Institutional Review Board (IRB) FORM
How to write?

Objectives:

NOT provided.

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Revised By: Maha AlGhamdi

Resources:

• 436 Lecture Slides + Notes

Important – Notes

436researchteam@gmail.com

Editing file

Title of the project

King Saud University	جامعة الملك سعود	For IRB use only:
Vice Rectorate for Graduate Studies & Scientific Research	وكالة الجامعة للدراسات العليا والبحث العلمي	Full Board [ ]
Deanship of Scientific Research	عمادة البحث العلمي	Expedited [ ]
Institutional Review Board	لجنة أخلاقيات البحث العلمي	Proposal No. _____

Research Proposal
Form # KSU-IRB 003E | **المقترح البحثي**

1. Basic Information | **1. البيانات الأساسية**

Title	عنوان المقترح البحثي
	باللغة العربية Arabic Title
	باللغة الإنجليزية English Title
Budget	الميزانية
Duration (months)	المدة بالشهر

Contacts — بيانات التواصل مع الباحث الرئيس

الهاتف	الجوال	البريد الإلكتروني

Principal Investigator — الباحث الرئيس

الاسم	الكلية	القسم	الرتبة العلمية	الرقم الوظيفي

Contacts of PI — بيانات التواصل مع الباحث الرئيس

الهاتف	الجوال	البريد الإلكتروني

توقيع الباحث الرئيس : _____ التاريخ: _____

IRB functions:

- Maintain high standards in the ethical conduct of research,
- Protection of human participants,
- Enabling faculty, staff and students for efficient research
- Review, approve, modify or disapprove research protocols
- Ensuring rules & regulations for Protection of Human Subjects
- Promotes awareness of rights & welfare of study participants,
- Advancing of knowledge, to facilitate highest quality of research.

IRB essentials:

- Clearly written research proposal submitted on specific institutional form in required structured manner
- Consent form answering necessary items including translated version
- Questionnaire and other tools including translated versions
- Justified itemized budget
- Time lines with tasks and responsible persons roles
- Any other item required (need to check with IRB Office)

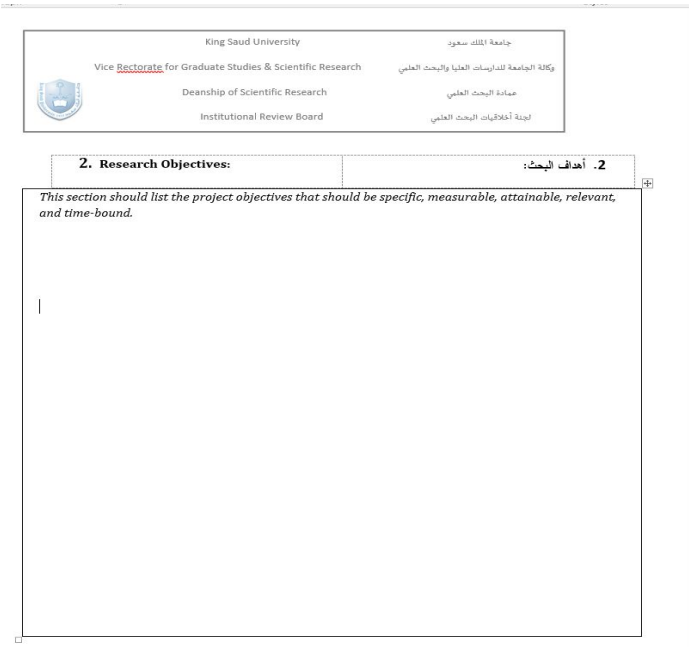
Content Layout – ksu IRB form

1. Summary
2. Rationale
3. Objectives, Hypothesis
4. Significance
5. Literature Review
6. Methodology: design, setting, population
7. Sampling & Sample Size
8. Data collection methods & tools
9. Pilot testing, prior experience
10. Plan of Analysis
11. Ethical considerations
12. References
13. Role of Investigators
14. Budget
15. Time lines

Hypotheses.

Research Question.

Objective.


King Saud University
جامعة الملك سعود
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2. Research Objectives: | 2. أهداف البحث:

This section should list the project objectives that should be specific, measurable, attainable, relevant, and time-bound.

Background \ Justification


3. Literature Review of the Research: | 3. أدبيات البحث:

436 TEAMS
436 Research Team

Methods

King Saud University — جامعة الملك سعود
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4. Research Methodology:	4. منهجية البحث:

Please fulfil the following points:

- *This section should include procedures and techniques to be used with explanation why these are considered the most suitable to the project questions; detailed description of the experiments and measurements; as well as methods to be used in data collection, analysis, and interpretation, i.e. statistical methodology (including sample size calculation, taking into account possibility of obtaining statistically significant results by using the minimum number of research subjects).*
- *Emphasis should be stressed on the following:*
  1. *Rationale for introducing any procedure, tool, or device that has not been used before.*
  2. *Rationale for using any substances that could be dangerous or harmful to the human subject or his surroundings and methods of disposal of said substances after research is completed.*
  3. *Plan for dealing with risky cases*
  4. *Plan for disposal of extra biological samples*
  5. *A summary of potential pitfalls and constraints that may be encountered and alternative plans that may be adopted in tracking such pitfalls and constraints.*
- *This section should, also, include a consent by applicants to the " Regulations of Research Bioethics on the Living Creatures ", when dealing with living creatures, parts of them, or their genetic materials.*
- *Research sample shall be determined according to the following consideration:*
  a. *Characteristics of sample from which the subjects will be selected*
  b. *Criteria for inclusion and exclusion of human subject*
  c. *Methods through which initial contact and selection are carried out*
  d. *Means of providing complete information to potential participants in the research or their representative*

Methods

- Study design.
- Setting \ Time period.

Study Subjects:

- Target population.
- Sample size.
- Sampling Technique.

Methods cont.

- Study variables.
- Outcome variables.
- Statistical analysis.

Ethics

- Approval from the ethics committee.
- Consent form.
- Ensure participants confidentiality.
- Declarations
- Acknowledgments
- Competing interests ,Financial or otherwise
- Availability of data and materials
- Author contribution
- Consent for publication

The Title

- A good title is defined as the fewest possible words that adequately describe the contents of the paper.
- The title is extremely important and must be chosen with great care as it will be read by thousands, whereas few will read the entire paper
- Indexing and abstracting of the paper depends on the accuracy of the title. An improperly titled paper will get lost and will never be read.
- Titles should neither be too short nor too long as to be meaningless
- Waste words (studies on, investigations on, a, an, the etc) should not be used.
- Syntax (word order) must be very carefully considered
- It should contain the keywords that reflect the contents of the paper.
- It should be meaningful and not general
- It should be concise, specific and informative
- It should capture the fundamental nature of the experiments and findings

Examples

Action of Antibiotics on Bacteria

1. Action: should be defined
2. Antibiotics: should be listed
3. Bacteria: should be listed

How to Prepare the Title

- Make a list of the most important keywords
- Think of a title that contains these words
- The title could state the conclusion of the paper
- The title NEVER contains abbreviations, chemical formulas, proprietary names or jargon
- Think, rethink of the title before submitting the paper
- Be very careful of the grammatical errors due to faulty word order
- Avoid the use of the word “using”

❖ Summary / abstract of proposal

- **Research Problem:** Microbial resistance & misuse of antibiotics in children
- **Research Significance**: Misuse can be reduced at population level
- **Research Objectives**: To determine the KAP of parents in (setting) …on misuse of antibiotics during (time period)
- **Research Methodology**:

✓ Study design; study setting; sample size; sampling technique; data collection methods (e.g. questionnaire; lab investigations; measurements; data analysis plan (including software; techniques, etc)

✓ Through this brief description (200 words in KSU IRB) capture the reader/reviewer's interest

❖ Research problem / Question

F	Feasible	Adequate # of subjects, Technical expertise, Affordable, & Manageable
I	Interesting	Getting the answer is important to investigator, peers & community
N	Novel	Confirms, refutes or extends previous findings
E	Ethical	Amenable to be approved by IRB
R	Relevant	To scientific knowledge, clinical & health policy, and for future research

Background & Rationale

What is known about the topic?

What is not known about it?

Why is this research important ?

State EVIDENCE
- Biological
- Epidemiological
- Experimental

Study will lead to;
Advancement in knowledge

Justify the target population

❖ IRB requires consistency in Literature review

1. What is known about topic backed by the recent/relevant literature ?
2. Chronology of knowledge development (funnel phenomenon; broad to specific)
3. Are there any gaps in knowledge of the subject?
4. Which openings for research other researchers have identified?
5. How does this study intends to bridge any identified gaps/
6. References appropriately cited

❖ Objectives and hypothesis

Objective: S-M-A-R-T

(Specific-Measurable-Achievable-Realistic-Time scaled)

To determine the relationship of dietary intake of saturated fats over past six weeks and intimal thickness of coronary artery in Saudi adults visiting PHC centers in central Riyadh in 2015

Hypothesis

It is hypothesized that > 20% of recommended saturated fat intake in Saudi adult population will be associated with 50% increased intimal thickness of coronary artery when compared to the normal intimal thickness measured by XYZ

❖ significance

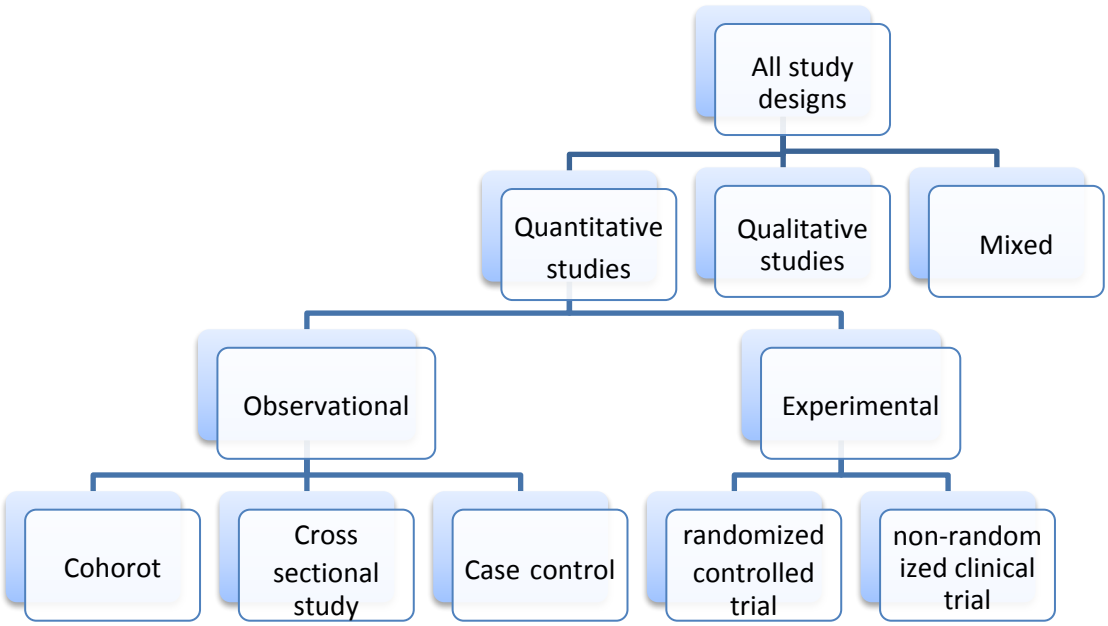
- What will be the effect or outcome of the expected results of this study ?
- A large population segment will be affected (improved health status)
- The expected results will help to design specific locally applicable health educational interventions for parents that could be advised at the time of prescription to reduce misuse of antibiotics
- Dietary interventions at population level to reduce saturated fat intake
- Further research, trials to reduce saturated fat intake and maintain intimal thickness, and prevention strategies.

❖ Methods: described in details

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is obtained when required
- Informed consent is appropriately documented
- Data and safety monitoring is adequate
- Privacy and confidentiality are protected
- Additional safeguards are in place for vulnerable populations

❖ design, setting, & Population

- Justify study design based on research question, whether observational or experimental, hospital / community based, & type of population
- Inclusion/Exclusion Criteria keeping ethical guidelines
- Procedures to determine eligibility and if any test will be needed
- Enrollment/Randomization procedures (if experimental)
- Study Procedures: Risks of Investigational Agents/Devices (side effects)
- Reporting of Adverse Events/Unanticipated risk to Participants or others
- Study Withdrawal/Discontinuation
- Statistical Considerations
- Privacy/Confidentiality Issues, Follow-up and Record Retention



❖ Sampling and sample size

- IRB requires a proposal which is scientifically sound and has statistical power
- A sampling scheme is to be described to address selection bias and unnecessarily including or excluding some vulnerable population
- Adequate power and number of participants to detect a meaningful/hypothesized difference

❖ Data collection methods and tools

- Referenced and validated questionnaire
- Appropriately worded, communicated
- Sensitive and Personal questions
- Study team collecting data is well trained in Ethics, communication skills, data collection procedures, and in obtaining any laboratory or other tests
- Length of questionnaire and tools (whether will be exhausting to patients/participants)
- Compliance and follow up procedures

❖ Plan of analysis

- Standard definitions defining exposures, outcomes, and other variables
- E.g. The primary endpoint is change in serum cholesterol levels at 30, 60, 90 and 120 days in experimental and control group.
- Types of variables
- Descriptive and inferential statistics
- Tests of significance
- Statistical considerations

❖ Ethical considerations

- Consent taking includes relevant information
- Training for consent taking process
- Confidentiality at all levels
- Equitable selection of study participants
- Specific method and location of enrolment is to be described
- What procedures will be followed if laboratory results are not within normal limits?
- How will missing data or incomplete forms be handled
- Quality assurance methods

❖ Other important items

- References need to be provided for all facts, figures, and evidence
- PI is responsible for the study conduct and all procedures
- Role of Investigators : clear responsibilities and roles
- Budget justifiable with duration / by year
- Time lines and task management details

❖ IRB Decision

- APPROVED
- MODIFY / REVISE
- REJECT

Problems with approvals / delays

1. Insufficient information upon which to determine risk/benefit
2. Benefit > Risk not made explicit
3. Study Design Inadequate
4. Informed consent Issues
5. Privacy/confidentiality Issues Not Addressed
6. Selection of Subjects Not Equitable or Described
7. Research and Clinical Care Difficult to Distinguish
8. Unethical Study
9. Administrative Details Not Addressed Appropriately
10. Response format is ambiguous

THE END