**Research Protocol Form "Approval Requirements"**

Dear KBMS Trainee:

This document is prepared to facilitate the process of approval on your research protocol. Kindly read below instructions carefully in order to guide you to the basic requirements necessary for approval by research protocol ethics committee:

1. This document composed of three sections and 11 pages, section (I) request letter, section (II) research protocol scientific form, section (III) research protocol ethics form.
2. Section (I) has to be prepared by the trainee, section (II) should be signed by all three members of the research protocol scientific committee; the establishment of aforementioned committee is the responsibility of the head of training center ( the research protocol scientific committee should composed of head of the training center, supervisor of the research, and the third member has to be nominated by the head of the training center) , lack of any signature means not eligible for the next step, then section (III), research protocol ethics committee will review all the documents to decide the eligibility of the documents for the process of approval. The trainee should comply with aforementioned steps to avoid any delay on the process of approval on research protocol.
3. This document should be attached with below mentioned papers; otherwise the document will not be revised by the research protocol ethics committee.
4. A copy of consent form prepared by the trainee; if applicable.
5. KBMS official letter on appointing of the supervisor for the trainee and the title of his/her research title. *The name of the supervisor and trainee in both request letter by the trainee (section I) and KBMS official letter should match.*
6. Upon fulfillment of all above requested documents and conduction of the meeting by research protocol ethics committee; feedback on your request will be shared with you soon via SMS and KBMS website.

**SECTION (I)**

**بؤ** / **ليذنةى نةريتى تويَذينةوةى ثزيشكى**

/ **ليذنةى زانستى تويَذينةوةى ثزيشكى**

**بابةت/ ثةسةندكردنى ثروَتوَكوَلَى تويَذينةوة**

سلاَو ورِيَز/

هاوثيَض فةرمانى كارطيَرِى ئةنجومةنى كوردستان بوَ ثسثوَرِية ثزيشكيةكان كة تايبةتة بة دةستنيشان كردنى سةرثةرشتيارى تويَذينةوةم ذمارة ( ) لة بةروارى ( ). داوا لة بةريَزتان دةكةم رةزامةندى بفةرموون بؤ ثةسةندكردنى ثروتوَكوَلَى تويَذينةوةكةم بة ناونيشانى:

( )

لةطةلَ رِيَزم

**واذوو:**

**ناوي سيانى رِاهيَنراو:**

**بةروار:**   20 / /

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| **SECTION (II)**  **Research protocol scentific form** |

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| 1. **Research Title:** |

1. **Principle Investigator:**

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| 1. ناوى سيانى (بة كوردى): |

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| b. Full name (in English): |

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| c. ثسثوَرِى (بة كوردى): | ناوى ئةنجومةن (بة كوردى) : |

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| d. Specialty (in English): | Name of council of clinical specialty: |

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| e. Training center: |

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| f. Full Address: | Phone no.: | Email: |

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| g. Qualification (برِوانامة): |

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| h. Affiliation (ميلاك): | Ministry of Health | Ministry of Higher Education & Scientific Research |
| Ministry of Peshmarga | others, please identify ---------------------------- |

1. **Co-investigators (if applicable) (mention name, qualification, and affiliation of each):**

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1. **Research Supervisor:**

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| 1. ناوى سيانى (بة كوردى) : |

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| b. Full name (in English): |

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| c. ثسثوَرِى (بة كوردى): |

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| d. Specialty (in English): |

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| e. Training center: |

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| f. Full Address: | Phone no.: | Email: |

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| g. Qualification (برِوانامة): |

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| h. Affiliation (ميلاك): | Ministry of Health | Ministry of Higher Education & Scientific Research |
| Ministry of Peshmarga | others, please identify ---------------------------- |

1. **Research Co- Supervisor (if applicable):**

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| a. ناوى سيانى (بة كوردى) :د. بشار حنا عازر | b. Full name (in English):Dr Bashar Hana Azr |

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| c. پسپۆڕی (بە كوردى):نەشتەرگەری دڵ و سینگ و موولوولەکانی خوێن | d. Specialty (in English):Consultant cardiothoracic and vascular surgeon |

1. **Introduction:**
2. **Aim (s) of the study** *(The aim of the study, i.e. the overall purpose of the study, should be clearly and concisely defined. The aims are broad statements of desired outcomes, or the general intentions of the research, emphasize what is to be accomplished (not how it is to be accomplished) and address the long-term project outcomes, i.e. they should reflect expectations of the research topic)***:**

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| The aim of this study is to evaluate the impact of endoscopic-assissted beating heart minimally invasive direct coronary artery bypass (MIDCAB) on reducing mortality, morbidity and the need for renal replacement threapy in patients with stage 2 and higher chronic kidney disease (CKD). Given the high mortality rate in this population, this research seeks to explore the effectiveness of the new surgical technique in improving patient outcomes and overall quality of life. |

1. **Specific objectives of the study** *(Are the steps you are going to take to answer your research questions or a specific list of tasks needed to accomplish the goals of the project)* **:**

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| The study will retrospectively collect data from medical records of at least 100 patients who underwent traditional CABG and 100 patients who underwent EA-MIDCAB, all with CKD stage 2 and above. It will:  1. Analyze the 30-day mortality rates in both groups.  2. Evaluate the incidence of postoperative complications in both groups.  3. Determine the need for renal replacement therapy (RRT) in both groups.  4. Assess the overall mortality in both groups.  A comprehensive statistical analysis will be performed to assess the effectiveness of these procedures in this high-risk patient population. |

1. **Patients / Subjects/ Materials and methods of study:**

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| 1. **Study design:**   **Retrospective Case-control Study** |

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| 1. **Study duration: Surgeries performed between January 1, 2020, and May 31, 2024** |

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| 1. **Study setting (place of the study, city, governorate):** Erbil cardiac center, Shar private hospital. Erbil, Kurdistan governorate**.** |

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| 1. **Sampling method and sample size:**   The sampling method is convenient sampling method from files of patients who underwent cardiac surgery in Shar private hospital.  The sample size is composed of 200 cases, 100 cases underwent Minimally invasive cardiac surgery and 100 cases underwent traditional coronary artery bypass grafting. |

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| 1. **Inclusion criteria:** 2. **Isolated coronary artery bypass grafting (CABG) with chronic kidney disease (CKD) stage 2 and above. Elective Cases** 3. **Elective cases** 4. **Surgeries performed between January 1, 2020, and May 31, 2024 patients with completed medical records available for analysis.** |

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| 1. **Exclusion criteria:**   **Combined surgeries (CABG plus other concomitant procedures)  Emergency operations Patients with other systemic comorbidities like CVA, malignancy** |

1. **Statistical analysis** *(Brief description of statistical methods used and the statistical significance of the findings (when appropriate) giving references to the statistical methods and defining statistical terms and abbreviations. Computer software and version used should be specified)***:**

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| IBM SPSS statistics software (version 28) for data analysis and chi square test to determine the significance of our findings. |

1. **Date of Research Protocol Presentation (Day/month/year):**

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**APPROVAL OF RESEARCH PROTOCOL SCIENTIFIC COMMITTEE**

*(****Note:*** *this section should be filled by the Research protocol scientific committee members.* *The establishment of aforementioned committee is the responsibility of the head of training center* ***( the research protocol scientific committee should include head of the training center, supervisor of the research, and the third member has to be nominated by the head of the training center)****. If the following information and signatures missed from the form; then the research protocol considered not approved by Research protocol scientific committee. Hence; not fulfills the requirement of submission to Research Protocol Ethics Committee.).*

1. **Member (should be the supervisor of the Research Protocol):**

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| **Full name :**  **Date (day/month/year):** | **Signature:** |

1. **Member:**

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| **Full name :**  **Date (day/month/year):** | **Signature:** |

1. **Head of Research Protocol Scientific Committee:**

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| **Full name :**  **Date (day/month/year):** | **Signature:** |

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| **SECTION (III) ReseaRCH protocol EthicS form** |

1. **Participants informed consent:**
2. Will informed written consent be obtained? Yes No

If yes, please:

1. Outline the consent process in full. (How will consent be obtained, when, by whom and from whom etc?)

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| Informed written consent will be obtained prior to any study-related activities. Participants will be provided with information about the study, including the possibility of contributing to future research projects. The consent process will involve the following steps:   * **When:** Consent will be obtained at the time of surgery agreement or during the initial consultation process. * **By Whom**: A trained member of the research team or the treating doctor will obtain consent while communicating effectively with the participant. * **From Whom**: Consent will be sought from all eligible adult participants who meet the inclusion criteria and have the capacity to provide informed consent.   Participants will have the opportunity to ask questions and will be informed that their participation is voluntary. |

1. Attach a copy of the consent form; it should be in a language that the participants understand.

A copy of the consent form in the participants' native language will be attached.

1. If no, please justify. You must provide a full and detailed explanation as to why informed consent will not be obtained.

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1. Will participants be informed of their right to refuse to participate and their right to withdraw from this research study?  Yes  No

If no, please justify.

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1. **Adult participants capacity (aged 18 y or over):**
2. Will all adult research participants have the capacity to give informed consent?  Yes No
3. If no, please elaborate.

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1. **Access to health care records:**
2. Does the study involve access to healthcare records (hard copy / electronic)? Yes No
3. If yes, please elaborate (how you will access the health care records?).

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| Access to patient archives will be obtained with formal permission from the hospital administration. All information will remain confidential, and the research team will sign a non-disclosure agreement to ensure patient privacy and data security. |

1. Who will access these healthcare records?

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| Authorized members of the research team who have received ethics and confidentiality training will access the healthcare records. |

1. Will consent be taken from patients by research team members to access their healthcare records? Yes No

If no, please justify:

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| Direct patient consent to access healthcare records is not feasible due to the retrospective nature of the study, where records of previously treated patients will be analyzed. Instead, institutional permission will be secured, and ethical guidelines for data handling will be strictly adhered to. |

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| **EXAMPLE of INFORMED CONSENT FORM** |

(Should be written in a language that participants understand i.e.: Kurdish, Arabic or English)

**PROJECT TITLE**

**PROJECT SUMMARY**

By signing below, you are agreeing that: (1) you have read and understood the participant information sheet, (2) questions about your participation in this study have been answered satisfactorily, (3) you are aware of the potential risks (if any), and (4) you are taking part in this research study voluntarily.

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Participant’s Name

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Participant’s signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name of person obtaining consent Signature of person obtaining consent

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| **نموذج من موافقة البحث باللغة العربية** |

**عنوان البحث:**

**ملخص البحث:**

بتوقيعكم أدناه توافقون على :**أولا:**قرأت وفهمت نموذج من موافقة المشاركة في البحث ,**ثانيا:** جميع الأسئلة حول أشتراككم في البحث أجيبت بشكل مرضي, **ثالثا:** مدركون بوجود اي خطورة (اذا وجدت ) عند مشاركتكم في هذا البحث ,**رابعا:** أشتراكك في هذا البحث يكون طوعيا .

أسم المشارك :

تأريخ و توقيع المشارك :

أسم و توقيع الباحث :

***ناوی توێژینەوە لێرە بنووسە:***

***کورتەی تۆێژینەوە:***

***لەخوارەوە واپەسن، بە ئیمزا کردنی ئەم بەڵگەنامەیە، دەڵێن: یەکەم- تۆ شیکردنەوەو ئەگەرەکانت لەسەر بەشداریکردن لە ئەم لێکۆڵینەوەیە چاک و ئاڕاستە کرابووە. دووەم- هەموو پرسیارەکانت دەربارەی بەشداریکردن لە تویزینەوە وەلام دراوەتەوە بە شێوەیەکی دلنیایی. سییەم- بۆ تۆ ڕوونکرایەوە بە هەر ریسکی جێبەجێکردن.چوارەم- بەشداریکردنت بە تەنها لەسەر خواستی تۆیە.***

***ناوی بەشدار بوو:***

***بەرواری و ئیمزای بەشداربوو:***

***ناو و ئیمزای ئەو کەسەی کە شیکردنەوەی داوا بە نەخۆش:***

Meeting Code:

Date :



**Kurdistan Higher Council of Medical Specialities**

**RESEARCH PROTOCOL ETHICS COMMITTEE**

**Title of the project: Endoscopic coronary surgery: DHF technique**

**Names of the Principle investigator: Darya Nadir Saeed**

**Names of the Co-investigator:**

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| **Ass. Prof. Dr.Maaroof Tahseen Hassan**  **Head of the Ethics Committee** | | |
| **Prof. Dr. Abdullah Faqiyazdin Ahmed**  **Member** |  | **Prof. Dr. Sherzad Ali Ismael**  **Member** |
| **Dr. Moayad Abdullah Wahab** |  | **Ari Nawzad Abdullah**  **Member** |
| **Member** |  |  |

**Mohammed Abdullah Azeez**

**Member**