**An-Najah National University**

**Institutional Review Board (IRB)**
**Application Form**

Please complete this application for any research involving human subjects conducted only under the auspices of An-Najah National University (NNU), by or under the supervision of any faculty or staff, including students projects under supervision of researchers affiliated to NNU. For guidance, consult the IRB office or refer to local regulations and guidelines.

**IRB Application Checklist**

Before submitting, please ensure that you:

1. Have completed the required IRB training and attached your certificate(s)
2. Filled out every section of this form, or marked it as "N/A" where not applicable
3. All necessary information are provided clearly and transparently for review
4. All required appendices are attached
5. The application has been approved by the principle investigator
6. The application is submitted by the principle investigator or co-investigator who is a full-time academic staff at An-Najah National University

**Please be advised that:**

* Incomplete applications are not going to be processed.
* Applications requiring full board approval may require longer time depending of the scheduale of the full board meetings.

**Please do Not include this cover page in the submitted application**

**An-Najah National University**

**Institutional Review Board (IRB)**
**Application Form**

**For official use only**

**Ref. Number:** Click or tap here to enter text. **Date received:** Click or tap here to enter text.

1. **Cover page**

**Title of Research Project**:

Comparison of the Effects of Haloperidol versus Dexmedetomidine on Agitation among Non- intubated Patients with Traumatic Brain Injury, An Observational,

Prospective Study

**Applicants Information**

* **Principal Investigator (PI)/Main supervisor**:
* **Title and Full name**: Dr. Fatima Hirzallah
* **Employee ID number:** 2514
* **Department**: nursing and midwifery
* **Faculty**: medicine and health sciences
* **University:** An-Najah National University
* **Contact Information: Email fatimahirzallah@najah.eduPhone**: 0599149318
* **Co-Investigators:**
* **Role:** (Check one)

[x]  Co-Supervisor

[ ]  Student

[ ]  Collaborator

* **Title and Full name**: Dr. Tawfeq Abu Eisha
* **Employee ID number:** Click or tap here to enter text.
* **Department**: Click or tap here to enter text.
* **Faculty**: Click or tap here to enter text.
* **University:** Click or tap here to enter text.
* **Contact Information: Email** **tawfeq.abueiasha@sah.ps** **Phone: 0599388668**
* **Co-Investigators:**
* **Role:** (Check one)

[ ]  Co-Supervisor

[x]  Student

[ ]  Collaborator

* **Title and Full name**: Nuha Abu Awad
* **Employee ID number:** 11952235
* **Department**: Medical and Health Sciences
* **Faculty**: Faculty of Graduate Studies
* **University:** An-Najah National University
* **Contact Information: Email** **noha.aboawad@sah.ps** **Phone: 0599642553**

Copy/paste the above section to include more co-investigators as needed

(Attach IRB training certificates for all listed personnel)

1. **Level of IRB Review Requested**

*(Check one according to the IRB Guidelines of An-Najah National University). Clarifying these terms upfront will save time by reducing incorrect submissions or requests for further clarification.*

[x]  Exempt Review: Minimal risk studies that fit into categories defined by 45 CFR 46 (e.g., educational research, surveys). See the guidelines for more information.

[ ]  Expedited Review: Studies involving no more than minimal risk, but which do not qualify for exemption (e.g., non-invasive clinical procedures). See the guidelines for more information.

[ ]  Full Board Review: Research that poses more than minimal risk to participants, such as clinical trials or studies involving vulnerable populations. (If chosen, describe risks justifying full review) See the guidelines for more information.

Click or tap here to enter text.

1. **Initial evaluation queries**
* The research can be classified as a prospective study

[x]  Yes

[ ]  No

* The research can be classified as a clinical trial

[ ]  Yes

[x]  No

* The researchers will collect blood samples from the volunteers

[ ]  Yes

[x]  No

* The researchers will collect biological specimens for research purposes by noninvasive means.

[ ]  Yes

[x]  No

* The research involves a collection of data from voice, video, digital, or image recordings made for research purposes.

[ ]  Yes

[x]  No

* Research investigates individual or group characteristics or behavior

[x]  Yes

[ ]  No

1. **Critical queries**
* The research includes testing new clinical uses, toxicity, or pharmacokinetics of already approved drugs or medical devices in human subjects.

[x]  Yes

[ ]  No

* The research includes testing the therapeutic and/or toxic effects of a plant on human subjects.

[ ]  Yes

[x]  No

* The research includes testing new clinical uses and/or toxicity of new (nonapproved) treatments/procedures/drugs/medical devices in human subjects.

[ ]  Yes

[x]  No

* The human subjects will be assigned randomly into different treatment groups.

[ ]  Yes

[x]  No

* The survey used in the research includes sensitive/stigmatic or embarrassing questions (e.g. illegal behavior, alcohol use, addiction, sex, AIDs..etc)

[ ]  Yes

[ ]  No

[x]  Not applicable

* The research involves genetic testing.

[ ]  Yes

[x]  No

* The research involves vulnerable populations *(children, elderly, pregnant women, prisoners, racial/ethnical minorities, Individuals with cognitive impairments, individuals with impaired decision-making capacity, Individuals in emergency situations or terminal illnesses)*

[ ]  Yes

[x]  No

1. **Research Purpose and Significance**
* **In one sentence, state the overall purpose of the study (max 25 words)**:

To compare the effects of haloperidol versus dexmedetomidine for the treatment of agitation in non-intubated patients with TBI in the ICU

* **Summarize previous work and the specific reasons for conducting this study (max 300 words) (include citations if relevant)**:

 For patients with traumatic brain injury (TBI) who are admitted to the intensive care unit (ICU), agitation is a common and difficult consequence. It may result in a higher risk of self-harm, disruptions to medical treatment, extended hospitalizations in intensive care units, and higher healthcare expenses. Therefore, improving clinical outcomes, guaranteeing patient safety, and promoting patient recovery all depend on effective agitation treatment (Feng, Zhao, and Wang, 2022).There are some insights into the effects of haloperidol and dexmedetomidine in terms of pharmacological therapy, but further studies are required to create thorough treatment guidelines. To better understand and treat agitation in TBI patients, the literature clearly shows a need for training programs, standardized evaluation instruments, and well-planned investigations. Through a methodical comparison of Haloperidol and Dexmedetomidine. This study will offer thorough proof of their safety and effectiveness in agitation management for non intubated TBI patients in the ICU. For patients suffering from traumatic brain injury (TBI), dexmedetomidine is the perfect sedative due to its advantageous characteristics, which include its brief duration of action, analgesic benefits, ease of arousability, and sympatholytic effects Several publications demonstrate its effectiveness and safety for patients with head injuries compare to haloperidol (Soltani et al., 2021). Even though these drugs are widely used, there is a dearth of research assessing their safety and effectiveness in the particular scenario of TBI-induced agitation in intensive care units. It is essential to comprehend how these medications affect patients differently to create evidence-based guidelines and improve treatment regimens. Through tackling these goals and despite the lack of study regarding this topic in Palestine.

1. **Study Participants and Recruitment**
* **Total number of participants** (Estimate): 60 patient
* **Check all that apply**:

[x]  Adults (18+ years)

[ ]  Children (under 18)

[x]  Specific health characteristics (specify): Trumatic Brain Injury Patients

[ ]  Specific gender: Click or tap here to enter text.

[ ]  Specific ethnicity/race: Click or tap here to enter text.

[ ]  Institutional affiliations: Click or tap here to enter text.

1. **Recruitment of Participants**
* **Recruitment methods** (Check all that apply):

[ ]  Flyers posted in public places (attach copy in the appendix)

[ ]  Emails (attach copy in the appendix)

[ ]  Announcements at public gatherings/classes

[x]  Recruitment through other methods (describe briefely in the box below):

Click or tap here to enter text.

* **Will there be any specific exclusion or inclusion criteria (e.g., gender, ethnicity)?**

**Inclusion Criteria**

1. Both male and female patient
2. Age above 18 years
3. Mild or moderate TBI (GCS = 9-15)

**3.8 Exclusion Criteria**

1. Allergy to haloperidol or dexmedetomidine
2. History of moderate to severe dementia; Parkinson’s disease; and brain injury
3. Chronic use of antipsychotic drugs
4. Long QT intervals (> 500 ms)
5. History of a malignant neuroleptic syndrome
6. Family history of dystonic drug reactions
7. Torsade’s de pointes syndrome
8. Pregnancy
9. Intubated patient on a mechanical ventilator (MV)
10. Both male and female patient
11. Age above 18 years
12. Mild or moderate TBI (GCS = 9-15)

**3.8 Exclusion Criteria**

1. Allergy to haloperidol or dexmedetomidine
2. History of moderate to severe dementia; Parkinson’s disease; and brain injury
3. Chronic use of antipsychotic drugs
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5. History of a malignant neuroleptic syndrome
6. Family history of dystonic drug reactions
7. Torsade’s de pointes syndrome
8. Pregnancy
9. Intubated patient on a mechanical ventilator (MV)
* **Will informed consent be obtained?** (Attach consent forms in the appendix)

[x]  Yes

[ ]  No

* **How will consent be obtained?** (Check one):

[x]  Signed consent form (submit a copy)

[ ]  Verbal consent (submit a copy)

[ ]  Waiver of written consent (Provide a justification in the box below). *Hint: A waiver of written consent may be granted when obtaining a signed consent form is impractical or would pose additional risk to the participant (e.g., in studies involving anonymous surveys on sensitive topics). In such cases, participants may give oral consent or implied consent (e.g., by completing an online questionnaire), or when verbal consent may be used for minimal-risk phone interviews where a signed document isn’t feasible.*

Click or tap here to enter text.

* Importnt: Ensure consent forms meet university and IRB guidelines.
* **Who will be interacting with the participants?** (check all that apply)

[x]  Principal Investigator

[x]  Co-Investigators

[ ]  Research assistants

[ ]  Other (Example: polling organization personnel) Describe in detail: Click or tap here to enter text.

[ ] There will be NO interaction with the participants- this is an analysis of pre-existing cleansed data. (IF YOU CHECKED THIS CHOICE, GO DIRECTLY TO SECTION 8.)

* **What will your interaction with participants entail?** (check all that apply)

[ ]  Administering questionnaires/surveys or conducting interviews in person.

[ ]  Administering questionnaires/surveys using the Internet. If chosen, you must attach a copy of the email solicitation you will be sending to potential participants.

[ ]  Check I certify I have attached a copy of the email solicitation I will use as an appendix.

[ ]  Conducting a focus group.

* *Note: If you are conducting a focus group, you must attach a script as an appendix that describes your general interaction with the participants and includes elements such as ensuring participants will only address each other by numbers/pseudonyms and the questions you will ask during the focus group.*

[ ]  I certify I have attached the script for conducting the focus group session as an appendix.

[ ]  Obtaining biometric data (List all types to be collected. Examples: height/weight)

Click or tap here to enter text.

[ ]  Obtaining biological specimens (List types to be collected. Examples: blood, urine, saliva)

Click or tap here to enter text.

* If you are obtaining biological specimens, you MUST check the following statement:

[ ]  **I certify that all specimen collection, including venipuncture and urine collection, will be performed by trained personnel using procedures recognized as standard, professional, legal and ethical medical practices.**

[x]  Other types of data collection interactions not listed above (describe):

The patients who meet the inclusion criteria will receive standard ICU care. Patients in the haloperidol group will be administered 2.5 mg of haloperidol intravenously every eight hours. Patients in the dexmedetomidine group will be given 0.5-0.8µg/kg of dexmedetomidine through intravenous infusion. Agitation levels will be assessed using the RASS scale.

* List and describe all EQUIPMENT you will use. *(Examples: “paper and pencil questionnaires; digital tape recorder; standard medical office standing scale; standard sterilized venipuncture equipment,* etc.”)

Paper questionnaire

**Paper and pencil questionnaires**

* Will you perform experimental manipulation or an intervention on the participants? *(An experimental manipulation or intervention is an activity you perform on participants designed to change a state or condition, such as teaching participants new knowledge or skills.)*

[x]  No, I am only collecting data from participants.

[ ]  Yes, and the experimental manipulation or intervention will consist of (describe):

Click or tap here to enter text.

[ ]  Not applicable

 (YOU MUST ATTACH A COMPLETE DESCRIPTION OF ALL EXPERIMENTAL MANIPULATIONS OR INTERVENTIONS YOU PLAN TO PERFORM AS AN APPENDIX)

1. **Data Collection Sites**
* **Location(s)** (Check all that apply):

[x]  Specific location(s) (e.g., clinic, community center): Provide complete address:

Specalized Arab Hospital -Nablus

* + Participants' homes

[ ]  Via the internet

[ ]  Pre-collected data (from another institution or researcher)

* If collecting data from specific locations (e.g., clinics, schools), submit letters of permission on official letterhead.
1. **Confidentiality and Data Security**
* **Will data be coded with pseudonyms or codes?**

[x]  Yes

[ ]  No

* **Will data collection tools contain any personal identifiers (e.g., names, student IDs)?**

[ ]  Yes

[x]  No

* **Who will keep the data?**

The student herself and co supervisor

* **How will data be stored?** (Check all that apply):

[x]  Locked file cabinet

[ ]  Password-protected computer

[ ]  Other (specify): Click or tap here to enter text.

* **Who will have access to the data?**

[x]  Only PI and co-investigators

[ ]  Other: Click or tap here to enter text.

* **How long will data be stored before being destroyed?** Click or tap here to enter text.
1. **Participant Risks and Benefits**
* **Potential risks** (Check one):

[x]  Minimal risks i.e. no greater than daily life, (describe in the box below): *Example:*There is minimal risk to participants, though they may experience mild emotional discomfort when answering questions related to personal health behaviors. We will offer participants the option to skip questions they are uncomfortable with

[ ]  More than minimal risks (describe in the box below): *Hint: In this section, describe any physical, psychological, social, or legal risks that participants might face due to their involvement in the study. Additionally, outline how you will minimize or manage these risks. Benefits could include personal health improvements, knowledge gained, or societal benefits*

No intervention

* **Measures to minimize risks**:
* **Will participants receive compensation or incentives?**

[ ]  Yes (describe): Click or tap here to enter text.

[x]  No

* **Potential benefits** (Check one):

[x]  Direct benefit to participants (describe):

For patients suffering from traumatic brain injury (TBI), dexmedetomidine is the perfect sedative due to its advantageous characteristics, which include its brief duration of action, analgesic benefits, ease of arousability, and sympatholytic effects. Several publications demonstrate its effectiveness and safety for patients with head injuries compare to haloperidol (Soltani et al., 2021

[ ]  Indirect benefit (enhancement of general knowledge):

Click or tap here to enter text.

[ ]  Not applicable

1. **Statement of Risk/Benefit Ratio**

[ ]  I certify that the potential risks in this study are outweighed by the potential benefits.
**PI initials**: Click or tap here to enter text.

1. **Appendices**

Attach the following documents where applicable, and check the box beside each submitted document.

[ ]  IRB Training Certificates

[x]  Consent Forms (if applicable)

[x]  Data Collection Tools (if applicable)

[ ]  Recruitment Flyers or Emails (if applicable)

[ ]  Script for conducting the focus group session (if applicable).

[ ]  Letters of Permission from the authorized personel at the data collection site (if applicable)

[x]  References

[ ]  Experimental Manipulations (if applicable)

1. **Declaration**

[x]  We hereby declare that the information provided in this application has been completed truthfully and to the best of our knowledge. We acknowledge that we are solely responsible for any inaccuracies, false information, or discrepancies in the submitted application and any supplementary documents.

1. **Signature Page**

*Electronic signatures are accepted for submissions. Researchers may use secure e-signature platforms such as Adobe Signor a scanned copy of their physical signature*

**Principal Investigator (on behalf of the research team):**

* + Name: Dr Fatima Hirzallah
	+ Department: Nursing and midwifery department
	+ Signature: Fatima Hirzallah
	+ Date: 11/5/2025

**Data coolection tool**

**Patient Code #**: ………………

**Randomize group** ( ) haloperidol ( ) Dexmedetomidine

**Section One: Demographic Characteristics**

1. Age, y
2. Gender,
3. APACHE II Score
4. GCS Score
5. RASS Score
6. Medical History

**Section Two: Assessment Score**

1. **Comparison of the Mean Score of Consciousness (GCS) in the Two Groups**

|  |  |  |
| --- | --- | --- |
| Time | Dexmedetomidine Group | Haloperidol Group |
| First day |  |  |
| Second day |  |  |
| Third-Day |  |  |
| Fourth Day |  |  |
| Fifth day |  |  |
| Sixth Day |  |  |
| Seventh Day  |  |  |

1. **Comparison of the Mean Agitation Score (RASS) of Patients in the Two Groups**

|  |  |  |
| --- | --- | --- |
| Time | Dexmedetomidine Group | Haloperidol Group |
| First day |  |  |
| Second day |  |  |
| Third-Day |  |  |
| Fourth Day |  |  |
| Fifth day |  |  |
| Sixth Day |  |  |
| Seventh Day  |  |  |

1. **Comparison of the Mean APACHE II Scores of Patients in the Two Groups**

|  |  |  |
| --- | --- | --- |
| Time | Dexmedetomidine Group | Haloperidol Group |
| First day |  |  |
| Second day |  |  |
| Third-Day |  |  |
| Fourth Day |  |  |
| Fifth day |  |  |
| Sixth Day |  |  |
| Seventh Day  |  |  |

 **Section Three: Observation and Monitoring**

1. Need for additional Sedation ( ) Yes ( ) No
2. Complication Observed: ( )Neurological deterioration

 ( ) Extrapyramidal Symptoms ( )Drowsiness ( )Seizure ( )ECG Changes ( )Bradycardia ( )Hypotension

**Section Four: Outcome measurement**

1. Total ICU LOS / day
2. Total Hospital LOS/ day
3. Final GCS Score
4. Final RASS Score
5. Discharge status ( ) Improved ( ) Stable ( ) Died

**Participant Information Sheet**

 

**جامعة النجـــــــــــــــــــــاح الوطنية**

**كلية التمريــــــــض والقبـــــــــالة**

**An –Najah National University**

**Faculty of**

**Nursing and midwife Department**

أنا الطالبة نهى عوض من كلية الدراسات العليا تخصص تمريض العناية المكثفة في جامعة النجاح الوطنية أقوم بعمل بحث علمي لغاية إتمام رسالة الماجستيروالتي هي بعنوان **مقارنة بين تأثيرات هالوبيريدول وديكسميديتوميدين على الهياج لدى المرضى غير الموصولين بالأنبوب والذين يعانون من إصابات دماغية رضحية، دراسة رصدية مستقبلية**

**Comparison of the Effects of Haloperidol versus Dexmedetomidine on Agitation among Non- intubated Patients with Traumatic Brain Injury, An Observational,**

**Prospective Study**

**ICUs Palestinian hospitals of Nablus City**

fjdh

**الهدف من الدراسة :**

 مقارنة تأثيرات هالوبيريدول مقابل ديكسميديتوميدين لعلاج الهياج لدى المرضى غير الموصولين بجهاز التنبيب والذين يعانون من إصابات دماغية في وحدة العناية المركزة**نوع الدراسة:**دراسة كمية سيتم تطبيقها على المرضى بطريقة عشوائية.

**مكان الدراسة : ا**لمستشفى العربي التخصصي

**العينة التي نجري عليها الدراسة :** 60 مريض تعرضو للإصابة على الدماغ واستدعت حالتهم الصحية الدخول لقسم العناية المكثفة وحصل معهم هياج ما بعد الإصابة وتكون اعنمارهم فوق 18 سنة

**الحالات المستثنية من الدراسة :**  عمر المريض اقل من 18 سنة وغير موجود بالعناية المكثفة

**الوقت الذي سنجري فيه الدراسة :** خلال شهر 5 و 6 من سنة 2025

**التأثيرات السلبية للمشاركة فيالدراسة:**لا يوجد تأثيرات سلبية متوقعة نتيجة المشاركة في الدراسة.

**سرية المعلومات :** لحمايةخصوصيتك سوف يتم تسجيل النتائج مع رمز سري دون استخدام الاسم ,الوصول الى هذه المعلومات يتم فقط من قبل الباحثة للدراسة والأفراد المرخص لهم . مع ذلك , تتم مراجعة سجلات الدراسة من قبل اللجنة الاخلاقية في جامعة النجاح الوطنية . ستتم مراقبة السجلات الخاصة بك ويمكن مراجعتها دون انتهاك السرية وأية بيانات يمكن ان تنتج عن هذه الدراسة لن تذكر اسماء المشاركين في الدراسة .

**المشاركة الطوعية/الانسحاب:**ان المشاركة في هذه الدراسة طوعية تماما يمكنك سحب موافقتك في اي وقت بالتواصل مع الباحثة.

**الاتصال للحصول على اجوبه على اسئلتك ومخاوفك أو شكواك :** اذا كانت لديك اي اسئلة ,مخاوف اوشكاوي , يرجى الاتصال بالباحثة على الارقام المدرجه على الصفحه الاولى من هذه الموافقة .

**الموافقة على المشاركة في الدراسة :** اعطي موافقتي بحرية على المشاركة في الدراسة .

**References**

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