**Research Proposal Ethics Form**

Code AU-REC-APP-F01

Issue 01/01-10-2011

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| --- |
| **Section 1: Applicant Details** |
| Full name (English) |  |
| الاسم كاملا باللغة العربية  |  |
| Faculty |  |
| Department |  |
| Phone |  |
| E-mail |  |
| Position | [ ]  Student 🡺 [ ]  MSc [ ]  PhD [ ]  Staff 🡺 [ ]  Lecturer [ ]  Assoc. Prof. [ ]  Prof.  |
| Co-researchers (from inside and outside the University)(add more rows when necessary) | Name: Faculty: Department:[ ]  Assiut University [ ]  Other:………………………….. |
| Name: Faculty: Department:[ ]  Assiut University [ ]  Other:………………………….. |
| Name: Faculty: Department:[ ]  Assiut University [ ]  Other:………………………….. |
| Name: Faculty: Department:[ ]  Assiut University [ ]  Other:………………………….. |
| Name: Faculty: Department:[ ]  Assiut University [ ]  Other:………………………….. |
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| **Section 2: Research study**  |
| **Section 2:1 Study details and funding** |
| Full study title |
|  |
| العنوان باللغة العربية  |
|  |
| **Study Dates**(Estimate of the duration of the study)   |
| Study expected start date | Month: Year: |
| Study expected end date | Month: Year: |
| **Study Funding**How is the study supported financially?  |
| [ ]  Self-funded [ ]  University [ ]  External grant,  Fund name……………………………No./ID:………… |
| **Section 2:2 Study summary** |
| Background and objectives. (maximum 200 words)   |
|  |
| Summary of research methodology (what experiments are you going to conduct to achieve the objectives?) (maximum 200 words) |
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| **Section 3: Human Participants** |
| Does the study involve human participants or their tissue or data?  | [ ]  Yes [ ]  No (proceed to Section 4) |
| **Section 3.1: Participant Selection** |
| Describe your participants?  |
|  |
| How will you select the participant sample? |
|  |
| How will you determine the sample size?  |
|  |
| **Section 3.2: Responsible team members** |
| List the team members responsible for interacting with participants and/or their samples/data |
| 1. **………………………..**
2. **………………………**
 |
| **Section 3.3: Participant Recruitment** |
| How will you contact potential participants? Please select all that apply. |
| [ ]  Telephone calls[ ]  Face-to-face approach[ ]  Emails[ ]  Social media[ ]  Other: …………………….. |
| **Section 3.4: Ethical considerations** |
| Risk benefit assessment |
|  |
| Confidentiality (dealing with data and data dissemination should be confidential) |
|  |
| Informed consent (fill the form)  |

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| **Section 4: Animal studies** |
| Does the study involve animals or their tissues and data? | [ ]  Yes [ ]  No (proceed to Section 5) |
| **Section 4.1: Animal selection, housing and euthanasia**  |
| What are your animal species, sex and number?  |
| Species: Sex: Number: |
| Where will you get the animals from? |
|  |
| What will be the maximal time an individual animal is held? |
|  |
| Describe the type of housing, location and no. of animals/cage or bin to be provided. |
|  |
| How will you adjust the animal housing and management? |
|  |
| How did you determine the number of animals to be used?  |
|  |
| How will you perform animal euthanasia?  |
|  |
| What will happen to animals at the completion of the study?  |
|  |
| How will you dispose the experiment waste? |
|  |
| **Section 4.2: Responsible team members** |
| List the team members responsible for conducting the animal study |
| 1. **………………………..**
2. **………………………**
 |
| What are their qualifications and experience in animal handling? |
|  |

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| **Section 5: Chemicals, toxins and biohazardous materials** |
| Does the study involve hazardous materials? [ ]  Yes  [ ]  No (proceed to section 6) |
| What is the type of hazardous materials involved? Please select all that apply. |
|  [ ]  Natural toxin or venom:………………………………….  [ ]  Radioactive materials:…………………………………… [ ]  Biohazards (including bacteria, viruses and cancer cells):…………………………………….. [ ]  Chemical hazards (including explosives, flammables, combustibles, and carcinogens):……………… [ ]  Others: ……………………………….. |
| How will researchers protect themselves and the environment from the said hazard?  |
|  |
| How will you dispose the hazardous material/waste? |
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| **Section 6: Data Collection and Storage** |
| **Section 6.1 Data Collection and Analysis** |
| What methods will you use to collect data in the study? Please select all that apply.  |
| [ ]  Interviews[ ]  Questionnaires/surveys[ ]  Focus groups[ ]  Observation[ ]  Secondary sources[ ]  Clinical measurement[ ]  Digital media[ ]  Sample collection[ ]  *In-vitro* experiments[ ]  Other:………………………………………………………….  |
| How will you record your data and transfer it to secure storage? |
|  |
| **Section 6.2 Data Storage, Access and Security** |
| Where will you store the data? Please select all that apply. |
| [ ]  PC\ hard drive[ ]  Cloud (OneDrive, google drive,……)[ ]  Other:……………………………………………………… (including secure physical storage) |
| Who will have access to the data? |
|  |
| How will you maintain the security of the data and transfer it between co-researchers?  |
|  |
| **Section 6.3 Data Disposal** |
| When and how will you destroy personal data? |
|  |

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| **Section 7: Other Ethical Issues** |
| Are the study participants or animals exposed to any risks? [ ]  Yes [ ]  NoIf yes, how will you address and manage these risks? |
|  |
| Are there any potential risks to researchers and any other people because of the study?  |
|  |
| How will the results of the study be reported and disseminated? Please select all that apply. |
| [ ]  Peer reviewed journal[ ]  Conference presentation[ ]  Thesis[ ]  Report to funders[ ]  Media[ ]  Other: ………………………………. |

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| **Section 8: Supporting Documentation** |
| Please fill in the supplementary files in the end of the document:  [ ]  The research proposal (1-2 pages + questionnaire/survey (if any)) [ ]  Informed consent (if applicable) [ ]  Conflict of interest statement  [ ]  Co-researchers/team members details + signatures [ ]  Applicant CV  [ ]  Department head approval  |

**Research proposal**

Code AU-REC-APP-F02

Issue 01/01-10-2011

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| **Background** |
|  |
| **Objectives** |
|  |
| **Methodology** If study includes animal experiments, list If study includes human studies, list If study includes hazardous materials, list your precautions for management and disposal  |
|  |

**Informed consent (نموذج الموافقة المستنيرة لإجراء بحث طبي على مشارك متطوع)**

Code AU-REC-APP-F03

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أنت مدعو(ة) للمشاركة ببحث علمي سريري سيجرى في جامعة أسيوط. الرجاء أن تأخذ(ى) الوقت الكافي لقراءة المعلومات التالية قبل أن تقرر(ى) إذا كنت تريد(ين) المشاركة أم لا. بإمكانك طلب إيضاحات أو معلومات إضافية عن أي شيء مذكور في هذه الإستمارة أو عن هذه الدراسة ككل من طبيبك. علما بأنك لن تتحمل أى تكاليف اضافية.

**الاسم:**

**النوع:**

**السن:**

**تاريخ الميلاد:**

**الرقم القومى:**

**التاريخ**:

**المكان الذي سوف تتم فيه الدراسة: ..................**

**الخلفية العلمية: ........................................................................................**

الهدف من اجراء البحث: ..............................................................................

وصف طريقة عمل البحث وتفسير مجرياته: ..............................................................................

الفوائد المتوقعة من البحث: ..............................................................................

التأثيرات السلبية وردات الفعل والمخاطر المحتمل حدوثها التي يمكن ان يسببها الإشتراك في هذا البحث: ................................

البدائل المتاحة: ..............................................................................

سرية المعلومات: سوف تعامل معلوماتك بسرية كاملة ولن يطلع على بياناتك سوى الباحث الرئيسى

حقوق المشارك: من حقك الامتناع عن المشاركة فى هذا البحث وفى هذه الحالة ستتلقى علاجك المعتاد وأيضا من حقك الانسحاب من المشاركة فى هذه الدراسة فى أى وقت دون ابداء أسباب ولن يكون عليك أية عواقب سلبية وبدون أن تطالب أو تتحمل أى تكاليف وسوف يتم إخبارك بأى معلومات جديدة قد تظهر خلال البحث والتى يمكن أن تؤثر على الاستمرار فى الدراسة.

**عند وجود أى استفسار لديك يمكنك الاتصال ب:**

**اسم الباحث الرئيسى: تليفون:**

**إقرار الباحث:**

لقد أطلعت بالتفصيل على التعهد بالإشتراك في البحث مع *(إسم المريض، ممثله القانوني)،* وأفهمت المريض الغاية من هذه الدراسة ومن أخطارها وفوائدها. لقد أجبت المشترك على جميع الأسئلة التي تقدم بها بوضوح تام وتعهدت له بإعلامه عن أي تغيير يطرأ في موضوع هذا البحث.

**إسم الباحث التوقيع**

**إقرار المريض بالمشاركة في البحث:**

أنا الموقع أدناه وبعد أن اطلعت واستوعبت كل جوانب هذا البحث وأجبت عن كل أسئلتي أوافق بملئ إرادتي على المشاركة في هذه الدراسة وأنا على علم تام بأنني أستطيع الإتصال بالدكتور .............................................................................. وذلك إذا أردت توجيه أي سؤال وكما إنني أعلم أنه يمكنني الإنسحاب من المشاركة في هذه الدراسة في أي وقت شئت حتى بعد التوقيع على هذه الوثيقة وإن العناية التي أتلقاها لن تتأثر بهذا الإنسحاب وإنني سوف أزود بنسخة من هذه الوثيقة.

**إسم المريض أو ممثله القانونى/قريبه أو وصيه:**

**التوقيع أو البصمة: الرقم القومى: التاريخ:**

**إسم الشاهد:**

**التوقيع: الرقم القومى**

**Conflict of interest statement**

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This is to state that there are **no conflicts of interest** involved in carrying out the work described in this research study (if there is any conflict, please include it here:……………………………………………………………………………………………).

This is to state that all **co-researcher(s) have approved** the research proposal and all information in this form.

Applicant name: ….………………………….

Signature:

# الميثاق الأخلاقي للبحث العلمي

Code AU-REC-APP-F05

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نقر نحن الموقعون ادناه الباحثين لليحث المقدم بعنوان

(اللغة العربية)...............................................................................................................................

اللغة الانجليزية:.............................................................................................................................

أننا قد اطلعنا علي وثيقة الميثاق الأخلاقي للبحث العلمي بجامعة أسيوط و أننا موافقون علي كل ما جاء بها من بنود و ملتزمون بتنفيذها من أجل "بحث علمي أخلاقي و نزيه"

1. أي فوائد للبحث العلمي هي لصالح المجتمع.
2. Respect the integrity and dignity of persons whom I work with (the participants and the members of the research team).
3. Follow the “Do no harm” principle. Any risks must be clearly communicated to subjects involved.
4. Recognize the rights of individuals to privacy, personal data protection.
5. Respect the requirement of informed consent and continuous dialogue with research participants.
6. Not imposing more than is necessary on research subjects or going beyond stated objectives.
7. Treat societal queries seriously - a researcher’s first obligation is to listen to the public and engage with them in constructive dialogue, transparently, honestly and with integrity.
8. Treat animals with respect and works under humane conditions before, during and after the research.
9. Do my best to prevent dual use of research data.
10. Respect biodiversity and do not impose irreversible change that threatens the environment or ecological balance.
11. Disseminate my data under the umbrella of good ethics in publication: clear authorship, no plagiarism, no scientific fraud, no duplicate publication, no violation of intellectual property.
12. Keep specific features within an image not enhanced, obscured, removed, moved, or introduced.
13. Keep my research data stored in a suitable form and place -under my own responsibility- for 10 years after publishing my research.

**Co-researchers/Team members**

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Position | Role | Signature |
| 1. ……………………………………… (applicant)
 |  |  |  |
| 1. ……………………………………..
 |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Applicant CV**

Code AU-REC-APP-F06

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|  |  |
| --- | --- |
| **Name** |  |
| **Department/Faculty** |  |
| **Position** |  |
| **Education (obtained degrees and date)** |
| Degree: Date:Degree: Date: |
| **Research interest** |
| ………………………;………………….;…………………. |
| **Publications in the last five years (maximum 10 included)** |
| 1. ………………..
2. …………………..
3. ………………..
 |

**Organization/ Department approval**

Code AU-REC-APP-F07

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This is to approve the submission of the research proposal entitled: …………………………………………………………………………………………………………………………………………………………………………………………………………………………….……………

by:

Name:………………………………………………

Department: ……………………………………..

Position: …………………………………………

to Assiut University research ethics committee (AUREC).

**Department head**

**Name:……………………………………**

**Signature:**

**Date: / /**