Study Protocol

Title: A Randomized Controlled Trial on the Application of Artificial Intelligence (AI) in Skin Assessment for Pressure Injury Prevention and Staging by Critical Care Nurses

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مستشفى الملك فيصل التخصصي ومركز الأبحاث

King Faisal Specialist Hospital & Research Centre

Gen. Org. مؤسسة عامة

Jeddah Branch - فرع جدة

Institutional Review Board (IRB)

Application for Approval of Research Proposal

RESEARCH PROPOSAL PACKAGE

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No.
Submission Date:

1. IRB RESEARCH PROPOSAL - COVER PAGE

Title of Proposal: A Randomized Controlled Trial on the Application of Artificial Intelligence (AI) in Skin Assessment for Pressure Injury Prevention and Staging by Critical Care Nurses	**Duration of Study:**

2. DEPARTMENTAL APPROVAL

Title of Proposal: A Randomized Controlled Trial on the Application of Artificial Intelligence (AI) in Skin Assessment for Pressure Injury Prevention and Staging by Critical Care Nurses

Approval - Departmental Research Committee:

The Committee has reviewed this proposal and attests to its scientific validity.

Departmental Research Committee Designee	Signature	Date

Approval - Department Head(s):

I have reviewed this proposal and approve the participation of the concerned personnel of my department in it.

PARTICIPANTS	DEPARTMENTAL CHAIRMAN /UNIT HEAD	SIGNATURE

Declaration of Conflict of Interest:

All investigators must declare any potential conflict of interest with respect to this research proposal. The presence of such conflict of interest must be explained (see below). The lack of such declaration by investigators involved with this proposal is taken as evidence of the absence of any conflict of interest.

Conflict of Interest:

NAME	SIGNATURE	EXPLANATION

3. ABSTRACT

Should not exceed 200 words and should include:

- *The importance of the research topic*
- *The research hypothesis, question or statement, specific objectives and the significance of the outcome*
- *OUTLINE the methods that will be used to accomplish the research specific objectives*

Background

Pressure injuries are a common issue in healthcare, especially in ICU patients due to immobility and critical conditions. Traditional skin assessments by nurses are effective but vary due to differences in skill and experience. This variability can impact early detection of pressure injuries. Using artificial intelligence (AI) in skin assessment offers promise by utilizing image recognition to identify high-risk patients, monitor skin changes, and suggest timely interventions.

Aim

The aim of this study is to examine the effectiveness and impact of AI-assisted skin assessments and PI staging in critical care settings, by comparing its accuracy, reliability, and nurses' confidence and knowledge with those of traditional assessment methods employed by critical care nurses.

Methods

Experimental Research design, with a control and Intervention group will be followed. The setting will include the medical intensive care unit. Critical care nurses (91) will be randomized. Pre and post intervention data on the knowledge and confidence re skin assessment and pressure injury staging will be collected using

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tools that will be piloted. Control group nurses will assess the skin using standard self-assessment techniques, whilst the nurses in the intervention group will use an artificial intelligence app. A senior wound care expert will complete a third assessment which will form part of the verification process. The National Pressure Injury advisory Panel gudielesmes will be used for the assessment. Patients will be consent solely for the purpose of the skin assessment.

Conclusion

Understanding the burden of pressure injuries in ICU settings has prompted researchers and clinicians to explore innovative approaches for early detection and informed assessment

Keywords

Artificial intelligence, critical care, intensive care, nurses, pressure injurie

4. RESEARCH PROPOSAL

Title of Proposal: : **A Randomized Controlled Trial on the Application of Artificial Intelligence (AI) in Skin Assessment for Pressure Injury Prevention and Staging by Critical Care Nurses**

Introduction

May include background information related to the research topic (Importance of the topic), the purpose in carrying out this research, and the importance of potential (expected) findings.

Background

Pressure injuries (PIs) are among the most prevalent issues encountered worldwide in healthcare settings (Feuchtinger et al., 2007), yet they are largely preventable (Slawomirski et al., 2017). A meta-analysis estimates the global incidence of hospital-acquired pressure injuries at about 5.4 per 10,000 hospital patients per day (Li et al., 2020). While the global prevalence of pressure injuries in hospitalized adults is around 12% (Li et al., 2020; Rodgers et al., 2021), the prevalence of hospital-acquired pressure injuries typically ranges from 7% to 9% (Li et al., 2020; Rodgers et al., 2021). These injuries can lead to extended hospital stays, increased healthcare costs, and severely affect patient outcomes, leading to complications such as infections and prolonged pain (Gorecki et al., 2009). Resources required to treat PIs, including nursing time and incremental wound care costs, significantly burden healthcare systems. Treating broken skin PIs can cost healthcare organizations between $20,900 and $151,700 per injury (Bouyer-Ferullo et al., 2021). The

annual treatment costs to the US healthcare system associated with hospital-acquired pressure injuries (HAPIs) exceed $27 billion (Padula & Delarmente, 2019).

PIs are preventable complications acquired in healthcare settings (European Pressure Ulcer Advisory Panel et al., 2019) and are influenced by the quality of nursing care (Burston et al., 2014; Sim et al., 2018; Twigg et al., 2019). These injuries result in unnecessary harm, including pain, psychological distress, reduced quality of life, and, in severe cases, death (Gorecki et al., 2012; Jackson et al., 2017; Jackson et al., 2018; Kim et al., 2019). As a result, healthcare professionals, researchers, and safety experts have focused on strategies to prevent them. Numerous approaches to risk assessment and prevention have been explored (Beeckman et al., 2021; Lovegrove et al., 2021; McLaren-Kennedy et al., 2023). However, pressure injuries still affect approximately 8% of hospitalized patients (Li et al., 2020), with rates being higher in specific high-risk groups, such as the elderly (Rasero et al., 2015), critically ill patients (Labeau et al., 2021), and those with spinal cord injuries (Shiferaw et al., 2020).

ICU patients are particularly vulnerable to PIs due to their immobility and the critical nature of their health conditions (Jacq et al., 2021). The development of PIs in ICUs is a complex, multifactorial process that can be difficult to prevent (Labeau et al., 2021). Contributing factors such as neurological impairments, life-saving medical treatments, fluid resuscitation, vasoactive medications, and pathophysiological conditions that hinder repositioning all increase the risk of PI formation in ICU patients (Gefen et al., 2021). As a result, ICUs experience a higher incidence of PIs compared to other healthcare environments, placing significant physical, psychological, and financial strain on patients who are among the most critically ill in the healthcare system (Chaboyer et al., 2018).

Preventing HAPIs is a critical aspect of patient safety and quality of care, and is often considered an indicator of nursing care quality, as nurses are primarily responsible for assessing patients' risk for PIs and managing skin integrity. While prevalence is not an absolute measure, it serves as an outcome indicator (rather than a process measure) to reflect the quality of care provided. Previous research has indicated that nurses' knowledge of skin assessment, PI risk factors, and positive attitude toward prevention measures play key roles in reducing the incidence of PIs (Taliier et al., 2027).

However, research also indicates that nurses' knowledge about the prevention and treatment of pressure injuries (PIs) is not optimal. For instance, Gunningberg and colleagues (2012) assessed 415 healthcare professionals in Sweden (including RNs, nursing assistants, and student nurses) and found a mean score

of 58.9% on a test designed to evaluate PI prevention knowledge. Similarly, Karabag Aydin and Karadag (2013) studied 237 nurses in Turkey on their understanding and practices regarding deep tissue injury and stage 1 PIs, revealing a mean score of 48.85 out of 100. Sving and colleagues (2014) conducted a 1-day prevalence study involving 825 patients in both a university-based and community-based hospital in Sweden. They found that preventive interventions were implemented in 44.1% to 58.7% of patients at risk for PIs. A recent survey of 347 nurses attending the 2013 and 2015 Wound Management Congresses found a mean score of 57.37 ± 14.26 out of 100 on 27 items related to pressure injury knowledge and practices (Aydin et al., 2019).

Further, literature reveals limited evidence regarding the accuracy of nurses' skills and knowledge in PIs staging and documentation. A 2012 wound care study found that only 55% of 647 nurses could correctly identify the stages of PIs in their patients. Additionally, just 32% of respondents reported receiving adequate education on chronic wounds during their basic nursing training. In a quality improvement initiative led by Dahlstrom et al., aimed at enhancing the identification, documentation, and treatment of PIs, complete documentation (including stage, size, and location) improved from 29% to 46% after implementing a wound assessment form and point-of-care reminders. However, despite this improvement, more than 50% of the documented injuries were inaccurately recorded. These findings highlight ongoing challenges with nurses' ability to accurately stage and document pressure injuries.

Further, nurses' confidence in conducting skin assessments plays a crucial role in the early detection and prevention of pressure injuries (PIs). Studies show that confidence in performing skin assessments positively impacts nurses' ability to identify pressure injuries early and implement effective preventive strategies. For instance, when nurses feel confident in their skills, they are more likely to conduct thorough assessments and take timely actions to prevent pressure injuries (Stechmiller et al., 2011). Conversely, lack of confidence can lead to missed detections, delayed interventions, and increased risk of complications for patients (Bergstrom et al., 2019). Training and continuous education are key to enhancing nurses' confidence in skin assessment, ensuring that they feel capable of using assessment tools and applying clinical judgment accurately (Coleman et al., 2017). Furthermore, improved confidence has been linked to better patient outcomes, as nurses are more likely to engage in preventive measures such as repositioning and using pressure-relieving devices (Tawfik et al., 2020).

Preventing pressure ulcers has been a longstanding nursing concern, with Florence Nightingale noting in 1859 that bedsores were often a result of poor nursing rather than the disease itself (Nightingale, 1859).

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While some attribute pressure ulcer development to inadequate nursing care, many clinicians see it as a systemic failure involving the entire healthcare team, including nurses, physicians, physical therapists, and dietitians (AHRQ, 1992). Despite being a multidisciplinary responsibility, nurses play a major role in prevention. The 1992 guidelines from the U.S. Agency for Healthcare Research and Quality (AHRQ) continue to serve as a foundational resource for pressure ulcer prevention, highlighting key processes such as risk assessment, skin care, and patient education (AHRQ, 1992).

Comprehensive skin assessments are essential for identifying early skin changes, which can contribute significantly to preventing PIs (Mitchell, 2018; Shi et al., 2018). These assessments provide an opportunity to reposition patients, educate them about skin health, and implement protective measures (Moore & Paton, 2019). Several studies indicate that frequent comprehensive skin assessments can reduce the risk of developing PIs (Fischbein, 2023; Moore & Paton, 2019; Mitchell, 2018; Shi et al., 2018; Coleman et al., 2018; Hommel et al., 2017; Coyer et al., 2017; Reddy et al., 2006).

The National Pressure Injury Advisory Panel (NPIAP) staging system is a widely used framework for classifying the severity of PIs. This system helps healthcare professionals assess and document the extent of tissue damage in patients with pressure injuries, guiding treatment and management decisions. The NPIAP staging system classifies pressure injuries based on the severity of tissue damage. It includes Stage I, characterized by non-blanchable redness of intact skin, Stage II, involving partial-thickness loss of skin, Stage III, with full-thickness skin loss potentially extending into subcutaneous tissue, and Stage IV, where there is extensive damage to deeper structures like muscle or bone. The system also includes unstageable, where necrotic tissue, and Deep Tissue Pressure Injury (DTPI), marked by deep, non-blanchable discoloration or a blood-filled blister, obscure the depth. These stages help guide the assessment, treatment, and prevention of pressure injuries in clinical settings. (National Pressure Injury Advisory Panel, 2016).

Accurate staging of PIs is essential for effective nursing care management (García-Fernández, et al, 2014). However, other skin conditions, such as friction injuries, moisture-associated skin damage (MASD), incontinence-associated skin damage (IAD), and mixed-etiology wounds, which also cause skin inflammation, may present similarly to PIs, resulting in incorrect staging. This misclassification can lead to inappropriate treatment, especially in the case of MASD, which is often mistaken for stage 1 or 2 PIs (Beeckman et al, 2007; Ham et al, 2025).

Problem Statement
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Pressure injuries represent a significant clinical challenge within the ICUs where patients are often immobilized, have compromised skin integrity, and face numerous other health risks. These injuries can lead to extended hospital stays, increased healthcare costs, and severely affect patient outcomes, causing complications such as infections and prolonged pain (Gorecki et al., 2009). Despite existing preventive measures, hospital-acquired pressure injuries (HAPIs) remain prevalent, particularly among vulnerable populations like critically ill ICU patients who face additional challenges in preventing these injuries due to their complex medical needs. Furthermore, despite advancements in PI prevention protocols, the knowledge gap among healthcare professionals about PI risk factors, staging, and prevention strategies still exists, contributing to suboptimal outcomes. This highlights the need for continuous education and improved clinical practices to reduce the incidence of pressure injuries in healthcare settings.

Understanding the burden of pressure injuries in ICU settings has prompted researchers and clinicians to explore innovative approaches for early detection and informed assessment. Traditional methods of skin assessment, typically performed by nurses, have proven effective but are subject to variability in skill and experience among nursing staff. This variability can impact the accuracy of detecting early-stage pressure injuries, highlighting the need for more reliable assessment techniques (Labeau et al, 2021). Implementing artificial intelligence (AI) as a tool to assist in skin assessment and staging of pressure injuries holds great promise in addressing this challenge. AI-driven technologies, such as image recognition, can support clinical decision-making by identifying high-risk patients, monitoring changes in skin integrity, and recommending appropriate interventions in real time. By integrating AI into pressure injury prevention and management strategies, hospitals can improve patient outcomes, reduce the incidence and severity of HAPIs, and optimize resource utilization. Furthermore, AI can standardize wound care approaches, ensuring consistency in both assessment and nursing documentation. Ultimately, the integration of AI into these strategies can enhance patient safety and improve overall healthcare efficiency (Dweekat et al, 2024).

As of March 2025, AI tools for pressure injury assessment are gaining traction in healthcare settings due to their potential to improve patient care and clinical efficiency. AI models have demonstrated significant improvements in accuracy and efficiency, with deep learning-based models achieving 74% Intersection over Union (IoU) and 83% accuracy for wound bed segmentation, outperforming the Braden Scale's 54% accuracy (Keller, 2024). These tools also save time, with AI systems reducing wound assessment time and potentially saving up to 250 labor hours per day in a 500-bed facility (Keller, 2024). Additionally, predictive

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AI models have shown a 20% improvement in predicting patients at risk of pressure injuries, with an accuracy of over 74% (Keller, 2024). Despite not being universally adopted, AI adoption is expanding, with hospitals and research institutions actively developing AI-powered systems (Liu et al., 2025; Keller, 2024; Alderden et al., 2024). The AI wound care market is projected to grow from $3.32 billion in 2025 to $7.65 billion by 2030 (Kronikare, 2025). However, challenges remain in integrating AI tools, including data privacy, algorithm training, and equitable access (Liu et al., 2025; Keller, 2024).

AT THE CURRENT INSTITUTION, WITHIN THE CRITICAL/INTENSIVE CARE UNITS

As illustrated in Figure 1, the organization recorded 150 cases of stage two and above HAPIs in 2024. Of these, 76 cases (51%) occurred in the critical care setting. The cost for a one-day stay in the MSICU is 8,300 SR, excluding additional procedures. The cost of wound or pressure injury dressings varies depending on the consumables used for each patient. However, based on the average cost for a medium-sized dressing with twice-daily changes, the daily cost per patient is approximately 200 SR.

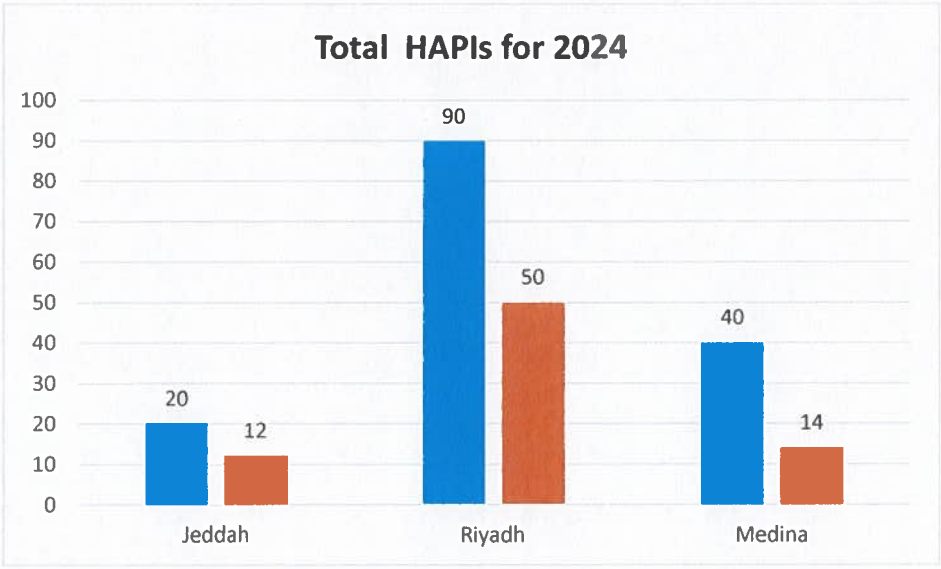

Figure 1 : Total HAPIs for 2024

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Conceptual Framework

This study will be guided by the Donabedian's Model of Quality Care which focuses on three key components: structure, process, and outcome:

This model emphasizes that high-quality healthcare requires optimal structure, effective processes, and positive outcomes, providing a comprehensive approach for evaluating and improving healthcare services.

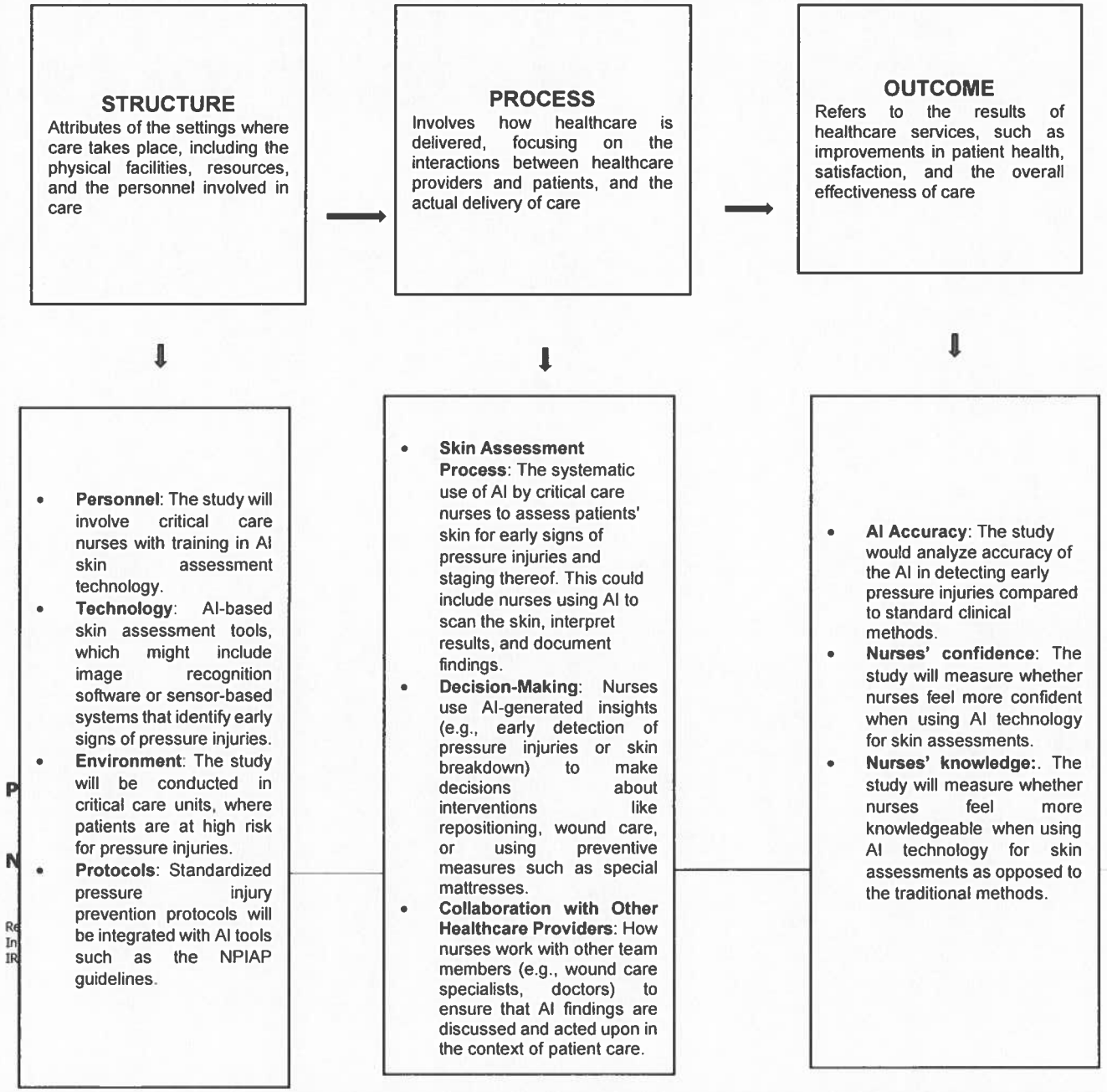

Figure 2: Donedebian's Framework of Quality Care (Donabedian,1988)

Aim

The aim of this study is to examine the effectiveness and impact of AI-assisted skin assessments and PI staging in critical care settings, by comparing its accuracy, reliability, and nurses' confidence and knowledge with those of traditional assessment methods employed by critical care nurses.

Objectives

- To evaluate the accuracy and reliability of AI-assisted assessments and PI staging in comparison to standard assessments by critical care nurses.
- To assess nurse knowledge and confidence in using AI for skin assessment and PI staging versus comparison to standard assessments by critical care nurses.

Research Hypothesis

H1

AI-assisted skin assessments and pressure injury staging will demonstrate greater accuracy and reliability compared to standard assessments by critical care nurses.

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Methodology

May include: 1. Inclusion Criteria and Exclusion Criteria, which will be used in selecting the research participants; 2. Registration, 3. Randomization Process, 4. Data gathering methods, 5. Procedures, Designated Central Laboratories, 6. Follow-up, 7. Safety and Efficacy Parameters, 8. Expected Outcome, 9. Sample Size, and 10. Statistical Methods.

Methodology

Research Design

The study will follow a basic experimental research design- pre post-test design.

Research Setting

The research setting will include the Medical Surgical Intensive Care (MSICU) at King Faisal Specialist Hospital and Research- Center- Jeddah. MSICU is an 18-bedded unit, which houses patients who are requiring intensive care for conditions such as :

- All critically ill Medical patients requiring intensive care or observation.
- Respiratory failure, cardiac failure, liver failure and/or renal failure.
- Critically ill Hematology/Oncology, Immuno-compromised patients.
- •Shock (Cardiogenic, Septic, Anaphylactic, Neurogenic).
- Neurological cases – ischemic or hemorrhagic pathologies

Population

The study will include critical care nurses. Table 1 below provides information re the breakdown of the total number of nurses:

Job Title	Occupied
STAFF NURSE III	2

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STAFF NURSE I	86
NURSE CLINICIAN	1
NURSE CLINICIAN	1
Total	90

Sampling technique and sample size:

All critical care nurses who are eligible and who consent to participate will be included for a possible total of up to n=90. The study will focus on one ICU initially (the MSICU) to assess feasibility of the proposed methods. A simple random sampling approach will be followed for allocation into the control (n=45) and intervention group (n-46).

Inclusion criteria

- Nurses working within the organisation for at least 6 months
- Nurses involved in direct patient care for over 50% of their work time.
- Skin assessments and staging for patients at risk for developing pressure injuries (Using the Braden Scoring system).
- Adult Patients (18 years and older)
- Patients who are currently admitted to the ICU and are receiving critical care treatment.
- No current severe skin conditions patients without active severe dermatological conditions (e.g., large open wounds, severe rashes) that would interfere with the AI-based skin assessment process.

Exclusion criteria

- Nurses working within the organization for less than 6 months
- Nurses involved in direct patient care for less than 50% of their work time
- End-of-Life Care or Terminal Illness- patients receiving end-of-life care or those with a terminal diagnosis, where the prevention of pressure injuries may not be a priority and where participation in the study may not align with their care goals.

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- Severe or active dermatological conditions- patients with active skin conditions such as severe rashes, burns, or other dermatological issues that could interfere with accurate skin assessments by AI or confound the study results.
- Recent Skin Grafts or Advanced Wound Care- patients who have recently undergone skin grafts or those receiving complex wound care treatments that are outside the scope of typical pressure injury prevention practices.
- Inability to Maintain Required Positioning for Skin Assessment- patients who are physically unable to remain in the necessary position for the skin assessments, either due to severe mobility restrictions or critical medical conditions.

Current practice

At KFSHRC, nursing staff in critical care areas follow a standardized skin assessment protocol aligned with the National Pressure Injury Advisory Panel (NPIAP) standards for pressure injury prevention, as outlined in hospital policy (CIPP-3818: Pressure Injury Prevention and Skin Integrity Maintenance). A comprehensive head-to-toe skin assessment is conducted within the first two hours of patient's admission, transfer, or the beginning of each shift, using visual inspection to evaluate skin integrity and identify early signs of pressure injuries. The Braden Scale, a validated tool for pressure injury risk assessment, is used for all patients aged 18 years and older. A Braden score of ≤18 indicates increased risk, requiring appropriate preventive measures. High-risk areas, including the sacrum, buttocks, heels, occipital region, and elbows, receive special attention during assessments. For patients identified as at risk, skin assessments are performed at least every two hours during repositioning, in addition to a daily pressure injury risk assessment documented in the Integrated Clinical Information System (ICIS). The frequency of assessments is increased in response to clinical deterioration or newly identified risk factors, such as hemodynamic instability, impaired mobility, moisture-associated skin damage, decreased perfusion, or compromised nutritional status. If a pressure injury is identified, it is documented in ICIS, and patients with Stage 2 or higher injuries are referred to the Wound Care Specialist or Nurse champion for further evaluation, staging, and treatment recommendations. By adhering to the evidence-based hospital protocols, this systematic approach ensures early detection of pressure injury risk and timely implementation of preventive interventions, promoting patient safety and skin integrity in critical care settings.

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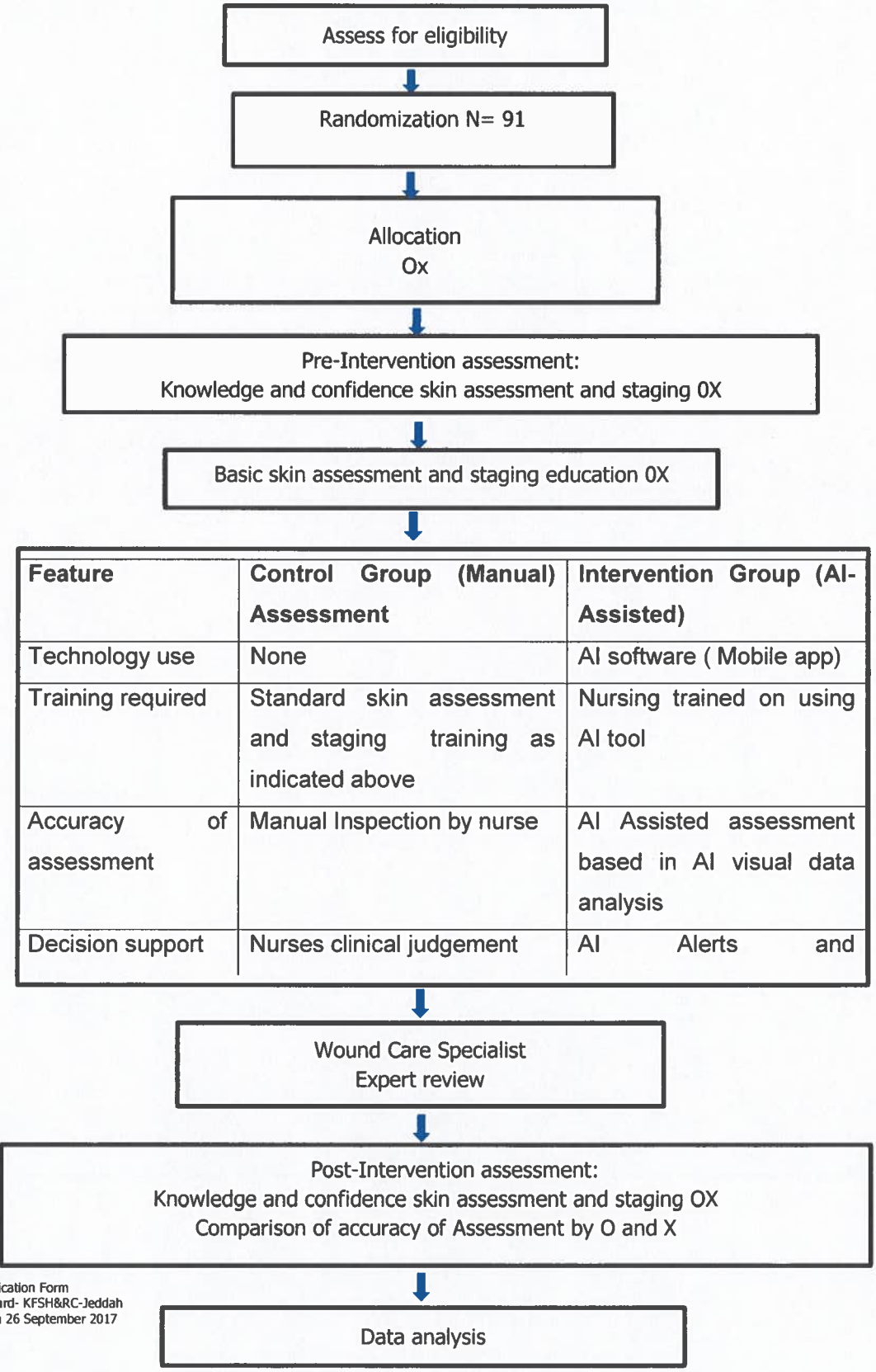
Intervention – See below flo



Feature	Control Group (Manual) Assessment	Intervention Group (AI-Assisted)
Technology use	None	AI software (Mobile app)
Training required	Standard skin assessment and staging training as indicated above	Nursing trained on using AI tool
Accuracy of assessment	Manual Inspection by nurse	AI Assisted assessment based in AI visual data analysis
Decision support	Nurses clinical judgement	AI Alerts and

Principal Inve

Name (print)

Expert assessment:

In this randomized controlled trial, the wound care expert responsible for evaluating the outcomes will be blinded to the study group assignments to prevent any potential bias. The expert will independently assess the skin, which will be de-identified and presented without any information regarding whether the assessments were conducted using the AI tool or through traditional methods by the critical care nurses. This ensures that the wound care expert's evaluation is based solely on the clinical characteristics of the skin, without influence from the method of assessment. By performing her own independent assessment, the expert maintains objectivity, allowing for an unbiased comparison of the nurses in the intervention and control group in pressure injury prevention.

Pre-education on skin assessment

1. To enhance nurses' proficiency in using a structured risk assessment approach—such as the Braden Scale—within 2 hours of admission, every 12 hours, or upon a change in condition, considering additional risk factors, and implementing individualized care plans based on the overall risk assessment and Braden subscales to effectively prevent pressure injuries.
2. To equip nurses with the skills to perform comprehensive skin assessments—using visual inspection and palpation—upon admission, transfer, and every shift, focusing on identifying erythema, discoloration, edema, and temperature changes across all bony prominences and during every patient turning, ensuring timely interventions and accurate documentation for pressure injury prevention.
3. To equip nurses with the skills to perform specialized skin assessments for diverse patient populations, including techniques for assessing patients with dark skin tones, monitoring skin under medical devices, confidently staging pressure injuries, and ensuring timely interventions for pressure injury prevention.
4. To enhance critical care nurses' knowledge and skills in utilizing Artificial Intelligence (AI) tools for accurate skin assessment, early detection, accurate staging, and effective prevention of pressure injuries.

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Choice of Artificial Intelligence Tool:

ChatGPT will be utilized in this research project specifically to assist in the skin assessment of the intervention group, where critical care nurses will use AI tools to evaluate pressure injuries based on the National Pressure Injury Advisory Panel (NPIAP) guidelines. The NPIAP guidelines provide a standardized approach to assessing pressure injuries, including identifying stages of injury, determining tissue damage, and evaluating risk factors. ChatGPT will assist in reviewing and synthesizing the NPIAP guidelines to ensure that the AI tool is being used in alignment with current best practices for pressure injury assessment. The model will also help analyze the AI-assisted skin assessment results, comparing them to NPIAP standards to evaluate the tool's accuracy in identifying the severity of pressure injuries, determining the proper staging, and ensuring proper documentation of skin conditions. By using ChatGPT, the research team can efficiently analyze the AI's effectiveness in applying NPIAP criteria for accurate and consistent skin assessments.

To standardize the use of cameras in the current research study particularly when using the camera for image capturing consistent camera specifications such as, lighting, and positioning will be maintained. Different phone models will be used, hence their performance will be tested to ensure consistency. Photos will be taken under controlled lighting conditions, with established positioning guidelines to maintain the same distance, angle, and orientation for each shot, potentially using a tripod or stand for consistency. Additionally, a standardized camera app will be used across all devices to ensure uniform settings. Training for all personnel involved in the study is essential to ensure adherence to protocols, and regular testing and validation of images will be conducted to ensure quality is maintained. Clear protocols for storing and labeling images will be used and is necessary for proper tracking and analysis for the use of the AI. The study team will ensure that at least three cellphones will be provided to the unit, to avoid any personal cellphones being used so that personal phones are not used.

Data collection

Data will be collected by:

1. **A questionnaire :**

Section 1: Demographic section of participants

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Section 2; **The Pressure Ulcer Prevention Knowledge Assessment Instrument (PUPKAI)** is a tool designed to assess knowledge on preventing and recognizing pressure ulcers through multiple-choice questions. It can be used in a self-report or interview format and consists of 26 items organized into six themes: Aetiology and Development (6 items), Classification and Monitoring (5 items), Risk Assessment (2 items), Nutrition (1 item), Preventive Interventions to reduce pressure/shear (7 items), and Preventive Measures to reduce pressure duration (5 items). Each item has three response options, with one correct answer. The highest possible score is 26, and a score of 16 (60%) is considered proficient (Beeckman, et al, 2010)

The psychometric properties of PUPKAI have been evaluated. Beekman et al (2010) reported good internal consistency (Cronbach's alpha = 0.77) and strong test-retest reliability (intra-class correlation = 0.88). The content validity index ranged from 0.78 to 1.0. However, differences were noted in the test's performance across different groups, indicating variations in known-groups validity. Item difficulty ranged from 0.27 to 0.87, and discrimination values ranged from 0.29 to 0.65. The original version has been widely used in studies (Shouli et al, 2024; Dirgar et al, 2022; Liu et al, 2017).

Section 3: **Skin Assessment Confidence Scale (SACS)** is a tool designed to assess the confidence levels of nurses in performing skin assessments related to pressure injury prevention. It provides a structured way to measure nurses' self-reported confidence in various key tasks such as identifying early signs of pressure injury, using risk assessment tools, recognizing different stages of pressure injury, and implementing preventative measures. Each item is rated on a 5-point scale (1 = Not Confident, 5 = Very Confident), with a total score that reflects overall confidence. Scores range from 10 to 50, with higher scores indicating greater confidence:

- Total Confidence Score: Add the scores for all 10 questions.
  - 10-20: Low Confidence
  - 21-30: Moderate Confidence
  - 31-40: High Confidence
  - 41-50: Very High Confidence

The SACS was self-developed and will be piloted with nurses from other intensive care areas namely SCIU, CCU, MICU, SICU-for an acceptable reliability coefficient of ≥.60. In addition, a Test-Retest method will be

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included which will include administering the scale to a group of nurses at two different time points (e.g., one month apart) to assess the stability of the scale over time. A high correlation (e.g., above 0.8) between the two sets of responses would suggest good test-retest reliability. There will be no significant interventions (like training or skill development) take place between the two testing points that might affect participants' responses.

Content validity was ensured by consultation with subject matter experts: Wound Care Specialists, and Wound champions with the current organization who reviewed each item to ensure it accurately reflects the necessary skills and knowledge for skin assessment and pressure injury prevention. These experts were asked to rate each item for relevance to the domain of skin assessment and pressure injury prevention on a Likert scale (e.g., 1 = Not Relevant, 4 = Very Relevant). Items with low relevance scores was revised or removed.

3. **Skin Assessment Checklist** : NPAIP

See supporting documents attached

Data analysis

Continuous variables will be assessed for distribution by comparing median and mean values, by observing skewness, kurtosis, and results from normality tests, and by observing the data graphically. Univariate results will be presented according to distribution of the data as mean ± standard deviation or median (interquartile range) and categorical variables will be represented with frequencies. PUKAT tool results will be scored as previously described (Beeckman, et al, 2010) and SACS will be scored as indicated once scale reliability is confirmed. Bivariable analyses will be used to compare demographics, survey results, and wound assessment between study groups using Chi-square and Fisher's exact tests and Student's t-tests or the non-parametric equivalent as applicable. Agreement between study group assessments and the assessment of the wound care specialist will be analyzed using interrater reliability and Kappa statistics. Survey results from pre and post the education assessment will also be compared using correlation analysis and/or paired t-tests for results within study groups and independent sample t-tests between study groups

Ethical considerations

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Patients

Even though patients will not be randomized into the control and experimental groups, patients will be used in the assessments by nurses included in the study.

Informed Consent:

Patients will be provided with clear, comprehensive information about the study, including its purpose, the use of AI, and potential benefits and risks. They will be informed about their rights to withdraw from the study at any point without any negative impact on their medical care. For patients who are unable to give consent (e.g., unconscious or critically ill), a legally authorized representative should be asked to provide consent on their behalf.

Confidentiality:

All patient data, including AI-assisted skin assessment images and personal health information, will be kept confidential and stored securely in compliance with hospital policies.

Non-Maleficence (Do No Harm):

The AI system will be tested and proven to be safe, and all care should be provided in a way that prevents harm. No unnecessary risks should be introduced to patients, and the system should be monitored for any adverse effects throughout the study.

Justice (Fair Treatment):

Patients must be selected based on clear, appropriate criteria, ensuring that no groups are unfairly excluded or overrepresented. All patients should have equal access to the benefits of the study, and no one should be unfairly disadvantaged by the use of AI in skin assessments.

Respect for Autonomy:

Patients will retain their right to make informed decisions regarding their participation. They should understand that their participation is entirely voluntary and can be withdrawn at any time without affecting

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Nurses

Informed Consent and Autonomy:

Nurses involved in the study will receive clear, detailed information about the study's goals, the role of AI in skin assessments, and the expected outcomes. They should have the opportunity to voluntarily agree to participate in the study. Like patients, nurses also have the right to withdraw from the study at any time.

Training and Competence:

Nurses will be trained to use the AI system effectively. This includes understanding how to incorporate AI-driven assessments into their clinical practice, interpreting AI-generated results, and knowing when human intervention is needed. Ongoing education should be provided to ensure they remain confident and capable in

Justice (Fair Treatment):

Nurses should be involved in the study equally and fairly, with no discrimination. They should have equal access to training and resources related to the AI system, ensuring a level playing field across the clinical team.

Accountability:

Nurses must remain accountable for their actions and decisions when using AI tools. While AI can provide valuable insights, nurses are responsible for ensuring that the final clinical decisions, particularly in patient care, are made by considering the full context and not solely relying on AI-generated assessments.

Workload Considerations:

The introduction of AI should not place undue burden on nurses. It is essential that AI tools are designed to support nurses in their role, reducing workloads where appropriate, and not adding additional complexity or stress. It is critical that AI tools be implemented in a way that enhances workflow efficiency without overwhelming staff.

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

Confidentiality:

No identifying information will be collected for nurses.

5. WORK PLAN AND RESPONSIBILITIES

Detailed description of the protocol work plan is mentioned in the original documentation. Please refer to the submitted documents. The following Table summarizes the job responsibilities of involved members:

Task	Investigator(s)
Conceptualization of the idea	
Writing of the research proposal	
Confidence Scale Validation	
Accessing IRB Approval	
Collection of data	
Analysis of the data	
Write up of findings	
Complete the discussion	
Drafting of the manuscript	

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

6. REFERENCES (comprehensive literature review)

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Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

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Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

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Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

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Name (print) _____ **Signature:** _____ **Date:** _____

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Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

7. BUDGET SHEET

PERSONNEL (NAME)	POSITION ON PROJECT	% TIME	GR/STEP	YEAR 1	YEAR 2
A) total for personnel:				SR	SR

EQUIPMENT *(use separate sheet if required)*	YEAR	
B) total for equipment:	SR	SR

SUPPLIES AND MATERIALS *(use separate sheet if required)*	YEAR	
C) Total for materials and supplies:	SR	SR

other expenses *(use separate sheet if required)*		AMOUNT	
category	purpose		
D) Total for other expenses:		SR	SR

TOTAL BUDGET (A → D)	SR	SR

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

Suggested Sources of External Funding

Company	Address	Relationship to research proposal
None		

8. Pharmacy Information Sheet *(page 1 of 2)*

Title of the Proposal:

IRB #: (if available) _____ **Principal Investigator:** _____

Drug Name										
	ROU	EXP	ROU	EXP	ROU	EXP	ROU	EXP	ROU	EXP
Dose										
Administration Route										
Administration Frequency										
Length of Treatment										
Drug Status*										
Number of Patients										
Provider: Hospital or Sponsor (Identify sponsor)										
Total Drugs Required (Pharmacy will calculate)										
(For Pharmacy Use) medication Cost	Rou	Exp	Rou	Exp	Rou	Exp	Rou	Exp	Rou	Exp
Research Pharmacist time					_____ (hrs) X		_____ SR/hr		= SR _____	

2 If this is a randomized study, who is responsible for Randomization?

_____

3 Over what period of time do you intend to accrue the patients?

* The Pharmacy Department must seek approval through the MOH in order to import drugs. Approval of the proposal by the IRB does not guarantee that the drugs will be approved by the MOH. Being a registered or

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

investigational drug in any of the five reference countries (USA, Canada, UK, Sweden, Saudi Arabia) would help in obtaining MOH approval.

Please use the following abbreviations: **HF** – on Hospital formulary; **MOH** – registered by the Saudi Ministry of Health; **USA** – registered in USA; **CA** – registered in Canada; **UK** – registered in UK; **SW** – registered in Sweden; **USAI** – being investigated in USA; **CAI** – being investigated in Canada; **UKI** – being investigated in UK; **SWI** – being investigated in Sweden.

PHARMACY INFORMATION SHEET (page 2 of 2)

Title of the Proposal:

IRB#: (if available) _____ **Principal Investigator:** _____

This part is to be completed by the Pharmacy Department:
(Check (✓) appropriate box(es) and complete)

☐ The Pharmacy Department has assigned a Research Pharmacist to provide information and assistance in the conduct of this proposal. If you have any questions, please call the Office of the Institutional Review Board at extension 2984.

The Pharmacy department will provide the following:

I. Drug keeping and dispensing
II. Preparation of Drug
III. Drug Information (physician, nurse, pharmacist, *etc*)
IV. MOH permit for import, release from customs
V. Patient counseling for drug information, compliance, medication handling, and return of unused products (if required)
VI. Maintain and submit to IRB, upon completion/termination of the study, investigational drug records of:
    (a) inventory, delivery to KFSH&RC: Date, amount, lot #, expiration date, *etc.*
    (b) use by each study subject
VII. Follow the trial randomization procedure
VIII. Supply the drugs listed on page 1 of this form

☐ Pharmacy Department will be happy to provide the above, provided the following issues have been satisfactorily addressed:

1.
2.
3.

☐ The Pharmacy Department will not be able to assist with this project due to the following:

_____

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

_____

_____

☐ Total Pharmaceutical cost (routine care) _____ *SR* Total Pharmaceutical cost (experimental) _____ *SR*

9. BIOLOGICAL HAZARDS

Title of the Proposal:

Does the proposed research involve any toxic chemical?

1. **Please name chemicals and describe the nature of the hazard involved:**

_____

_____

2. **Does the proposed research involve any hazardous micro-organism?**

If yes, name the organisms and describe the nature of hazards expected.

_____

_____

Also describe facilities, safety measures and procedures to protect personnel and environment.

_____

_____

3. **Does the proposed research involve radioactive materials?**

If yes, describe the materials, half-life and methods of disposal and personnel protection.

_____

_____

4. **Does the proposed research involve recombinant DNA?**

This form page completed by:

NAME (PRINT) _____ SIGNATURE: _____ DATE: _____

APPROVED BY: _____ SIGNATURE: _____ DATE: _____
(Head of Pharmacy Department)

Describe the nature of genes to be cloned, organisms and plasmids to be used.

_____

_____

10. Informed Consent

- ☐ for research involving the administration of drugs, use of devices or performance of procedures
- ☐ for research with no direct benefit to participant

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____