Beni-Suef University

Faculty of Pharmacy

Research Ethics Committee
(Medical Clinical Researches)

جامعــة بني سويــف

كليـــة الصيـــدلـــة

لجنة أأخلاقيات البحث العلمي
(البحوث الطبية الإكلينيكية)

PLEASE READ THE FOLLOWING BEFORE FILLING UP THIS FORM

- This form should be filled by faculty and students who are conducting research that involves human subjects, human tissues (such as blood, urine, saliva, archived biopsy tissues, epithelial swabs…etc) and/or human data (such as records).

- All sections in this form should be filled.

- You can save and continue filling this form at anytime.

- Before submitting this form, make sure that all the relevant documents (informed consent…etc) are in PDF format and are added to the end of this form. You should submit one single file containing all your materials.

Thank you.

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Application for Approval of a Project Involving Human Subjects

Section A: APPLICATION DETAILS

A1: Application details

To be filled by the Research Ethics Committee's secretary.

Application No._____

Date received_____

Project title

Title should be concise and representative of the proposed study

Project category

Faculty and external research projects will be reviewed by Research Ethics Committee. Student (undergraduate and postgraduate) research projects must be first assessed by the designated member of the Research Ethics Committee in each of the colleges of Medicine, Dental Medicine, Pharmacy and Health Sciences. The designated member will give the appropriate recommendations after the initial assessment.

Select your project category:

☐ Faculty research project
☐ Postgraduate student research project (*must be supervised by a faculty member*)
☐ Undergraduate student research project (*must be supervised by a faculty member*)
☐ Others, *please give details*

A2: Project funding and duration

☐ Internal funding from the University of Beni-Suef. *Details*;

☐ Funding from a national research institute. *Details*;

☐ Funding from overseas. *Details*;

☐ This research is self-funded

What is the proposed starting date? (dd/mm/yyyy)_____

What is the expected duration of this research? _____

A3: Applicants' details

The Research Ethics Committee should make sure that the principle investigator and the co-investigators have the necessary qualifications and expertise to conduct this research.

Name of the Principle Investigator:
In case of undergraduate student research projects, the principle investigator will be the supervising faculty member

_____

Academic rank (*applicable to faculty members*):

_____

Address:

_____

Mobile Tel.:_____Email: _____

Names and contact details of the all co-investigators

Use an additional sheet if required

Name:_____
Position:_____
College/Institute:_____
Tel.:_____
Email: _____

Name:_____
Position:_____
College/Institute:_____
Tel.:_____
Email:

Name:_____
Position:_____
College/Institute:_____
Tel.:_____
Email: _____

Name:_____
Position:_____
College/Institute:_____
Tel.:_____
Email: _____

Name:_____
Position:_____
College/Institute:_____
Tel.:_____
Email: _____

Section B: DETAILS OF THE RESEARCH PROJECT

B1: What is your research question(s)?

B2: Briefly outline the background to this research. You should focus on the rationale behind doing this research and explain its significance.

A short statement as to the background of the research proposal needs to be provided. If the proposed study replicates previous studies, the researcher needs to state why it is necessary to do what has already been done. This part should be written in a language that is clear and understandable to individuals with no background knowledge on the research topic. Please put the references as a separate attachment.

B3: What are the general and specific objectives?

Reviewer's comments (*to be filled by REC members*)

SectionC: METHODOLOGY

C1: Study Design

Choose the design that conforms to your research proposal.

☐Quantitative

Choose the appropriate design.

Observational

- ☐Cross-sectional
- ☐Case control
- ☐Cohort
- ☐Other, specify_____

Experimental

- ☐Randomized control trial
- ☐Community interaction study
- ☐Laboratory experiment
- ☐Other, specify_____

☐Qualitative

Give details,

C2: Please explain how your selected design relates, or is appropriate, to fulfilling your objectives?

Reviewer's comments (*to be filled by REC members*)

C3: Study population

Specify the population from which the sample will be drawn.

Explain your sampling method if you are going to be using one.
The researcher needs to describe clearly how the sample will be selected.

What is the needed sample size?
The number of participants needs to be given and justified.

What is the sample size justification?
The number of participants needs to be given and justified.

What are the inclusion criteria?

What are the exclusion criteria?

C4: Research instrument

The researcher should provide information about the tool to be used for collecting the data. For example, will the researcher use interview questionnaires, anthropometric measurement, laboratory procedures, sampling of body tissues, analysis of archival tissues, administering any substances to participants, or requiring them to refrain from taking certain substances. Add those details as an attachment.

C5: Description of procedures

Outline the research procedures which you will perform in bullet points.

Reviewer's comments (*to be filled by REC members*)

Section D: ETHICAL CONSIDERATIONS

Items D1-D5 are very important, as they will determine whether the ethical principles in your research project have been satisfactorily met.

D1: Autonomy of research participants

For the research to be ethical, voluntariness to take part in the research should be guaranteed. Autonomy is achieved by obtaining each participant's consent, after receiving sufficient information about his/her involvement. The Research Ethics Committee will look into the completeness of the information given, and the process in which a consent is obtained (i.e. free of coercion or exploitation).

Are you in any relation with the research participants, which can influence their voluntary consent?

Such as recruiting students by faculty, or recruiting patients by their treating doctor.

☐ No
☐ Yes, *give details*

Are you requesting a waiver of consent?

Information sheet should always be presented to research participants. In rare cases, the signed informed consent can be waived.

☐ No
☐ Yes, *give details*

How will you guarantee understandability of the information which will be presented to the research participants?

As a general rule, the information in the informed consent must be in the participants' native language and must be written in simple and understandable terms.

Do you consider some, or all, of your sample to be vulnerable?

Vulnerable persons are those who might not be competent enough to give an informed consent freely because they have insufficient education, cognitive capacity, or freedom of choice. Those include, but are not limited to, prisoners, illiterate persons, physically or mentally retarded persons, refugees, impoverished persons, homeless, minors…etc. Vulnerable groups also include people who are positioned in a hierarchal structure with the researcher or the research institute, such as students, army recruits, employees…etc.

☐ No
☐ Yes, *give details*

Research participants should have the right to withdraw at any time from the research. Explain what will you do if a participant decided to withdraw from your research?

For example, how will the already obtained data or samples be managed?

Reviewer's comments (*to be filled by REC members*)

D2: Privacy and Confidentiality

Privacy related to the setting where the research will be taking place. Confidentiality related to the security of data collected during research.

Please explain how will you ensure the privacy of the research setting?

This includes the invitation to participate in research, and the conducting of the research itself. For example, examination will be conducted in a closed room…etc.
Write N/A if this is not applicable.

What steps have been taken to preserve confidentiality?

Will research data (or samples) be retained for further studies in the future?

☐ No
☐ Yes, *give details*

Where will the data (or samples) be stored?

Reviewer's comments (*to be filled by REC members*)

D3: Risks

It is important that the research identifies all foreseeable and unforeseeable risks of his/her research. The Research Ethics Committee needs to see that those have been thoroughly thought of and identified by the researchers, and that all possible steps to minimize them have been taken.

Does this study involve any physical risks to participants?

☐ No
☐ Yes, *give details*

Does this study involve any psychological risks to participants?

☐ No
☐ Yes, *give details*

Does the study involve any social risk to participants?

☐ No
☐ Yes, *give details*

Does the study involve any risk on the community's values?

☐ No
☐ Yes, *give details*

Does this study require participants to release information of sensitive or personal nature?

☐ No
☐ Yes, *give details*

Are there any other risks different from those encountered in everyday life?

☐ No
☐ Yes, *give details*

What steps have you taken to minimize any of the above risks if applicable?
Write N/A if not applicable.

Describe the circumstances under which the study could be stopped early.
Write N/A if not applicable.

If this is an experimental study, and you are using a double blind design, what will be your method to break the code in an emergency situation?
Write N/A if this is not applicable.

If this is an experimental study, will the research participants be insured against damages as a result of this research?
Write N/A if this is not applicable.

Reviewer's comments (*to be filled by REC members*)

D4: Benefits and Payments

The Research Ethics Committee needs to see the direct and indirect benefits given to research participants in order to weigh those against the risks.

Will participants receive benefits (direct or indirect) as incentive to participate in the research?

Such as free medical consultations, free blood tests…etc.

☐ No
☐ Yes, *give details*

Will participants receive any monetary incentives?

☐ No
☐ Yes, *give details. For example, you should specify the amount and the method of payment*

D5: Deception

Does the research involve any deception or withholding information?

☐ No
☐ Yes, *give details on why deception is the only possible research design.*

Will the consents be obtained after the conclusion of this study? Please explain your answer.

Reviewer's comments (*to be filled by REC members*)

Declaration

Title of the research project:

Name of the principle investigator:

I declare that information contained herein is, to the best of my knowledge and beliefs, accurate. I have attempted to identify all risks that may arise from conducting this research, and have discussed them in this document. I have the necessary qualifications, experience and facilities to deal with any emergencies and contingencies related to this research. I am obliged to notify the Research Ethics Committee of any unforeseeable risks or events which might occur during the conduct of this research. I declare that I will make no modifications to any of the methodologies stated in this form without the prior approval of the Research Ethics Committee.

Signature:

Checklist

	Attached	N/A
Section A: Letter from the funding institute	☐	☐
Section A: CV of researcher (if external to BSU)	☐	☐
Section B: References	☐	☐
Section C: Research instruments *(For example, questionnaires, data sheets…etc)*	☐	☐
Section D: Information sheet (*The final version in the participant's language*)	☐	☐
Section D: Informed consent form (*The final version in the participant's language*)	☐	☐
Section D: Recruitment announcement *(The final version)*	☐	☐

ALL ATTACHMENTS SHOULD BE ADDED TO THIS FORM, AND IN PDF FORMAT.

Requirements for the information part of the informed consent

The information sheet should include the following elements:

a. Be in the research participants' native language. The burden of accurately and formally translating the informed consent should be on the researchers.
b. Be written in simple, yet professional language. The form should be free from any linguistic and structure errors.
c. The title should clearly state the words "*research*", or "*study*" if in English, and the equivalent word if other languages are used.
d. The names, titles and contact details of the researchers.
e. The purpose of the research.
f. The research site, and how will privacy be guaranteed?
g. A statement on how will confidentiality of the collected data be safeguarded.
h. The participants' expected time commitment, and the overall duration of the research project.
i. The exact procedures which the participant will be involved in. This should preferably be written in a bullet point format. The use of photos and diagrams which would simplify this engagement are strongly encouraged.
j. The risks and discomfort which the participant will need to bear during the research, and after its completion (if relevant).
k. Benefits (if any) that the participant will get out of his/her participation. This could be financial, free consultations, free blood tests…etc.
l. A statement about voluntary participation, and the right to withdraw at any time without any consequences to this decision.
m. Whether there will be an insurance to cover damages as a result of this research, and/or to compensate for injury.
n. Contact details of a third party to contact in case of concerns of complaints. Usually, this third party is the chair of the REC.
o. A statement about any unforeseeable risks.
p. The circumstances under which the research would be terminated.

نموذج الموافقة المستنيرة على المشاركة في البحث

(اسم البحث)

الباحثون:

تحت إشراف:

الغرض من الدراسة:

الاجراءات / الاعمال المطلوبة من المشارك:

الفترة الزمنية المطلوبة للمشاركة

المخاطر:

الفوائد للمشارك والمجتمع:

بدائل المشاركة:

حماية خصوصية المشارك و سرية البيانات: (سوف تعامل معلوماتك بسريه كامله ولن يطلع على بياناتك سوى الباحث الرئيسى .بعد انتهاء الدراسة)

المشاركة تطوعية:

تكاليف المشاركة في البحث:

التعويض:

الحق في الانسحاب: مكفول في اي وقت.

البدائل المتاحة في حالة عدم المشاركة:

لمعرفة المزيد عن هذه الدراسة يمكنك الاتصال ب رقم تليفون

في حالة وجود شكوى يرجي الاتصال بمقرر لجنة مراجعة اخلاقيات البحوث

ا.م.د / رغده رشدى سيد رقم تليفون 0101064766

إذا كنت توافق على الاشتراك في هذه الدراسة قم بالإشارة في المكان المناسب في الجزء التالي:

: لقد تم شرح كل المعلومات الواردة في هذه الاتفاقية.

: لقد قرأت وفهمت المعلومات الواردة في هذه الاتفاقية.

اسم المشارك:	**التوقيع:**