Northeast Ohio MEDICAL UNIVERSITY

NEOMED

Institutional Review Board
Expedited Review Approval

DATE: **September 26, 2023**
TO: Marc Basson, M.D., Ph.D., M.B.A.
FROM: Mehool Patel, M.D., NEOMED IRB Chair
SUBJECT: Approval of "Comparison of sleep and stress in medical students between American and Egyptian medical schools, and its effect on performance "
PROTOCOL #: 23-029

DETERMINATIONS/DECISION:

Please note evidence of IRB approval from the Faculty of Medicine of Alexandria must be obtained for involvement of their students as subjects in this study. Please provide documentation of review to the NEOMED IRB office as soon as available.

The NEOMED Institutional Review Board approved the above-mentioned minimal risk protocol on 09/26/2023 in accordance with human subject research regulations found at 45 CFR 46 for the expedited approval of the research category listed below:

☒Category 7- Individual or group characteristics or behaviors that are not exempt

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

As PI of the study you must provide the NEOMED IRB with an annual protocol check point. In September, 2024 you will receive an e-mail from the IRB asking a few short questions regarding the current status of your project. You may answer the questions by return e-mail. In addition to completing an annual check point, other responsibilities as PI of the study include:

- Conducting the project exactly as described in the approved IRB protocol.
- Ensuring that all study personnel are current in human subjects research on-line training.
- Reporting any unexpected or adverse events immediately to the IRB.
- Filing any changes to the protocol by completing an Amendment/Addendum Form.
- Maintaining research records as required. Records must be kept for a minimum of 3 years after completion of the study and may be audited at any time by the IRB.
- Informing the IRB should you wish to use the data for this project in any other projects.
- Closing your file with the IRB by filing a Study Completion Form as soon as the project is finished. All IRB forms may be found at https://www.neomed.edu/irb/forms/

Attached to this memo is the final approved protocol including the approved survey and consent. Please keep this packet with your research records. Protocol records must be kept for a minimum of 3 years after completion of the study and may be audited at any time by the IRB.

Prior to making any changes to this protocol, please submit an Addendum/Amendment Form for IRB approval. Changes which require addendum/amendment approval include, but are not limited to, the additional of new personnel, changes in the consent form, survey, or survey distribution methods.

1- **In response #9 (page 9) the word environmental is misspelled. On response to #11, sleep is misspelled. Please run this document through the editor program to eliminate spelling and grammarical errors. The pharase "We request to not include . ." (this is a split infinitive) should be phrased as "We request not to include . . . Additionally, the English spoken in Egypt is British English and there may be nuances of spelling that needs to be addressed though on review I could not find any directly.**
We apologize for any errors; we checked all the documents and corrected any spelling or grammar errors and highlighted them in yellow.

2- **On subject population choice, adults and students at NEOMED are chosen. Do we need to address other end-stage international medical students as well given the vast majority of the participants will be international students?**
We chose other as an additional option for this question added "medical students from Egyptian universities".

3- **On the survey, the time needs to be clarified if American standard time presentation or 24-hour time presentation. I suspect it will be different between American students and Egyptian students. I would recommend 24-hour time to be consistent and not misinterpreted for the study.**
In Egypt, they use the American time system not the 24hr system, so this should be fine as written.

4- **The numbering on the questionnaire is odd with the whole energy that is sequential and increasing versus each section which is then we number starting from one. Would eliminate the secondary numbering system as it is odd.**
When we extract the survey as a PDF, google forms automatically numbers the question, but in the actual survey using the link, these numbers won't be seen. The reviewer can see how the actual survey works by going to the following link:
Sleep and medical student - Google Forms

5- **Question 38.8—"top of things". This is a colloquial US phrase. Unsure that would be easily translated into Egyptian understanding. I would run through the questions and ensure that there is no other colloquial phrases that may be difficult to interpret by an Egyptian student.**
The phrase (and indeed the entire survey) was compiled and written by an Egyptian native and was reviewed by Egyptian professors who are collaborating with us as well as a noncollaborating Egyptian student, so we don't think Egyptian students who all speak English will have any trouble with this colloquial phrase.

6- **Question 82 states if they wish to be contacted leave an email. There is no line or field for the email.**
If the respondent selects "Yes" for the question about being recontacted again, the survey automatically takes the participants to the contact information section, where there is a place to

add their name and e-mail. The survey extracted in the form of pdf doesn't show this feature, but the reviewer can see how the actual survey works by going to the following link: Sleep and medical student - Google Forms

7- **On the consent page which is page 47 of this document, the word anxiety is capitalized and does not need to be. It is in the paragraph titled key information about this research.**
We apologize and have corrected this.

8- **Since this is being administered to students, please include in the Key Information section that participation in the study will in no way effect their academic standing.**
The point is well taken. We added "Participation in the study will in no way affect the student's academic standing." In the key section of the consent.

9- **Additionally, the consent form appears just to be for NEOMED students. Is this correct? If it supposed to be for Egyptian students, the contact information would be inappropriate as it is a US-based and not also Egyptian based contact options.**
The consent is for all students. We added the Alexandria Faculty of Medicine ethics' committee e-mail as a contact option on the consent for those wishing to contact other authorities in addition to the NEOMED IRB contact information.

10- **Please correct the spelling of the university on the advertisement. Northeast is one word.**
We apologize for the error and have corrected the name of the university in the flyer.

11- **Please note**: Although this was not requested by the reviewer, we also removed Dr. Basson's name from the contact information on the consent form and replaced this with Dr. Elsayed's name. As we explained in the original protocol (final paragraph of the response to question 10), although Dr. Basson is indeed the principal investigator, we don't want NEOMED medical students to feel in any way impelled to participate by knowing that this study is being conducted by their dean and so have requested that the IRB endorse this deviation from the usual procedure. If the IRB disagrees, we are willing to put Dr. Basson's name back in, but we feel that this will reduce the possibility of students feeling coerced by external factors beyond their particular interest in the study itself.

Institutional Review Board (IRB)
Office of Research and Sponsored Programs

FOR USE WITH STUDIES INVOLVING BEHAVIORAL or BIOMEDICAL HUMAN SUBJECTS RESEARCH

EXEMPT, EXPEDITED AND FULL BOARD REVIEW PROCESS FORM

Form APRIL2023

Application Instuctions:
Please answer all questions contained in this application. If a question is non-applicable, type "N/A" to indicate you have read the question. Please submit a signed, scanned copy to: Trish Wilson, Regulatory Affairs Coordinator, paw@neomed.edu. Please submit the application as one complete document, not separate e-mails or attachments. Individual e-mailed attachments over several different e-mails will not be accepted. Full board review materials for projects above minimal risk must be submitted three weeks prior to the IRB's scheduled meeting date. Please expect an exempt or expedited review for minimal risk research to take a minimum of 10 business days. Please plan accordingly since application revisions may be required after the application's initial review which require additional time to complete.

For is list of common errors made when completing this application, please click here.

PRINCIPAL INVESTIGATOR ASSURANCE:

I agree to follow all applicable policies and procedures of Northeast Ohio Medical University (NEOMED) and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to the following:

- Perform the research as approved by the IRB under the direction of the Principal Investigator by appropriately trained and qualified personnel with adequate resources;
- Understand that the parameters of the research cannot be modified without approval by the NEOMED IRB (except where necessary o eliminate apparent immediate hazards to participants);
- Agree to maintain research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
- Will retain research-related records for audit for period of at least three years after the research as ended (or longer, according to sponsor or publication requirements) even if I leave the University;
- I will file an Amendment Form with the NEOMED IRB to amend the study (to request a change in PI) or to terminate the research if I leave the University or am unavailable to conduct or supervise the research personally (e.g. sabbatical or extended leave);
- Agree to inform all Co-Investigators, research staff, employees, and students assisting in the conduct of the research of their obligations in meeting the above commitments.
- All student conducted/mentored projects must have a faculty member as PI list on this application.

Principal Investigator Signature:

I verify that the information provided in this IRB Application is accurate, complete and an appropriate activity for submission to the IRB. Please be reminded the NEOMED IRB's only authority is to review, approve, and provide oversight of activities that meet the federal definition of human subject research and does not include projects conducted for the purpose of class, course, or program evaluation, quality improvement, or institutional effectiveness. For information on these types of projects, please contact the Office of Institutional Research at 330-325-6333.

Principal Investigator: _____ _____ Date:_____9/22/2023_____

If this is a student project, signature of student: _____ Date: _____

APPLICATION PACKAGE CHECKLIST

1. Materials appearing in the list below must be developed, in written form and submitted as part of this application package.

Check the boxes to indicate which documents will be included in this package. (To check the box double click the box, click on "checked" under default option.)

☒ **The Application Form**

☒ **Questionnaires/surveys or other data collection instruments.**

☒ **Consent form(s) or an Information Sheet**.
All studies must include either a Consent Form or an Information Sheet, depending on the type of study. An Information Sheet is used for minimal risk studies and does not require the Investigator to retain a signed copy on file, while a Consent Form is used to document consent by signature of the subject and must be signed and retained by the PI. The NEOMED Consent Form template and Information Sheet template may be found on the NEOMED IRB website.

☒ **Advertisement Materials** (e.g., emails, fliers, websites) Include anything that will be used to promote your study

☐ **HIPAA/Data Use form**. You are required to complete a HIPAA Application for the use of identifiable health information in research. HIPAA applications can be found on the NEOMED IRB website.

☒ **Human Subjects Training Certificates**
Certificates must be renewed every three years and must be current for all investigators listed at the time of submission. Expired or incomplete training of any investigator will delay the review and approval of this application. NEOMED's training in human subjects research is through CITI and is found at https://www.citiprogram.org.

☐ **Letter of commitment**. Provide documentation that indicates support of this project if you are conducting research at institutions/agencies outside NEOMED, or with individuals who are not NEOMED employees or students.

☐ **Please specify any additional materials relevant to the study that are included:**_____

PROTOCOL NAME AND DURATION

PROTOCOL TITLE: Comparison of sleep and stress in medical students between American and Egyptian medical schools, and its effect on performance.

PROJECT PERIOD: Start Date: 9/24/2023
End Date: 12/31/2024

If this is a student mentored project for academic credit, please list the name of the program/course below:

PERSONNEL

1. **All personnel listed below must complete current human subject research training at www.citiprogram.org prior to submitting this application. Training that is "in process" or "expired" will not be accepted.**

PERSONNEL (Name, Degrees) -List PI first -List everyone engaged in the research*	*EMAIL*	*PHONE*	*NEOMED DEPARTMENT* (Institution's name if outside of NEOMED)	*CITI HUMAN SUBJECT TRAINING DATE* -must be less than three years old to be valid	*ROLE*- -List 1 PI only (no Co-PI) -List Co-Investigators -List student investigators –List Consultants
Marc Basson, MD, PhD, MBA	mbasson@neomed.edu	330-325-6753	Neomed, Dean's office	4/19/2023	PI
Jaidaa Mekky, MD, PhD	jaidaamekky@gmail.com		Alexandria Faculty of Medicine	09/17/2023	Co-Investigator
Nesreen Elsayed Morsy, MD, PhD	neselmorsy@mans.edu.egy		Mansoura Faculty of Medicine	09/18/2023	Co-Investigator
Marwa Yassien Badr, MD	drmoroneuro@yahoo.com		Tanta Faculty of Medicine	09/18/2023	Co-Investigator
Ahmed Adham Elsayed, MD	adham-raafat94@hotmail.com	701-885-1437	Neomed, Anatomy and neurobiology	8/11/2023	Co-Investigator
Hoda Omran	hodaomran100@outlook.com		Alexandria Faculty of Medicine, Medical Student	09/18/2023	Student Investigator
Omar El Kholy	omarkholy15@gmail.com		Alexandria Faculty of Medicine, Medical Student	09/15/2023	Student Investigator
Alaa Dean Esmail	aesmail1@neomed.edu	330-307-5553	Neomed, Medical student	6/7/2023	Student Investigator
Abdullah Ali	aali5@neomed.edu	216-310-9176	Neomed, Medical Student	7/25/2023	Student Investigator

*** Add additional rows, if necessary**

2. PERSONNEL ROLES

Please list below each person appearing in section 1 "Personnel" and explain the role each will play in the project.

Response to 2:
Marc Basson, M.D., Ph.D., M.B.A – leading, coordination, writing survey, advising, analyzing and interpreting data, writing manuscript.

Jaidaa mekky, MD - writing survey, collecting data, analyzing and interpreting data, writing manuscript.

Ahmed Elsayed, M.D. - writing survey, collecting data, analyzing and interpreting data, writing manuscript.

Nesreen Elsayed Morsy, MD, PhD- collecting data, analyzing and interpreting data

Marwa Yassien Badr, MD - collecting data, analyzing and interpreting data

Alaa Dean Esmail - writing survey, collecting data, analyzing and interpreting data, writing manuscript.

Abdullah Ali - writing survey, collecting data, analyzing and interpreting data, writing manuscript.

Hoda Omran - writing survey, collecting data, analyzing and interpreting data, writing manuscript.

Omar El Kholy - writing survey, collecting data, analyzing and interpreting data, writing manuscript.

FUNDING SOURCE AND COI

3. FUNDING SOURCE

Please check the appropriate boxes by double clicking the box, then selecting "checked" under default value.

Do you currently have, or anticipate having, a sponsor or funding agency (including if you plan on applying for funds) for this project? ☒ No ☐ Yes

If yes, identify the sponsor or funding agency:
Is the sponsor a for-profit corporation? ☐ No ☐ Yes

4. CONFLICT OF INTEREST

Do any of the study investigators listed in this application have a financial or other personnel conflict of interest that may effect the performance or reporting of the research performed in this application? Conflicts of interest may be actual or apparent. Please see NEOMED's policy titled "Financial Conflict of Interest in Research."
☒ No ☐ Yes If yes, please attach the COI management plan currently on file in the General Counsel's Office.

Have you submitted or do you intend to submit the study to any Federal Agency for sponsorship?
☒ No ☐ **Yes**: PHS policy requires assurance that the composition of the proposed study population benefits all persons at risk of the condition under study.

EXEMPT, EXPEDITED, OR FULL BOARD REVIEW

According to federal regulations, a protocol may be approved by the IRB through either an exempt, expedited, or full board review of the study. An exempt or expedited review is completed by 1 IRB member, a full board review is reviewed at a convened meeting of the 12 member committee and is used to review research determined to be above minimal risk to subjects. Please check below which type of review should be considered for your study:

5. TYPE OF REVIEW REQUESTED- Exempt, Expedited or Full Board

Please select the type of review category you are requesting by double clicking the box.

EXEMPT RESEARCH REVIEW:

(An exempt review procedure consists of a review of research involving the IRB chairperson or by one or more experience reviewers designated by the chair.)

CATEGORIES

☐ Educational Settings: 46.104(1)

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ Educational Tests and Survey Procedures: 46.104(2)

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

Please select:

☐ (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

☐ (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

☐ (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB** review to make the determination required by §46.111(a)(7).

Are provisions in place to protect the privacy of subjects and to maintain the confidentiality of data? ☐Yes No ☐

☐Benign Behavioral Interactions: 46.104 (3)

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

Please select:

☐ (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

☐ (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

☐ (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB** review to make the determination required by §46.111(a)(7).

Are provisions in place to protect the privacy of subjects and to maintain the confidentiality of data? ☐Yes No ☐

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ Secondary Research: 46.104 (4)

Secondary research use of information or biospecimens for which consent is not required:

Please select:

☐ (i) The identifiable private information or identifiable biospecimens are publicly available;

☐ (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

☐ (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

☐ (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

☐ Federal Department or Agency: 46.104 (5)

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

☐ Taste and Food Evaluations: 46.104 (6)

Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

EXPEDITED RESEARCH REVIEW

(An expedited review procedure consists of a review of research involving the IRB chairperson or by one or more experience reviewers designated by the chair.)

CATEGORIES

☐Category 1- Clinical Studies of Drugs and Medical Devices

Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

Please select:

☐ (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.

☐ (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐Category 2- Collection of Blood

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐Category 3- Biological Specimens Prospective Collection

Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐Category 4- Noninvasive Clinical Procedures

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐Category 5- Materials collected for Non Research Purposes

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

☐Category 6- Collection of Data for Research Purposes

Collection of data from voice, video, digital, or image recordings made for research purposes.

☒Category 7- Individual or group characteristics or behaviors that are not exempt

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

☐Category 8- Continuing review of research previously approved by the convened IRB as follows:

where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

where no subjects have been enrolled and no additional risks have been identified; or

where the remaining research activities are limited to data analysis.

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

FULL BOARD REVIEW

(A full board review procedure consists of a review of research involving the entire IRB committee at a convened meetingor and involves the presentation of the proposed research to the committee by the project's PI.)

☐ The research presented in the application is above minimal risk of harm to participants and does not meet any of the above criteria for exempt or expedited review. Review by the convened IRB committee is required.

DETAILED STUDY DESCRIPTION

In order to review your proposal, the Institutional Review Board must have very specific, detailed information. Please use non-technical language that is understood by nonscientific members to summarize the proposed research project. Define all abbreviations and terms not part of common language and use simple words and sentence structure as much as possible.

6. BRIEF STATEMENT OF THE RESEARCH HYPOTHESIS AND SUPPORTING RESEARCH QUESTIONS

A hypothesis is a tentative statement about the relationship between two or more variables.It is a specific, testable prediction about what you expect to happen in a study. Please see "IRB Application Errors" page 3, #5 for help on formulating a hypothesis with supporting research questions and scientific objectives.

Response to 5:

We hypothesize that there will be a difference between the stress factors and sleep quality between the medical students at American and Egyptian medical schools, and in return there will be a difference in academic performance.

7. PURPOSE OF THE STUDY

What are the specific scientific objectives (aims) of the research?

Response to 8:
The purpose of the study is to compare the stress factors, stress levels, and sleep quality, and its effect on academic performance between medical students and American and Egyptian medical schools. Participants will be given the chance to consent to be recontacted for a second study on a novel stress-reducing strategy and its effect on stress and performance.

8. BACKGROUND

State the background of the study. Include a critical evaluation of existing knowledge, and specifically identify the information gaps which the project is intended to fill. Describe previous work in animal and/or human studies that provide a basis for the proposed research and that support the expectation of obtaining useful results without undue risk to human subjects.

Response to 9:
The effect that stress has on sleep, and sleep on performance, is well known. Stress levels negatively impact the number of hours of sleep and the quality of that sleep, often leading to insomnia and a disrupted circadian rhythm.[1] It has been seen that a lower sleep duration correlates to worsening academic performance.[2] It has also been observed that stress levels have an inverse relationship with productivity.[3] Medical students are often under high burdens of stress and are sleep deprived.[4] [5]. American and Egyptian medical schools have differing environmental, cultural, curricular, and societal factors which have yet to be analyzed in terms of medical school performance, sleep. In addition, they differ in education systems, healthcare systems, and support systems. This study aims to identify the way these differences impact the sleep quality, stress levels, stress factors, and their effect on academic performance.

9. CITATIONS

List citations below or attach a copy of literature review.

Response to 10:

1. Kalmbach, D. A., Anderson, J. R., & Drake, C. L. (2018). The impact of stress on sleep: Pathogenic sleep reactivity as a vulnerability to insomnia and circadian disorders. *Journal of sleep research*, *27*(6), e12710. https://doi.org/10.1111/jsr.12710
2. Zeek, M. L., Savoie, M. J., Song, M., Kennemur, L. M., Qian, J., Jungnickel, P. W., & Westrick, S. C. (2015). Sleep Duration and Academic Performance Among Student Pharmacists. *American journal of pharmaceutical education*, *79*(5), 63. https://doi.org/10.5688/ajpe79563
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10. PROVIDE A BRIEF DESCRIPTION OF THE PROCEDURE(S) INVOLVING THE HUMAN SUBJECTS. Include all clinical procedures, surveys, focus groups or other interactions with participants.

Response to 10:

Medical students from America and Egypt will be asked to complete an online survey. The questions will ask about the participant's sleep quality, stress levels, stress factors, anxiety level, and academic performance. This survey is anonymous and does not require informed consent unless students wish to be recontacted. In this case, they must fill out an informed consent form. The information provided by these students will not be seen by anyone except for Dr. Mekky and Dr. Elsayed.

The survey will be promoted through institutional email, fliers around campus, classroom announcements, and social media (Facebook, Instagram, Linked-in, Twitter).

We request to not include Dr. Basson's name on the survey or recruitment material because we anticipate that the students may change their response or may be coerced into doing the research if they see the name of the dean on it. Dr. Basson and the medical students will not have access to any of the personal information provided by those who give consent to be recontacted.

CHARACTERISTICS OF THE SUBJECT POPULATION AND METHODS/PROCEDURES

11. SUBJECT POPULATION

Check all appropriate boxes below (double click the box, then select "checked" under default value)

- ☒ Adults
- ☐ Biomed Science Academy Students
- ☐ Cancer patients
- ☐ Children
- ☐ Cognitively or psychologically impaired
- ☐ Comatose
- ☐ Elderly
- ☐ Exclusion of minorities
- ☐ Females Only
- ☐ Fetuses
- ☐ Human *in vitro* fertilization
- ☐ Institutional residents
- ☐ Males Only
- ☒ NEOMED students/employees
- ☐ Non-English speaking
- ☐ Patients
- ☐ Physically Handicapped
- ☐ Pregnant women
- ☐ Prisoners or parolees
- ☐ Terminally ill
- ☐ Traumatized (Physical)
- ☐ Traumatized (Emotional

☒ **Other. Please explain: Medical students from Egyptian medical schools (all of whom speak English)**_____

12. NUMBER AND AGE-RANGE OF SUBJECTS

Indicate the anticipated number and age-range of subjects to participate in the study.

a) Total number of subjects to be invited to participate (e.g. recruited) in the study ? : ___2000 medical students from American universities, 28,000 medical students from Egyptian medical universities_____

b) Out of the number of subjects recruited above, how many do you expect to actually participate (e.g. enroll) in the study? ____15000_____

c) Total number of participants expected to enroll for multi-center research (if applicable):_____

d) Age-range of participants: _____18-40_____

13. LOCATION(S) OF RESEARCH TO BE CONDUCTED AT

☒ NEOMED (Rootstown)
☒ Teaching hospital or university (s), please list: Alexandria Faculty of Medicine, Mansoura Faculty of Medicine, Tanta Faculty of Medicine_____
☐ Other locations, specify:

14. METHODS AND PROCEDURES APPLIED TO HUMAN SUBJECTS

Read through the list carefully. Check all appropriate boxes:

☐ Audio and/or visual recording
☐ Behavioral observation
☐ Controlled substances
☐ Approved drug for non approved use, experimental
☐ Deception
☐ Device approved, non-approved use
☐ Existing data (data bank, data archives)
☐ EEG
☐ Electrical stimulation
☐ Genetic research
☐ Human biological specimens (biopsy, blood drawing, fetal tissue, stem cells, urine or fecal sample, excess pathological)
☒ Survey/questionnaire (must attach survey or questionnaire to application)
☐ Interviews and Focus Groups
☐ Microorganisms or recombinant DNA
☐ Physical exercise
☐ Placebo(s)
☐ Physical Manipulation
☐ Proton beam
☐ Radiation
☐ Radioisotopes
☐ Randomizations
☐ Potential development of commercial products from biological materials
☐ PI or Co-PI is the treating healthcare provider for participants
☐ Surgical or autopsy tissue
☐ Test(s), pen/pencil/computerized
☐ Treatment
☐ Venipuncture (≤450cc)

Other (please specify)
_____

Describe each of the following in the space below:

a) Identify all procedures that are considered experimental and/or procedures performed exclusively for research purposes.
b) Identify method(s) that will be used to identify and recruit prospective subjects. Attach a copy of any planned advertisements/notices and letters to potential subjects.
c) Explain criteria for inclusion and exclusion of participants, including criteria based on age, gender, pregnancy or childbearing potential, or racial/ethnic origin.
d) Explain how eligibility will be determined, and by whom.
e) Explain if vulnerable subjects will be included. If so, identify the subject groups and justify their involvement.
f) Explain if you will be performing clinical procedures as part of this research proposal.

Responses to 15:
a) We will be surveying medical students with an online survey.
b) Emailing all students from each participating medical school, posting flyers with a QR code to the survey around each campus, making announcements in classes, and posting on social media.
c) All medical school students ages 18-40 are able to participate in the study.
d) Being a medical student.
e) There are no vulnerable subjects.
f) There will be no clinical procedures to be performed.

15. FOR RESEARCH INVOLVING SURVEYS, QUESTIONNAIRES, INTERVIEWS AND FOCUS GROUPS

If YOU ARE DISTRIBUTING A SURVEYS:

Per NEOMED Policy, if you are conducting a survey of NEOMED faculty, staff, or students you must complete the a Survey Request Form and submit to the Office of Institutional Research (OIR). The OIR's role is to minimize the occurrence of survey fatigue, improve the integrity of Neomed data, and reduce oversampling Neomed students, faculty, employees. The OIR also provides support in the design and distribution of surveys, as well as in the analysis of survey results. Questions regarding the survey process may be sent to rlarson@neomed.edu.

Describe each of the following in the space below:

a) Setting
b) Mode of administering the instrument (e.g., by telephone, one-on-one, e-mail or group)
c) Provisions for maintaining privacy and confidentiality
d) Duration (This is not the project period, how long it takes to complete survey, focus group, etc.)
e) Intervals of administration
f) Overall length of participation.
g) Type of Survey Software to be used (Note: We do not accept Survey Monkey due to privacy issues unless it is a Gold or Platinum Edition) It is recommended that NEOMED's inhouse software "Qualtrics" be used through the Office of Institutional Research.

Responses to 16:
a) The study setting will be online.
b) The mode of administering is through email.
c) All submitted surveys will remain anonymous except those who wish to follow up. These medical students will sign an informed consent form and ensure only Dr. Mekky and Dr. Elsayed has access to this information.
d) It takes an average 5 – 10 minutes to complete the survey.
e) The survey will be given one time to medical students.
f) Participation will last an average of 5 - 10 minutes. because this is the length of the survey.
g) The survey software is Google Forms.

COVID SAFETY PLAN

For research involving in-person interactions or interventions with subjects:
In the space below, describe your COVID safety plan for keeping subjects and your research team safe:

Response:

Since this is an online survey, COVID-19 is at no greater risk of harming the study participants.

16. DATA COLLECTION, STORAGE AND CONFIDENTIALITY

Describe each of the following in the space below:

a) Explain how data will be collected and recorded.
b) Explain if data will be **anonymous** or **confidential**. (For help in this determination, refer to "IRB Application Errors)
c) Explain how the data will be kept secure, including who will have access to data and/or codes, whether subject identifiers will be released, and to whom (person, group or agency) the information may be released.

d) Explain what will happen to the data once they have been collected, analyzed, and reported (presentation/publication); provide timeline.

Responses to 17:
a) This data will be collected through Google Forms Survey software and recorded with data collection tools.
b) All submitted surveys will remain anonymous except those who wish to follow up. These medical students will sign an informed consent form and ensure only Dr. Mekky and Dr. Elsayed has access to this information and will remain confidential.
c) Only Dr. Mekky and Dr. Elsayed will have access to this information, and confidentiality will be maintained when recording and analyzing information.
d) It is anticipated that the data collection, analysis, and manuscript drafting will take approximately 6 to 12 months. We will then submit the manuscript for publication and will retain the de-identified and the date of the participants that consented to be recontacted for three years after publication on the PI's password secured NEOMED computer, after which it will be deleted.

17. POTENTIAL RISKS AND DISCOMFORTS

a) Describe the potential risks/discomforts associated with each intervention or research procedure.
b) If data are available, estimate (a) the probability that a given harm may occur, (b) its severity, and (c) its potential reversibility.
c) Describe the overall risk classification of the research: minimal, greater than minimal, significant, or unknown
d) Describe those procedure(s) to be utilized to prevent/minimize any potential risks or discomfort.

Responses to 18:
a) Anxiety caused by potentially uncomfortable questions.
b)
c) Minimal risk.
d) Only Dr. Mekky and Dr. Elsayed will have access to this information, and confidentiality will be maintained when recording and analyzing information.

18. POTENTIAL BENEFITS

a) Describe any potential benefits subjects may receive as a result of their participation in the research.
b) Describe potential benefits to society that may be expected from this research.
c) Describe the risk/benefit ratio of the research, compared with that of the available alternatives.

Responses to 19:
a) None.
b) Contribution to science and learning more about how Egyptian and American medical schools differ in terms of the stressors, sleep quality, and how they impact academic performance.
c) The benefits outweigh the risk.

19. COMPENSATION FOR PARTICIPATION

Describe all plans to compensate subjects, if applicable. Include cash or gift card compensation, services or other benefits instead of cash (e.g., travel reimbursement), and those conditions that may need to be fulfilled before full or partial compensation. Include prize drawings for items and gift cards in this section. If no payment/compensation/incentive is planned, that should be stated below.

REGARDING GIFT CARDS AND CERTIFICATES: Please note that gift cards and any other form of cash or cash equivalent are taxable regardless of the amount. The NEOMED accounting department must track the amounts each research participant receives. Any compensation or combination of compensations that add up to $600 for the calendar will be reported to the IRS by the issue of a 1099 Statement. All research participants receiving gift cards/certificates must be asked to complete an acknowledgement form before receiving the gift card. If your study requires that participant names be kept anonamyous, participants must complete the Receipt of Compensation Acknowledgement--Anonymous Form. All participants in studies which are not anonymous must complete the general Gift Card Acknowledge Form. The instructions and processes for uploading these forms to the Accounting office may be found on the Form Instructions. Questions regarding this process may be sent to purchasing@neomed.edu.

Response to 19:

N/A

20. FINANCIAL OBLIGATIONS OF THE SUBJECTS

a) Describe any financial obligations subjects will incur as a result of participating in the study.
b) Describe whether subjects have to pay for any of the treatment(s) they receive or tests performed in the research.

Response to 21:
a) N/A
b) N/A

21. EMERGENCY CARE AND COMPENSATION FOR RESEARCH-RELATED INJURY

a) If the research presents greater than minimal risk, describe what emergency care is available in case of research-related injury.
b) Identify who will be responsible for the cost of such care.
c) Identify whether subjects will be compensated for out-of-pocket expenses or lost wages if they suffer a research-related injury

Response to 22:
a) The research does not present greater than minimal risk.
b) N/A
c) N/A

INFORMED CONSENT/ASSENT PROCESS

22. ADULT INFORMED CONSENT PROCESS (Including parents and guardians)

All regulatory research requires an informed consent process which includes communication to subjects prior to, during, and following their participation in a study. Except in certain circumstances, the communication should be both written and verbal. Include each of the following in your description of the consent process:

a) Describe how and where the consent process will take place.
b) Describe how the consent process will be structured to enhance independent and thoughtful decision-making. Include those steps which will be taken to avoid coercion or undue influence.
c) Describe whether the subjects or their legally authorized representatives understand the information provided.
d) Describe whether all adult subjects have the capacity to give informed consent, or the likely range of impairment. If subjects are impaired, explain how, and by whom, their capacity to consent will be determined (See #24 informed assent for adults who are impaired).
e) Identify who will be inviting subjects to participate and what will they say. Identify by name and training the individual(s) authorized to describe the research to subjects/representatives and to invite their participation.
f) Identify and justify any personal identifiers that may be recorded.
g) Explain and justify if any information about the research purpose and design will be withheld from potential or participating subjects (non-disclosure), and describe plans for post-study debriefing.
h) If any of your anticipated participants are non-English speakers, or English is their second language, identify how the informed consent form and all written materials (e.g., recruitment letter, survey) have been translated in the native language of your partcipants. Describe the consent process using participants' native language (e.g., will a translator be used, who will serve as the translator in your study).

Response to 23:
a) The consent process will take place on the first page of the survey. A separate informed consent form, following the NEOMED informed consent guidelines, will be presented if the participant wishes to be recontacted.
b) The student must read the prompt and agree before moving on with the survey. The consent form provided during the recontacting process requires a signature.
c) The subjects understand the provided information.
d) All the adult subjects have capacity to give informed consent.
e) The investigators will recruit participants through email, the usage of flyers with QR codes, making announcements in classroom, and posting on social media.
f) If the student requests to be recontacted, personal identifiers of name and phone number will be recorded.
g) N/A
h) Survey is written in language all subjects can understand.

23. INFORMED ASSENT (For minors and persons impaired to give informed consent)

In addition to the questions above, answer the following:

a) Identify the reading level of the assent form. How has this level been confirmed? (e.g., computer program, education expert)
b) Explain the process of assent for minors, including how you provide information at an age appropropriate level of your subject population (if applicable)
c) Explain the process of assent for persons who are impaired (e.g., cognitively), including how you provide information at an understandable level and based on the needs of the participant.
d) Explain any actions that may be taken when minors or persons who are cognitively impaired *dissent* in the informed consent process, or who wish to withdraw at any point of the study.
e) Explain any actions that may be taken when minors or persons who are cognitively impaired *dissent* to more than minimal risk studies (if applicable)

Response to 24:
a) NA
b) NA
c) NA
d) NA
e) NA

24. CONSENT/ASSENT DOCUMENTATION:

Specify which method of consent will be used in your study (Check all that apply):

- ☐ Informational Sheet
- ☒ Adult Consent Form
- ☐ Parental or Guardian Consent Form
- ☐ Minor/Impaired Person Assent Form
- ☒ Waiver of Documentation of Signed Consent (Go to item #26 if checked)

25. WAIVER OF SIGNED CONSENT FORM:

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (Please check the appropriate box, IF YOU ARE REQUESTING A WAIVER OF SIGNED CONSENT)

☒ That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

- or-

☐ That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Note: Even if a waiver of signed consent has been granted, an informational sheet must be provided to subjects unless the research purpose and design involves non-disclosure or deception, or a valid justification can be made to the IRB for not using an Information Sheet.

CONSENT TO PARTICIPATE IN RESEARCH

Northeast Ohio MEDICAL UNIVERSITY

The information in red is for guidance and needs to be replaced with study specific information by the PI. Please remove/replace all red text, including these instructions.

Title: "Comparison of sleep and stress in medical students between American and Egyptian medical schools, and its effect on performance"

Principal Investigator: Dr. Ahmed Adham Elsayed Office: 4209 St, OH-44, Rootstown OH, 44272, Phone: 701-885-1437

KEY INFORMATION ABOUT THIS RESEARCH:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is listed later on in this form.

The purpose of the study is to compare the stress factors, stress levels, and sleep quality, and its effect on academic performance between medical students and American and Egyptian medical schools. Participants will be given the chance to consent to be recontacted for a second study on a novel stress-reducing strategy and its effect on stress and performance. You will be asked to complete a short survey. We expect that you will be in this research study for 5 – 10 minutes. The primary risk of participation is anxiety caused by potentially uncomfortable questions. The main benefit is contribution to science and learning more about how Egyptian and American medical schools differ in terms of the stressors, sleep quality, and how they impact academic performance. Participation in the study will in no way affect the student's academic standing.

Purpose of the study

You are invited to be in a research study of stress on sleep because you are a medical student in Egypt or America. The purpose of the study is to compare the stress factors, stress levels, and sleep quality, and its effect on academic performance between medical students and American and Egyptian medical schools.

Approximately 5000 subjects will participate in the study with up to 20000 recruited from this site. Participation in the study will be a minimum of 5 minutes.

Study Procedures and Duration

You will take a survey that will collect information on the type of medical student you are, the stressors in your life, your anxiety level, your depression level, your academic performance, and your sleep quality. If you choose, you can opt to be recontacted by the researchers to participate in future studies. The survey will take approximately 5-10 minutes.

Risks and Discomforts

The research survey may cause anxiety due to potentially uncomfortable questions.

Benefits

There will be no direct benefit to you from participating in this study. We hope this study provides information which contributes to the knowledge of stress related sleep disorders.

Costs
There is no cost to you for participating in this study.

Impartial Third Party Contact
If you wish to contact an impartial third party not associated with this study regarding any complaint you may have about the study or if you have questions about your rights as a subject in this study, you may contact Rebecca German, Human Protections Administrator, Northeast Ohio Medical University, Rootstown, Ohio, 44272, phone (330) 325-6499 or e-mail rgerman@neomed.edu for information and assistance. For Egyptian universities, you can e-mail ethics.comm@alexmed.edu.eg

Confidentiality
If you agree to become part of this study, your name will be held in confidence. Only the study staff, sponsor representatives involved in this study, independent ethics committees and inspectors from government regulatory agencies will have direct access to your records to check the study information.

Voluntary Participation / Early Withdrawal
Your participation in this study is voluntary. You can choose not to take part in the study, or you can quit at any time. You will not lose any benefits to which you are otherwise entitled. You will not be prevented from participating in future studies.

Significant New Findings
You will be told in a timely manner of any significant new information that may affect your willingness to stay in this study.

Conflict of Interest:
research team is not being compensated by the sponsor for conducting the study. The researchers do not hold a direct financial interest in the sponsor.

Data Use
This study includes the use of your identifiable data or biospecimen. The identifiers might be removed from the identifiable private information/biospecimens and after such removal, the information or biospecimens could be used for future research studies. The unidentifiable data could also be distributed by another investigator for future research studies without additional consent from you.

Return of Research Results:
Clinically relevant research results, including individual research results, will not be disclosed to you.

Informed Consent Statement
I have read the contents of the consent form and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent to participate in this study. Signing this consent document does not waive my right nor does it release the investigators, institution, or sponsors from their responsibilities. I may call Dr. Ahmed Adham Elsayed or one of his associates during routine office hours at 701-885-1437.

I have been given a copy of this consent form and have had this form explained to me.

Northeast Ohio
MEDICAL UNIVERSITY

Researchers at Northeast Ohio Medical University are recruiting medical students over the age of 18 to participate in a research survey that compares sleep, stress, and academic performance between American and Egyptian medical schools. Please scan the QR code below to fill out the survey.

Comparison of sleep and stress in medical students between American and Egyptian medical schools, and its effect on performance

* Indicates required question

Consent

1. You are being invited as medical students to participate in a sleep study by Dr. Mekky and the rest of the team. You will gain no benefit from this study and there is minimal to no risk, except questions that may be uncomfortable. If you wish to participate, please select "Yes." *
Estimated time to complete: 5-10 minutes.

Mark only one oval.

- ◯ Yes
- ◯ No

Demographics

2. Age

Mark only one oval.

- ◯ <20
- ◯ 21-25
- ◯ 26-30
- ◯ 31-35
- ◯ 36-40
- ◯ >40

3. University *

Mark only one oval.

- Northeast Ohio Medical University
- Alexandria Faculty of Medicine
- Mansoura Faculty of Medicine
- Tanta Faculty of Medicine
- Other

4. (If you chose other in the previous question).
What is the name of your medical school?

_____

5. Gender *

Mark only one oval.

- Male
- Female
- Other
- Prefer not to say

6. Medical education *

Mark only one oval.

- Preclinical
- Clinical

7. Working status (If you are currently employed in addition to medical school) *

Mark only one oval.

- Full time job
- Part time job
- Not working

8. Grades *

Mark only one oval.

- Excellent
- Passing
- At risk for not passing
- Prefer not to answer

9. Are you a citizen or permanent resident of the country in which you are attending medical school? *

Mark only one oval.

- Yes
- No

10. Are you from the state (For U.S. students) or local region (for non-U.S. students) of the medical school?

Mark only one oval.

- Yes
- No

11. Current debt load (student debt for university tuition): *

Mark only one oval.

- ◯ No debt
- ◯ $25 - $100
- ◯ $100 - $1000
- ◯ <$10,000 or equivalent
- ◯ $10,000 - $50,000
- ◯ $50,000-$100,000
- ◯ $100,000 - $200,000
- ◯ $200,000 - $300,000
- ◯ >$300,000
- ◯ Other: _____

12. Weight:

If prefer not to answer, please skip this question

_____

13. Please specify pounds or kilograms for the weight mentioned in the previous question.

Mark only one oval.

- ◯ Pounds
- ◯ Kilograms

14. Height: (Please specify meters or feet)
IF you use feet, please format as __ ft __ in. (e.g., 5 ft 0 in).
If you use meters, please format as __m (e.g.1.86m)

If prefer not answer, please skip this question

Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers
should indicate the most accurate reply for the majority of days and nights in the past month. Please answer
all questions

15. 1. During the past month, what time have you usually gone to bed at night? *

Example: 8:30 AM

16. 2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night? *

17. 3. During the past month, what time have you usually gotten up in the morning? *

Example: 8:30 AM

18. 4. During the past month, about how many hours, on average, of actual sleep did you get each night? (This may be different than the number of hours you spent in bed.) *

19. 5.During the past month, how often have you had trouble sleeping because you… *

Mark only one oval per row.

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
Cannot get to sleep within 30 minutes				
Wake up in the middle of the night or early				
Have to get up to use the bathroom				
Cannot breathe comfortably				
Cough or snore loudly				
Feel too cold				
Feel too hot				
Have bad dreams				
Have pain				

20. 6. During the past month, how often have you taken medicine to help you sleep (prescribed or “over the counter”)? *

Mark only one oval.

- Not during the past month
- Less than once a week
- Once or twice a week
- Three or more times a week

21. 7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity? *

Mark only one oval.

- Not during the past month
- Less than once a week
- Once or twice a week
- Three or more times a week

22. 8. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done? *

Mark only one oval.

- No problem at all
- Only a very slight a problem
- Somewhat of a problem
- A very big problem

23. 9. During the past month, how would you rate your sleep quality overall? *

Mark only one oval.

- Very good
- Fairly good
- Fairly bad
- Very bad

24. 10. Do you have a bed partner or roommate? *

Mark only one oval.

- No bed partner or roommate
- Partner/roommate in other room
- Partner in same room but not same bed
- Partner in same bed

25. 11.If you have a bed partner, ask them how often in the past month you have had:

Mark only one oval per row.

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
Loud snoring	◯	◯	◯	◯
Long pauses between breaths while asleep	◯	◯	◯	◯
Legs twitching or jerking while you sleep	◯	◯	◯	◯
Episodes of disorientation or confusion during sleep	◯	◯	◯	◯
Other restlessness while you sleep	◯	◯	◯	◯

Insomnia Severity Index

26. Insomnia Problem *

Mark only one oval per row.

	None	Mild	Moderate	Severe	Very severe
1.Difficulty falling asleep	◯	◯	◯	◯	◯
2. Difficulty staying asleep	◯	◯	◯	◯	◯
3. Problems waking up too early	◯	◯	◯	◯	◯

27. 4. How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern? *

Mark only one oval.

- ◯ Very satisfied
- ◯ Satisfied
- ◯ Moderately Satisfied
- ◯ Dissatisfied
- ◯ Very Dissatisfied

28. 5. How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life? *

Mark only one oval.

- Not at all noticeable
- A little
- Somewhat
- Much
- Very much noticeable

29. 6. How WORRIED/DISTRESSED are you about your current sleep problem? *

Mark only one oval.

- Not at all worried
- A little
- Somewhat
- Much
- Very much worried

30. 7. To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY? *

Mark only one oval.

- Not at all interfering
- A little
- Somewhat
- Much
- Very much interfering

PERCEIVED STRESS SCALE

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling how often you felt or thought a certain way.

31. 1. In the last month, how often have you been upset because of something that happened unexpectedly? *

Mark only one oval.

- Never
- Almost Never
- Sometimes
- Fairly Often
- Very Often

32. 2. In the last month, how often have you felt that you were unable to control the important things in your life? *

Mark only one oval.

- Never
- Almost Never
- Sometimes
- Fairly Often
- Very Often

33. 3. In the last month, how often have you felt nervous and “stressed”? *

Mark only one oval.

- Never
- Almost Never
- Sometimes
- Fairly Often
- Very Often

34. 4. In the last month, how often have you felt confident about your ability to handle your personal problems? *

Mark only one oval.

- Never
- Almost Never
- Sometimes
- Fairly Often
- Very Often

35. 5. In the last month, how often have you felt that things were going your way? *

Mark only one oval.

- Never
- Almost Never
- Sometimes
- Fairly Often
- Very Often

36. 6. In the last month, how often have you found that you could not cope with all the things that you had to do? *

Mark only one oval.

- Never
- Almost Never
- Sometimes
- Fairly Often
- Very Often

37. 7. In the last month, how often have you been able to control irritations in your life? *

Mark only one oval.

- Never
- Almost Never
- Sometimes
- Fairly Often
- Very Often

38. 8. In the last month, how often have you felt that you were on top of things? *

Mark only one oval.

- Never
- Almost Never
- Sometimes
- Fairly Often
- Very Often

39. 9. In the last month, how often have you been angered because of things that were outside of your control? *

Mark only one oval.

- Never
- Almost Never
- Sometimes
- Fairly Often
- Very Often

40. 10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them? *

Mark only one oval.

- Never
- Almost Never
- Sometimes
- Fairly Often
- Very Often

Beck's Depression Inventory

41. Choose what describes you. *

Mark only one oval.

- I do not feel sad
- I feel sad
- I am sad all the time and I can't snap out of it
- I am so sad and unhappy that I can't stand it

42. Choose what describes you. *

Mark only one oval.

- I am not particularly discouraged about the future.
- I feel discouraged about the future.
- I feel I have nothing to look forward to.
- I feel the future is hopeless and that things cannot improve.

43. Choose what describes you. *

Mark only one oval.

- I do not feel like a failure.
- I feel I have failed more than the average person.
- As I look back on my life, all I can see is a lot of failures.
- I feel I am a complete failure as a person.

44. Choose what descries you. *

Mark only one oval.

- I get as much satisfaction out of things as I used to.
- I don't enjoy things the way I used to.
- I don't get real satisfaction out of anything anymore.
- I am dissatisfied or bored with everything.

45. Choose what descries you. *

Mark only one oval.

- I don't feel particularly guilty.
- I feel guilty a good part of the time.
- I feel quite guilty most of the time.
- I feel guilty all of the time.

46. Choose what descries you. *

Mark only one oval.

- I don't feel I am being punished.
- I feel I may be punished.
- I expect to be punished.
- I feel I am being punished.

47. Choose what describes you. *

Mark only one oval.

- I don't feel disappointed in myself.
- I am disappointed in myself.
- I am disgusted with myself.
- I hate myself.

48. Choose what describes you. *

Mark only one oval.

- I don't feel I am any worse than anybody else.
- I am critical of myself for my weaknesses or mistakes.
- I blame myself all the time for my faults.
- I blame myself for everything bad that happens.

49. Choose what describes you. *

Mark only one oval.

- I don't have any thoughts of killing myself.
- I have thoughts of killing myself, but I would not carry them out.
- I would like to kill myself.
- I would kill myself if I had the chance.

50. Choose what describes you. *

Mark only one oval.

- I don't cry any more than usual.
- I cry more now than I used to.
- I cry all the time now.
- I used to be able to cry, but now I can't cry even though I want to.

51. Choose what describes you. *

Mark only one oval.

- I am no more irritated by things than I ever was.
- I am slightly more irritated now than usual.
- I am quite annoyed or irritated a good deal of the time.
- I feel irritated all the time.

52. Choose what describes you. *

Mark only one oval.

- I have not lost interest in other people.
- I am less interested in other people than I used to be.
- I have lost most of my interest in other people.
- I have lost all of my interest in other people.

53. Choose what describes you. *

Mark only one oval.

- I make decisions about as well as I ever could.
- I put off making decisions more than I used to.
- I have greater difficulty in making decisions more than I used to.
- I can't make decisions at all anymore.

54. Choose what describes you. *

Mark only one oval.

- I don't feel that I look any worse than I used to.
- I am worried that I am looking old or unattractive.
- I feel there are permanent changes in my appearance that make me look unattractive.
- I believe that I look ugly.

55. Choose what describes you. *

Mark only one oval.

- I can work about as well as before.
- It takes an extra effort to get started at doing something.
- I have to push myself very hard to do anything.
- I can't do any work at all.

56. Choose what describes you. *

Mark only one oval.

- I can sleep as well as usual.
- I don't sleep as well as I used to.
- I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
- I wake up several hours earlier than I used to and cannot get back to sleep.

57. Choose what describes you. *

Mark only one oval.

- I don't get more tired than usual.
- I get tired more easily than I used to.
- I get tired from doing almost anything.
- I am too tired to do anything.

58. Choose what describes you. *

Mark only one oval.

- My appetite is no worse than usual.
- My appetite is not as good as it used to be.
- My appetite is much worse now.
- I have no appetite at all anymore.

59. Choose what describes you. *

Mark only one oval.

- I haven't lost much weight, if any, lately.
- I have lost more than five pounds.
- I have lost more than ten pounds.
- I have lost more than fifteen pounds.

60. Choose what describes you. *

Mark only one oval.

- I am no more worried about my health than usual.
- I am worried about physical problems like aches, pains, upset stomach, or constipation.
- I am very worried about physical problems and it's hard to think of much else.
- I am so worried about my physical problems that I cannot think of anything else.

61. Choose what describes you. *

Mark only one oval.

- I have not noticed any recent change in my interest in sex.
- I am less interested in sex than I used to be.
- I have almost no interest in sex.
- I have lost interest in sex completely.

Skip to question 62

Hamilton Anxiety Rating Scale (HAM-A)

Below is a list of phrases that describe certain feeling that people have. Rate yourself by finding the answer which best describes the extent
to which you have these conditions.

62. 1. Anxious mood *

Worries, anticipation of the worst, fearful anticipation, irritability.

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

63. 2. Tension *

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

64. 3. Fears *

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

65. 4. Insomnia *

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

66. 5. Intellectual *

Difficulty in concentration, poor memory

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

67. 6. Depressed mood *

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

68. 7. Somatic (muscular) *

Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone.

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

69. 8. Somatic (sensory) *

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

70. 9. Cardiovascular symptoms *

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

71. 10. Respiratory symptoms *

Pressure or constriction in chest, choking feelings, sighing, dyspnea.

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

72. 11. Gastrointestinal symptoms *

Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

73. 12. Genitourinary symptoms *

Frequency of micturition, urgency of micturition, amenorrhea (loss of period), menorrhagia (heavy period), development of frigidity, premature ejaculation, loss of libido, impotence

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

74. 13. Autonomic symptoms *

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair (goosebumps)

Mark only one oval.

- Not Present
- Mild
- Moderate
- Severe
- Very severe

Generalized Anxiety Disorder 7-item (GAD-7)

Over the **last 2 weeks,** how often have you been bothered by the following problems?

75. Feeling nervous, anxious or on edge

Mark only one oval.

- Not at all
- Several days
- More than half the days
- Nearly every day

76. Not being able to stop or control worrying

Mark only one oval.

- Not at all
- Several days
- More than half the days
- Nearly every day

77. Worrying too much about different things

Mark only one oval.

- Not at all
- Several days
- More than half the days
- Nearly every day

78. Trouble relaxing

Mark only one oval.

- Not at all
- Several days
- More than half the days
- Nearly every day

79. Being so restless that it is hard to sit still

Mark only one oval.

- Not at all
- Several days
- More than half the days
- Nearly every day

80. Becoming easily annoyed or irritable

Mark only one oval.

- Not at all
- Several days
- More than half the days
- Nearly every day

81. Feeling afraid as if something awful might happen

Mark only one oval.

- Not at all
- Several days
- More than half the days
- Nearly every day

82. The investigators in this study may in the next year be proposing a research study involving a novel stress-reducing strategy. If you would be interested in being recontacted to be offered an opportunity to participate in that trial, please give us your email here. This information will be kept confidential and will not be made available to anyone except Dr. Mekky, a neuropsychiatrist and sleep specialist in Egypt who may send you an email in the future inviting you to participate in such a study. Would you be willing to be contacted for such a study? *

Mark only one oval.

- Yes
- No

83. Thank you for participation and by submitting you accept participating in this research. All your data are confidential. In case you have a comment please drop it here.

This information won't be shared with anyone from the medical school. They will only be available to Dr. Mekky, a neuropsychiatrist and sleep specialist.

Contact Information

84. By entering your electronic signature you acknowledge that you have received and understood this informed consent document

    Name:

    _____

85. Email Address:

    _____

If you are feeling depressed or anxious, please seek help within the university, or from outside resources.

If you are a NEOMED student, please consider contacting the Center for Student Wellness and Counseling, at 330-325-6757 or counseling@neomed.edu

If you are a student at a different university, please consider seeking help by contacting the appropriate counseling office within your university.

86. Thank you for participation and by submitting you accept participating in this research. All your data are confidential. In case you have a comment please drop it here.

    This information won't be shared with anyone from the medical school. They will only be available to Dr. Mekky, a neuropsychiatrist and sleep specialist.

    _____

Conclusion

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Congratulations!

You have completed OHRP's learning module:

Lesson 1: When HHS Regulations Apply

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Name: Hoda Aly Omran

Date: 18/9/2023

Conclusion

Go to Section: Wrap Up > Completion Certificate

Congratulations!

You have completed OHRP's learning module:

Lesson 2: What is Human Subjects Research?

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Name: Hoda Aly Omran

Date: 13/9/2023

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You have completed OHRP's learning module:

Lesson 3: What are IRBs?

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Date: 18/9/2023

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Lesson 4: Independent Review of Research

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Date: 18/9/2023

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Lesson 5: Human Research Protection Training

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Date: 18/9/2023

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Lesson 1: When HHS Regulations Apply

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Name: Jaidaa Mekky

Date: 09/17/2023

Conclusion

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You have completed OHRP's learning module:

Lesson 2: What is Human Subjects Research?

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Name: Jaidaa Mekky

Date: 09/13/2023

Conclusion

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Lesson 3: What are IRBs?

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Name: Jaidaa Mekky

Date: 09/17/2023

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Lesson 4: Independent Review of Research

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Date: 09/17/2023

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You have completed OHRP's learning module:

Lesson 5: Human Research Protection Training

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Name: Jaidaa Mekky

Date: 09/17/2023

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You have completed OHRP's learning module:

Lesson 1: When HHS Regulations Apply

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Name: Marwa yassien Badr

Date: 09/18/2023

Conclusion

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Congratulations!

You have completed OHRP's learning module:

Lesson 2: What is Human Subjects Research?

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Name: Marwa yassien Badr

Date: 09/13/2023

Conclusion

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You have completed OHRP's learning module:

Lesson 3: What are IRBs?

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Name: Marwa yassien Badr

Date: 09/18/2023

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You have completed OHRP's learning module:

Lesson 4: Independent Review of Research

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Name: Marwa Yassien Badr

Date: 09/18/2023

Conclusion

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You have completed OHRP's learning module:

Lesson 5: Human Research Protection Training

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Name: Marwa yassien Badr

Date: 09/18/2023

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Congratulations!

You have completed OHRP's learning module:

Lesson 1: When HHS Regulations Apply

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Name: Nesreen Elsayed Morsy

Date: 18/09/2023

Conclusion

Go to Section: Wrap Up > Completion Certificate

Congratulations!

You have completed OHRP's learning module:

Lesson 2: What is Human Subjects Research?

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Name: Nesreen Elsayed Morsy

Date: 18/09/2023

Conclusion

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You have completed OHRP's learning module:

Lesson 3: What are IRBs?

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You have completed OHRP's learning module:

Lesson 4: Independent Review of Research

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You have completed OHRP's learning module:

Lesson 5: Human Research Protection Training

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Date: 18/09/2023

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You have completed OHRP's learning module:

Lesson 1: When HHS Regulations Apply

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Name: Omar El Kholy

Date: 09/13/2023

Conclusion

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You have completed OHRP's learning module:

Lesson 2: What is Human Subjects Research?

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Name: Omar El Kholy

Date: 9/13/2023

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Lesson 3: What are IRBs?

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Name: Omar El Kholy

Date: 09/15/2023

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Lesson 4: Independent Review of Research

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Lesson 5: Human Research Protection Training

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Date: 09/15/2023