AN-NAJAH UNIVERS

PROTOCOL FOR HUMAN SUBJECTS RESEARCH

##### NEW PROJECTS ONLY

### *Investigator’s Assurance*

### By submitting this protocol, I attest that I am aware of the applicable principles, policies, regulations, and laws governing the protection of human subjects in research and that I will be guided by them in the conduct of this research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

To apply for human subjects IRB review:

#### Download this New Projects IRB Protocol and save it on a floppy disk or on your hard drive. You may then open it, type in all requested information, save the file (please use your last name and New Project Protocol as the title: e.g., Musmar New Project Protocol), and send the file as an e-mail attachment, along with your informed consent letter(s), to the Institutional Review Board at

#### “ irb@najah.edu”.

It is essential that you answer all questions on this form since this is the primary source of information used by Board members to make their decisions. Also, only include information necessary to answer the questions. Please keep your responses as free of jargon as possible.

1. Please also send, by campus mail, all supporting materials that cannot be e-mailed (e.g., measures, permission letters from off-campus sites) to the IRB at An-Najah University, Nablus, Palestine. If your research requires review by the full Board, you will be so notified and asked to provide an additional 12 copies of the supporting materials.

***PLEASE DO NOT INCLUDE THIS PAGE WITH YOUR SUBMISSION***

REV 9/08

Office of the Institutional Review Board

***PLEASE BE SURE TO COMPLETE ALL SECTIONS***

# Current Date of Submission: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_28th of September,2018\_\_\_\_\_\_\_\_

*IRB office use only*: Date received in IRB office (stamp)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If this is a revision in response to an IRB Report of Action (ROA)-approval pending, indicate the date of the ROA: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Title of Research:Clinical Application of Acute Physiology and Chronic Health Evaluation (APACHE) II Score and Sequential Organ Failure Assessment (SOFA)**In an Intensive Care Units Among Palestinian Hospitals at Nablus City.

|  |
| --- |
| Principal Investigator: Shireen Weldali, Nervana Omariya, Raneen Jabareen, and Moheb Zubeede . |
| Department/School:An –Najah national University- Faculty of medicine and health sciences- Nursing and midwifery department . |
| Room # where mail can be sent [shireenweldali@yahoo.com](mailto:shireenweldali@yahoo.com)Phone : Shireen Weldali:0568771956, Nervana Omariya:0599335554, Raneen Jabareen:0597064861, and Moheb Zubeede:0568072755 |
|  |
| Other Investigator: Dr. Fatima Hirzallah |
| Department/School : An –Najah national University- Faculty of medicine and health sciences- Nursing and midwifery department . |
| Room # where mail can be sent [fatmaherzallah@najah.edu](mailto:fatmaherzallah@najah.edu) |
| Phone 0599149318 |
| \*\*Faculty Sponsor (for Student Research): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Department/School\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Room # where mail can be sent \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Phone \_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Student Street Address Jenin\_ Sanour** |
| **City Jenin State Zip** |
| Type of Research (please check): |
| Dissertation \_\_\_\_\_\_ (PLEASE NOTE: IRB review of dissertation research                                             requires  prior successful proposal defense.) **PhD Defense Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| Master’s Thesis \_\_\_\_\_ |
| Class project \_\_\_X\_\_ |
| all other projects\_\_\_\_\_ |
| X \*\* If the primary investigator is a student, check here to indicate that your faculty sponsor has read the entire application, including cover letters, informed consents, and data collection instruments, and asserts that this application is accurate and complete. |
| **Dates Human Subjects Portion of Research Scheduled: from: 28\9\2018 to 12\11\2018 .** |
| **Site(s) of Human Subject Data Collection: An-\_najah National university hospital , Rafidia Hospital and Al \_Arabi Hospital.**  (*NOTE: If sites are administratively separate from the University, please submit approval letters, or indicate when they will be forthcoming.)*  Funding Agency (if applicable):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_No funding\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

### I. NATURE OF THE RESEARCH

In the judgment of the Principal Investigator, this research qualifies for which of the following types of review:

**Review Type: exempt (category) x expedited (category) full Board[[1]](#footnote-2)**

## II. PURPOSE OF RESEARCH

#### *Briefly describe the objective(s) of the research (please keep description jargon free and use 100 words or less; the IRB will file this information in our descriptions of approved projects).*

Significance of the study:

Clinical assessment of disease severity is an important part of medical practice to predict mortality and morbidity in Intensive Care Unit (ICU). Many scoring systems have beendeveloped for ICUs. Scoring in ICUshas been often used for individual patient or group prediction and forevaluating and comparing the performance of different ICUs. The Acute Physiology and ChronicHealth Evaluation (APACHE) II and Sequential Organ Failure Assessment (SOFA) score could be reliable in predicting hospital mortality and length of stay (LOS), and in various ICU (Milic et al.,2009). These scoring systems provide gross estimate of mortality risks in ICUs patients.

The objectives of this study are to :

1-Apply APACHE II score and SOFA score among Palestinian hospitals at Nablus city.

2-Assess the efficiency of APACHE II score and SOFA score in determination of hospital mortality and ICU LOS among Palestinian hospitals at Nablus city.

**3**\_ Use findings to make APACHE& SOFA scores as a protocol in Nablus hospitals’ ICU

III. METHODS

**Approximate number of subjects**: \_50\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Subjects will be (check only if applicable):**

**minors (under 18)**

**involuntarily institutionalized**

**mentally handicapped**

**Describe in detail how the subjects will be selected and recruited:**

The study will be approved by the Ministry of Health and An-Najah National university's Research Ethics Boards. A prospective study will be conducted in ICUs to the previously mentioned hospitals in which we will have a sample 50 patients, alladult patients ICU admitted medical and surgical who aged 16 years or above who remained in the intensive care unit for more than 24 hours, were included in the study.The participants will be provided with information about the purpose, method,**confidentiality of the study, and** voluntary for participationthat they will be free to withdraw from the study. Researchers will contact ICU nurses and informs him / her, in both written and orally about the study(Participant information sheet Annex No. I).

**Describe exactly what will be done to subjects once they have agreed to participate in the project**:

At the beginning of the study, the researcher repeats the information and ask participants for consent to

participate in the study.Once the participant agreed to participate in this research, he/she will start to apply APACHE & SOFA scores on the patients in the ICU.

ICU nurses will be scored (APACHE II-1st day; SOFA-1st day) on admission of patient, according to the scoring forms; APACHE II will be calculated, as recommended in the reference literature, from 12 physiological variables, including: vital signs, physiological variables, neurological score, urine output, age, and comorbid conditions (Appendix1). SOFA score will be calculated according to its design that evaluates six major organsystems (i.e. cardiovascular, respiratory, renal, hepatic,central nervous system, and coagulation)(AppendixII).We will also collect data on gender, age, type of admission, type of discharge (alive/died) and length of stay(LOS)in days in ICU. After the scoring completed, we will analysis the data statistically.

**What incentives will be offered, if any? \_\_\_\_\_\_\_\_\_\_no\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

IV. RISKS/BENEFITS TO PARTICIPANTS

**Identify possible risks to subjects:**

(NOTE: These may be of a physical, psychological, social or legal nature. If subjects are vulnerable populations, or if risks are more than minimal, please describe what additional safeguards will be taken.)

No risks to the subjects, since no interventions will be introduced.

**What are the benefits and how will they be optimized?**

During this study number of benefits will be optimized:

1**-**Predict mortality rate among our hospitals in Nablus city, thus through applications of this scores in ICUs we could stratifying patient according to disease severity by detecting the relationship between the high score and the length of stay as well higher chances of mortality.

2- Cost benefits to the hospitals; through early predicting to mortality rate and ICU length of stay (ICU), due to limited health resources and an increase in thecost of health management.

**Do benefits outweigh risks in your opinion? Yes X No \_\_\_\_\_\_\_**

**Are there potential legal risks to the Principal Investigator or University? Yes No \_\_\_\_X\_\_\_**

## V. INFORMED CONSENT

|  |
| --- |
| *Describe how participants will be informed about the research before they give their consent. Be sure to submit with this protocol a copy of the informed consent/assent letter(s) you will use. Please prepare your informed consent letter at the 8th grade reading level or lower as dictated by the needs of the subjects. (See IRB website for required elements of an informed consent.)*  **Please see participant Information Sheet (Annex I)**. |

VI. PRIVACY/CONFIDENTIALITY

|  |
| --- |
| *Please describe whether the research would involve observation or intrusion in situations where subjects have a reasonable expectation of privacy. If existing records are to be examined, has appropriate permission been sought; i.e. from institutions, subjects, physicians? What specific provisions have been made to protect the confidentiality of sensitive information about individuals?*  IRB as the research involve human participants, it is necessary to follow strict ethical principles. The participants are asked to give their consent, and they are assured that information provided would not be used against them. They are also assured that their right of confidentiality and anonymity is protected . Anonymity is maintained by numbering the participants and by destroying the names attached to the numbers after the researcher went back to a few participants to validate the transcriptions. Confidentiality is assured by guiding against unauthorized access to the data****.****  ****Every participant in the study received an explanation about the purpose, confidentiality of the study.**** Please see participant Information Sheet (Annex I). |

(Annex I)

**Participant Information Sheet**



**An –Najah National University**

**Faculty of**

**Nursing and midwife Department**

**جامعة النجـــــــــــــــــــــاح الوطنية**

**كلية التمريــــــــض والقبـــــــــالة**

نحن طلبة دائرة التمريض والقبالة من كلية الطب وعلوم الصحة في جامعة النجاح الوطنية ، نقوم بعمل بحث علمي **لتطبيق نظامي اباتشي و صوفا في المستشفيات الفلسطينية في مدينة نابلس**

**Clinical Application of Acute Physiology and Chronic Health Evaluation (APACHE)II score and Sequential Organ Failure Assessment**(**SOFA) scores inPalestinian hospitals ICUs at Nabluscity**

**ICUs Palestinian hospitals of Nablus City**

fjdh

**الهدف من الدراسة :**

السعي وراء تطبيق نظامي أباتشي و صوفا في مستشفيات نابلس بناءً على فحوصات وتحاليل المريض وتطبيقه كبروتوكول يعكس مدة مكوث المريض في قسم العناية المكثفة وبناء على ذلك تم وضع فرضيات ليتم دراستها وانتظار الموافقة من حضرتكم ليتم جمع المعلومات وفحصها .

**نوع الدراسة:**دراسة كمية سيتم تطبيقها على المرضى بطريقة عشوائية.

**مكان الدراسة :** بعض مستشفيات نابلس ( العربي التخصصي , رفيديا الحكومي ,مستشفى النجاح الوطني الجامعي )

**العينة التي نجري عليها الدراسة :** 50 مريض اعمارهم فوق ال 16 عام , مدة مكوثهم في قسم العناية المكثفة لا يقل عن 24 ساعة , محولين مباشرة من قسم الطوارئ وليس من الاقسام الاخرى .

**الحالات المستثنية من الدراسة :**  عمر المريض اقل من 16 عام ,المرضى المحولون من قسم اخر ,مرضى الحروق , المرضى الذين لم تتجاوز مدة مكوثهم في القسم 12 ساعة .

**الوقت الذي سنجري فيه الدراسة :** انتظار الموافقة من وزارة الصحة ثم نبدأ بجمع المعلومات عن المرضى ,فحص الفرضيات وتحليل النتائج بعدها ستستمر الدراسة من لحظة موافقتك على المشاركة فيها الى حين انتهاء الدراسة من تاريخ 28\9\2018 وحتى 12\11\2018.

**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 الباحثين 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 احد الباحثين .

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

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

"نموذج الموافقة "

تحية طيبة وبعد :

نحن طلبة دائرة التمريض والقبالة من كلية الطب وعلوم الصحة في جامعة النجاح الوطنية نقوم بعمل بحث علمي عن :

Clinical application of APACHE and SOFA scores in Palestinian hospitals ICUs at Nablus

ومشاركتكم في تعبئة هذه الاستبانة عبارة عن موافقة للمشاركة في البحث مع العلم ان البيانات التي سيتم جمعها ، سيتم التعامل معها بموضوعية وسرية ، اذ لن يتم جمع أسماء المرضى وسيتم التعامل معهم بأرقام بيانية فقط ،كما وأن المعلومات لن تصل الا للباحث فقط ولن تستخدم الا لأغراض خاصة بالمشروع ، ويمكن الانسحاب من المشروع في أي وقت .

أسماء الطلبة القائمين على هذا البحث:

ومشاركتكم في تعبئة هذه الاستبانة رقم ( ) و هي عبارة عن موافقة للمشاركة في البحث مع العلم ان البيانات التي سيتم جمعها ، سيتم التعامل معها بموضوعية وسرية , اذ لن يتم جمع أسماء المرضى والممرضين وسيتم التعامل معهم بأرقام بيانية فقط ،كما وأن المعلومات لن تصل إلا للباحث فقط ولن تستخدم الا لأغراض خاصة بالمشروع ، ويمكن الانسحاب من المشروع في أي وقت .

التوقيع: التاريخ:

أسماء الطلبة القائمين على هذا البحث:

رنين جبارين 0597064861

056877195 شيرين ولد علي

نيرفانا عمرية 0599335554

محب زبيدي 0568072755

المشرف: د. فاطمة حرز الله .

**(Appendix 1)**

**Acute Physiology and Chronic Health Evaluation (APACHE) II score to predict hospital mortality**

[**ClinCalc.com**](http://clincalc.com/)**»**[**Critical Care**](http://clincalc.com/CriticalCare)**» Acute Physiology and Chronic Health Evaluation (APACHE II) Calculator**

Use the *worst* value for each physiological variable within the past 24 hours.

Patient code

Hospital department

Diagnosis

Gender

|  |  |
| --- | --- |
| Age | years |
| Glasgow coma score | GCS information |
| **Vitals** | |
| Temp | C or F Temperature information |
| MAP | mmHg |
| Heart rate | bpm |
| Resp rate | bpm |
| **Oxygenation** | |
| FiO2 | % FiO2 information |
| PaO2 |  |
| Arterial pH |  |
| **Chemistry** | |
| Sodium | mEq/L |
| Potassium | mEq/L |
| Creatinine |  |
| Acute renal failure | No Yes |
| **Hematology** | |
| Hematocrit | % |
| WBC | x 109/L |
| Severe organ system insufficiency or is immunocompromised **[Severe organ system insufficiency or immunocompromised information](http://clincalc.com/icumortality/apacheii.aspx#Definitions)** | No Yes |
|  | |

**(Appendix II)**

**SOFA Calculator**

**Sequential Organ Failure Assessment (SOFA) severity of illness score for hospital mortality**

[**ClinCalc.com**](http://clincalc.com/)**»**[**Critical Care**](http://clincalc.com/CriticalCare)**» Sequential Organ Failure Assessment (SOFA) Calculator**

Use the *worst* value for each physiological variable within the past 24 hours.

Patient code

Hospital department

Diagnosis

Gender

|  |  |
| --- | --- |
| **Respiration** | |
| FiO2 | % |
| PaO2 | mmHg |
| Mechanical ventilation | No Yes |
| **Coagulation** | |
| Platelets | x103/mm3 |
| **Liver** | |
| Bilirubin |  |
| **Neurological** | |
| Glasgow coma score |  |
| **Cardiovascular** | |
| MAP | mmHg |
| Vasopressors | No Yes |
| **Renal** | |
| Creatinine |  |
| Urine output |  |
|  | |

1. All research that is either externally funded or greater than minimal risk must be reviewed by the full Board [↑](#footnote-ref-2)