV Template
- ❑ For retrospective studies, *or* department other than the Investigator, approval from the involved Unit. (Approval by the chairman of the department).
- ❑ Provide a brief description of the role of each investigator.
- ❑ Data Sheet/Questionnaire/Study tools developed by Investigator. If from other author, copyrights/permission to use *or* confirm 'open access for research & academic purpose).
- ❑ For Master student project: Letter from supervisor/institute as evidence of project
- ❑ Certificate of Bio-Ethics of each study member *completed free online* through

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المملكة العربية السعودية
جامعة الملك سعود
كلية الطب
مجلس أخلاقيات البحوث الطبية

نموذج طلب موافقة مجلس أخلاقيات البحوث الطبية

رقم البحث:

عنوان البحث :
الباحث الرئيس والقسم الذي ينتمي إليه :
الباحثون المشاركون والأقسام التي ينتمون إليها :
مدة البحث : شهراً الميزانية المقترحة :

Summary: (150 – 200 words)

- **Research Title:** (عنوان البحث)

- **Research Problem:** (مشكلة البحث وأهميت)

- **Research Significance:** (أهمية البحث)

- **Research Objectives:** (أهداف البحث)

- **Research Methodology:** (منهجية البحث)
  - Study design; study setting; sample size; sampling technique; data collection methods (e.g. questionnaire; lab investigations; measurements; data analysis plan (including software; techniques, etc)

This is only one page, not more

توقيع الباحث الرئيس : التاريخ :

ملاحظة: لا يقبل أي ملخص ما لم يقدم مطبوعاً باللغة العربية و موقعاً من الباحث الرئيس.

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المملكة العربية السعودية
جامعة الملك سعود
كلية الطب
مجلس أخلاقيات البحوث الطبية

مقترح مشروع بحثي
Research Project Proposal

Please, type either in English فضلاً، تتم الطباعة إما باللغة العربية أو الإنجليزية *or Arabic*

أسماء الباحثين * *Investigators Names	الرتبة العلمية Academic Title	الكلية/القسم College/Department	التوقيع Signature
-1			
-2			
-3			
-4			
-5			
-6			
-7			
-8			
-9			

* الاسم الأول: الباحث الرئيس.
الاسم الثاني: الباحث المشارك الذي يرشحه الباحث الرئيس ليتولى القيام بالبحث في حال تغيب الباحث الرئيس أو تخليه عن البحث.

* *First name indicates the Principal Investigator (PI).*
Second name is the co-investigator designated by the PI to assume all responsibilities, in case of the absence of the PI.

NOTE:

Please provide contact details where we can contact you in case of incomplete/missing documents.

Office Tel. No. _____ Department Tel. No. _____

Mobile No. (optional) _____ Email: _____

مشكلة البحث و أهميته

Research Problem and Significance

[Type here]

- Background of the topic
- Rationale
- Significance
- Research question

أهداف البحث

Research Objectives

Overall and specific SMART* objectives, including person, place and time (all objectives)

* SMART:
Specific
Measurable
Achievable
Relevant
Time-bound

Hypotheses

Literature Review

Latest relevant literature (international, regional, national, local as available and appropriate) using suitable search engines and methods

This could be 2-3 pages maximum, with suitable referencing

منهجية البحث
Research Methodology

(Please tick box [ ] if there is standard deviation to this form).

Study Design: (تصميم الدراسة)
(quantitative [observational, experimental]; qualitative, mix, etc)

Study Duration (مدة الدراسة) **(When the study will be conducted and its duration)**

Study Setting: (إعداد الدراسة) (where will the study be carried out, including secondary data collection places)

Target Population/Sample Size: (السكان المستهدفين / حجم العينة) **(Mention about the target population and narrative of sample size estimation with all assumptions and by using standard equations or soft wares)**

Inclusion Criteria: (معايير الاشتمال) **(Inclusion criteria for the study subjects, if any)**

Exclusion Criteria: (معايير الاستبعاد) **(Exclusion criteria for the study subjects, if any).**

Study Variables: (متغيرات الدراسة)**(All study variables such as: Age, gender,….. and outcome variables of the study:……..)**

Ethical Considerations: (الاعتبارات الاخلاقية) consent form to be attached, choose from the following as applicable to study design / objectives) :

1. The informed consent will be clear and indicates the purpose of the study and the right of the participant to withdraw at any time without any obligation towards the study team.
2. Participants anonymity will be assured by assigning each participants with a code number for the purpose of analysis only.
3. No incentives or rewards will be given to participants. Snack / refreshments may be provided to establish a bond with participants, with no obligation to participate.

Data Collection/Data Source: (جمع البيانات / البيانات المصدر) (e.g. questionnaire [sections / variables mentioned, with copy attached]; biochemical measurements [with references of techniques / kits]; physical measurements [with description of method / reference, as applicable])

Questionnaires/data Sheets from other authors ***(Copyrights or permission to use, or open access for academic and research purpose)***

Statistical Analysis: (تحليل احصائي) Data will be analyzed using SPSS 24.0 version statistical software. Descriptive statistics (mean, standard deviation, frequencies and percentages) will be used to describe the quantitative and categorical variables. Bivariate statistical analysis will be carried out using appropriate (Chi-square, student's t test, one-way analysis of variance and Pearson's correlation) statistical tests, based on the type of study and outcome variables. A p-value of <0.05 and 95% CI will be used to report the statistical significance and precision of results.

المراجع
References

Using standard methods of citing references, e.g. Vancouver style (New England Journal of Medicine) as

دور المحققين	
Investigators Names	Brief Description of the Role of Each Investigator
	e.g. Review of literature, study design, data collection, Data management and analysis, progress report, data analysis, final report and manuscript writing (as applies to each investigator)

الخطة الزمنية للبحث
RESEARCH TIME SCHEDULE

starting Date : / / 142 H.

تاريخ بداية البحث: / / 142 هـ

Items البند	التوالي المخطط للأعمال الرئيسة Planned sequence of major tasks	First Year السنة الأولى												Second Year السنة الثانية											
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
	Literature Review																								
	Questionnaire Design																								
	Data collection																								
	Data management and analysis																								
	Final report writing																								
	Presentation and manuscript writing																								

King Saud University Medical City

Institutional Review Board (IRB

CONFLICT OF INTEREST

Project Title: _____

Principal Investigator: _____

The researcher(s) must declare any potential conflict of interest that could affect the outcome of the proposed research in any form like:

- Any financial or other ties of the investigator(s) or a member of his/her family to any party directly or indirectly involved in the field of study such as:
  1- Holding stocks or shares
  2- Receiving educational or other research grant
  3- Employment opportunity
  4- Any gifts of any kind
- Career development opportunity
- Speaking arrangements
- Publication opportunity
- Providing advisory and consultancy services
- Board memberships
- Personal considerations or relationships
- Promises of any of the above

☐ If there is any Conflict of Interest, please report:

_____

_____

☐ No Conflict of Interest to report.

Investigator Name & Signature **Date**

نموذج موافقة مسبقة للمشاركة في دراسة قائمة على الاستبيان
رمز النموذج أ -KSU-REC 006QS
جامعة الملك سعود، الرياض، المملكة العربية السعودية

عنوان مشروع البحث: (يرجى إدراج عنوان الدراسة بالكامل)

اسم الباحث الأساسي:

اسم و عنوان الجامعة:

رقم الاتصال:

أعزائي المشاركين،

أود أن انتهاز هذه الفرصة و سؤالك إذا كنت ترغب المشاركة في هذه الدراسة القائمة على الاستبيان. يرجى الإجابة على الأسئلة إلي حد معرفتك. جميع المعلومات المطلوبة في استبيان هذه الدراسة سوف يتم التعامل معها بكل سرية. و اذا كنت ترغب في المشاركة تطوعياً في هذه الدراسة، يرجى التوقيع على هذا النموذج و سوف تحصل على نسخة و تحفظ في السجلات الخاصة بك.

تم التوقيع بواسطة:

اسم الباحث بالكامل:	
اسم الدراسة:	
التوقيع:	
التاريخ (يوم/شهر/سنة):	

( ) انا أوافق على المشاركة في هذه الدراسة و على استخدام المعلومات لأغراض البحث العلمي.

( ) أوافق على السماح للباحثين بوضع صوت صوتي في المقابلة لأغراض البحث (إذا كان قابل للتطبيق)

( ) انا أوافق على السماح للباحثين بالوصول إلى سجلاتي الطبية الموجودة، سواء كانت إلكترونية أو ورقية لدراستهم، وجمع البيانات بأثر مستقبلي، واستخراجها من الممارسات والإجراءات الروتينية .

For REC use only:
Expedited [ ]
Proposal No. _____

INFORMED CONSENT FOR QUESTIONNAIRE-BASED STUDY
Form # KSU-REC 006QS-E
King Saud University, Riyadh, Kingdom of Saudi Arabia

Research Project Title: [*please type the complete title of the study*]
Name of Principal Investigator:
Name and address of Institution:
Contact no:

Dear Participants,

I would like to ask this opportunity if you are willing to take part of this questionnaire-based survey. Please answer the questions to the best of your knowledge. All information asked in this study questionnaire will be treated confidential. If you are willing to participate voluntarily in this study, please sign this form and will be given a copy for your own records.

Signed by:

Investigator's Complete Name:	
Study Designation:	
Signature:	
Date (dd/mmm/yyyy):	

[ ] I agree to participate in this study survey, and to utilize the information for scientific research purposes.

[ ] I agree to allow the researchers to audiotape my voice as in interview for research purpose, (if applicable).

Study Delegation Log
Form # KSU-IRB 0023 E

Delegation of Authority Log

Investigator's Name:	Protocol Title:	IRB Project No.

List staff to whom the Principal Investigator (PI) has delegated significant study-related duties.

Name	Responsibilities	Initials	Signature	Start Date	End Date	PI Initials/Date

By initialing above, I, the PI, declare that during the conduct of the above study, I have delegated the following study-related activities:

Responsibilities Legend		
1. Obtain Consent 2. Screen Subjects 3. Obtain Medical History 4. Perform Physical Exam 5. Determine Eligibility 6. Obtain study samples	7. Laboratory processing 8. Shipping of samples 9. Review Safety parameters 10. Randomize Subjects 11. Dispense Study Drug 12. Administer IMP 13. Administer IDP 14. Drug Accountability	16. Complete Source Documents 17. Complete Case Report Forms 18. Provide Discharge Instructions 19. Make Follow-up Phone Calls 20. Others, specify _____

	15. Assess Adverse Events	

Signature of Principal Investigator: _____ Date: _____

*For more information, please visit the website of Research Ethics Committee in King Saud University (*http://dsrs.ksu.edu.sa/ar/comm_Policies*)*

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Certificate of Confidentiality

This document certify that the Principal Investigator……..

With Study protocol titled

……...

……

Ensure the confidentiality of **research participant's data and biological material** obtained either prospectively or from existing record, under strict privacy and security throughout the study duration, publication and at any public presentation.

Principal Investigator will disclose the custodianship of the study material, with (first) and (second) or if applicable, (third) party, who shares the same, or a part, inside or outside the Kingdom of Saudi Arabia, as stated in the submitted protocol. Patient Information Sheet/Informed Consent Form, should have clear description of the information shared.

The privacy must ensure:

- Secured Access to data and bio samples of research subject
- Security on subject's data and bio samples
- Secured electronic data access with user password
- De-identification of research subjects personal information at publication or public presentation
- Compliance on 'duration' of archiving and storage location specified in protocol, agreed and signed

The signatory acknowledge that s/he have read and understood this agreement and agree to be bound by its terms.

Signed by:

Principal Investigator

Signature: ……

Name: …… Date:

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CURRICULUM VITAE

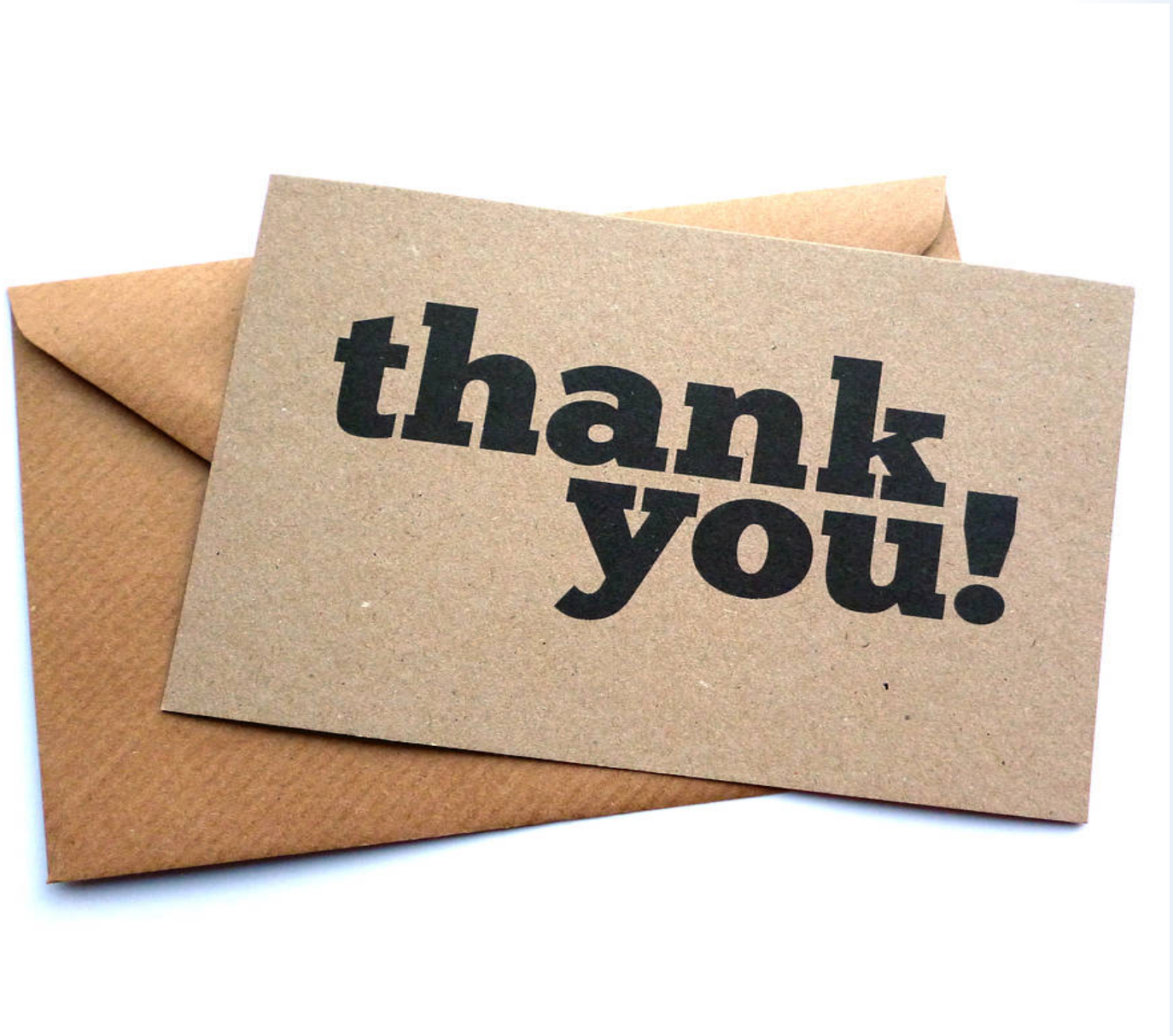
Name:		
Present appointment: (*Job title, department, and organization)*		
Address: (*Full work address)*		
Telephone number:	**KSU Email address:**	**Personal Email address:** *(optional)*
Qualifications:		
Professional Registration: *(Name of body, registration number and date of registration.)*		
Previous and other appointments: (*Include previous appointments in the **last 5 years** and other current appointments.)*		
Research Methodology Training Experience: *(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)*		
Research Ethical Training: *(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.)*		
Relevant Publications: *(Give references to all publications in the last two years plus other publications relevant to the current application.)*		
Signature:	**Date:**	

Tips for Successful Approval

- Complete all required forms.
- Complete all required information in each form.
- Make sure that all information is similar in all forms
- Provide a comprehensive literature review
- Clearly state the gap in the knowledge
- Clearly state the significance and implications of your research
- Provide detailed methodology

Tips for Successful Approval

- If multi-centres study, provide approval from other institutes.
- Provide the original proposal if applicable
- Submit it on time, avoid delay in submission
- Contact IRB office for any further clarification
  - Dr Taha Inam :tinam@ksu.edu.sa


thank
you!