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| Kingdom of Saudi ArabiaKING SAUD UNIVERSITY***College of Medicine******Institutional Review Board***  |  | ***المملكة العربية السعودية***جامعة الملك سعود ***كلية الطب******مجلس أخلاقيات البحوث الطبية*** |

**نموذج طلب موافقة مجلس أخلاقيات البحوث الطبية**

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| **رقم البحث:** |

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

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| **ملخص البحث (ما بين 150-200 كلمة)**1. **مشكلة البحث :-**
2. **أهمية البحث :-**
3. **أهداف البحث :-**
4. **منهجية البحث :-**
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| **توقيع الباحث الرئيس : التاريخ :** |

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| **ملاحظة: لا يقبل أي ملخص ما لم يقدم مطبوعاً باللغة العربية و موقعاً من الباحث الرئيس .**The Arabic page should be written as exact translation of the English cover-page. Usually the supervisor (faculty) is considered the principal investigator, unless agreed otherwise within the research group. |
| Kingdom of Saudi ArabiaKING SAUD UNIVERSITY***College of Medicine******Institutional Review Board*** |  | ***المملكة العربية السعودية***جامعة الملك سعود ***كلية الطب******مجلس أخلاقيات البحوث الطبية*** |

*Please, fill this page if the research proposal is submitted in* ***English****.*

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| **Research Title:**  |

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| **Summary:** (150 – 200 words)1. **Research Problem:**
2. **Research Significance:**
3. **Research Objectives:**
4. **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)

 This is only one page, not more |
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| Kingdom of Saudi ArabiaKING SAUD UNIVERSITY***College of Medicine******Institutional Review Board (IRB)*** |  | ***المملكة العربية السعودية***جامعة الملك سعود ***كلية الطب******مجلس أخلاقيات البحوث الطبية*** |

##### مقترح مشروع بحثي

**Research Project Proposal**

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

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| *التوقيع*Signature | *الكلية/القسم*College/Department | *الرتبة العلمية*Academic Title | *أسماء الباحثين*\*Investigators Names\* |
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\* 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:** For principal investigator from other college/hospital (outside KKUH) please provide contact details:

Office Tel. No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Department Tel. No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile No. (optional) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| مشكلة البحث و أهميته**Research Problem and Significance** |
| * Research Problem
* Rationale
* Significance
* Research question
* Hypotheses
 |

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| أهداف البحث**Research Objectives** |
| Overall and specific SMART\* objectives, including person, place and time\*SMART:**S**pecific**M**easurable**A**chievable**R**elevant**T**ime-bound |
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| أدبيات البحث**Literature Review**Latest relevant literature (international, regional, national, local as available and appropriate) using suitable search engines and methodsThis could be 2-3 pages maximum, with suitable referencing |

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| منهجية البحث**Research Methodology** |
| **We need details about the following:*** **Study design** (mention the exact type; quantitative [observational, experimental]; qualitative, mix, etc)
* **Study setting** (where will the study be carried out, including secondary data collection places and time period)
* **Participants/Study Population**

**Specify Inclusion, Exclusion criteria – age, gender, diagnosis, co-morbid conditions, etc and Sources and methods of selection of participants*** **Sample size** (using standard equations)
* **Sampling technique** (should be random, unless otherwise justified)
* **Data collection methods**

**# e.g. questionnaire forms / checklist (Predesigned or standard questionnaire format; mention source and reference****How will it be distributed (Self Administered or interview, observing, reviewing records,…****Describe sections of questionnaire and variables mentioned,** **Define main variables you modified or formulated especially outcome variables**#biochemical measurements [with references of techniques / kits]; #physical measurements [with description of method / reference, as applicable] #Comment on who will collect data (attach copy of the questionnaire). (preferred, both Arabic and English questionnaires) * **Pilot study** (needed for all studies, to test logistics of data collection, suitability / clarity of data collection tools, estimation of timing for data collection)
* **Data analysis plan** (including referenced software; brief description of techniques on preliminary basis, etc)
* **Ethical considerations** (consent form to be attached, choose from the following as applicable to study design / objectives)**:**
1. All participants will receive a written consent form. The interviewer will inform all participants about the purpose of the research, why they were chosen, all potential risks and benefits and hat they could refuse to participate, or could withdraw from the study at any point in time.
2. 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.
3. Participants anonymity will be assured by assigning each participants with a code number for the purpose of analysis only.
4. 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.
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| المراجع**References** |
| Using standard methods of citing references, e.g. Vancouver style (New England Journal of Medicine) as applies to Journal articles; books / book chapters; reports; theses; Internet citations, etc |

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| ROLE OF INVESTIGATORS (choose from the following menu, as applicable to each investigator / member in the research group) |
| 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)*  |
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**الميزانية التفصيلية**

**Detailed Budget**

**(not required for CMED-305 purposes)**

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| **المبلغ المطلوب****Funds in SR** | **Details التفاصيل**  |
| **مقدار الجهد بالشهر**Effort in months | **أسماء الباحثين** **Names of Investigators** |
| 1200X( شهر)=**(1)** *الباحثون***(1)** *Investigators* |  |  | *(1)* |
| 1000X( شهر)= |  |  | *(2)* |
| 1000X( شهر)= |  |  | *(3)* |
| 1000X( شهر)= |  |  | *(4)* |
| 1000X( شهر)= |  |  | *(5)* |
|  | *Total(1) مجموع البند (1) (لا يزيد عن 40% من الميزانية الإجمالية للبحث)* |

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| **المبلغ المطلوب**Funds in SR | **مقدار الجهد بالشهر****Effort in months** | **العدد****Number** |
| *Assistants(2)* |  | *(أ) مساعد باحث ( ) a) Research Assistant ( )*  |
| **(2)** *مساعدون* |  | *(ب) فني مختبر ( ) b) Lab Technician ( )*  |
|  |  | *(ج) طالب جامعي ( ) c) University Students ( )* |
|  |  | *(د) إداريون ( ) d) Secretaries ( )*  |
|  |  | *(هـ) مهارات أخرى( ) e) Other professionals ( )*  |
|  | *مجموع البند(2) Total (2)* |

**\*\* في حال أن هذا البحث مدعوم يرجى إعطاء التفاصيل التالي:-**

**1- الداعم.**

**2- تفاصيل الميزانية.**

**\*\* If the project is funded, please provide:-**

 **1- Name of Sponsor**

 **2- Details of the budget**

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| *(3) مستلزما ت**( 3 ) Equipments, materials and supplies* | *(أ) الأجهزة والبرمجيات a) Equipments & software)* |
|  | *(ب) المواد (b) Materials* |
|  | *(ج) التجهيزات (c) Supplies* |
|  | *مجموع البند(3) Total (3)* |

*(4)*

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| (4) | *الرحلات الداخلية Domestic travel* |

(5)

*(5)*

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|  | *خدمات الحاسب الآلي Computer services* |

*(6)*

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| (6) | *خدمات أخرى Other services* |

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|  | *المجموع الكلي Grand Total* |

**الخطة الزمنية للبحث**

**RESEARCH TIME SCHEDULE \***

**تاريخ بداية البحث: / / 14 هـ** starting Date : / / 14 H.

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| البند Items |  التوالي المخطط للأعمال الرئيسة  Planned sequence of major tasks | السنة الأولى First Year | السنة الثانية Second Year |
| 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**  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 11 | **Questionnaire Design** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **Data collection** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **Data management and analysis** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **Final report writing**  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **Presentation (April, 2013) /** **manuscript writing (optional)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**\* The research group may wish to change the 6 months in this 2-year chronogram (GANTT Chart) into weeks, to become 24 weeks, equivalent to the 6 months we wish the CMED-305 project to be fulfilled during (Oct 2012-March 2013). Also the tasks proposed in this schedule are only examples, liable to changes / additions, as appropriate to the study in question.**