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IMPACT OF VISUAL ARTS IMMERSION ON CULTURAL COMPETENCY AND SELF-REFLECTION AMONG NURSES WORKING IN AN ACADEMIC HEALTH SYSTEM

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Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the study participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

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List of Abbreviations

AE	Adverse Event/Adverse Experience
AT	Aromatherapy
CFR	Code of Federal Regulations
CRF	Case Report Form
CSOC	Clinical Study Oversight Committee
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
FFR	Federal Financial Report
FWA	Federalwide Assurance
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
IRB	Institutional Review Board
MOP	Manual of Procedures
N	Number (typically refers to participants)
NIH	National Institutes of Health
NJSS	Nurse Job Satisfaction Survey
NYULH	NYU Langone Health
OHQ	Oxford Happiness Questionnaire
OHRP	Office for Human Research Protections
OHSR	Office of Human Subjects Research
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
US	United States

Protocol Summary

Title	Impact of visual arts immersion on cultural competency and self-reflection among nurses working in an academic health system
Short Title	Impact of visual arts immersion
Brief Summary	The purpose of this study is to enhance engagement, coping and self-reflection by attuning nurses to creative and observational skills drawn from a visual arts pedagogical framework. To fulfill this goal, we will cultivate an existing relationship between NYULH Nursing, the NYU Health Sciences Library, and museum educators at The Met to design and deliver an intervention of museum educator-led workshops that introduce nurses to arts appreciation skills to improve their practice and overall wellbeing. Participants will be asked to complete two surveys, pre- and post-intervention, Cultural Awareness Scale (CAS), which measures cultural awareness, sensitivity, knowledge and skills, and the Interpersonal Reactivity Index (IRI), which measures four separate aspects of empathy and its relationships with measures of social functioning, self-esteem, emotionality, and sensitivity to others. We will also solicit qualitative feedback via REDCap survey at the end of the intervention to gain insight into nurse's experiences of the art immersion program.
Objectives	The main objective is to determine if a visual arts educational intervention impacts nurse cultural competency and personal reflection skills. Secondary objective is to assess the feasibility of art immersion techniques for nurses as a broader pedagogical frameworks. We will solicit nurses' qualitative feedback about this aspect of the program.
Methodology	Mixed methods, quantitative pre-post survey and qualitative survey
Endpoint	The endpoint is 7 months from recruitment to final intervention session. The secondary endpoint is a further 3 months for completion of analysis and identification of findings.
Study Duration	The study will take 7 months to complete
Participant Duration	Subject participation will last 7 months from enrollment, to receive two arts education sessions.
Population	Participants will be drawn from the population of NYULH nurses on all campuses.
Study Site	NYULH
Number of participants	Up to 60 participants to be enrolled across NYULH campuses.
Statistical Analysis	Descriptive and inferential statistics will be used to analyze the data. Descriptive statistics will be used to describe the sample demographics. Dependent samples t-tests will be used to assess correlations and differences across time for the CAS and IRI surveys. Convergent analytic techniques will be used to link qualitative feedback to the quantitative survey results.

Key Roles

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1 Introduction, Background Information and Scientific Rationale

1.1 Background Information and Relevant Literature

Nurses comprise the largest segment of the healthcare workforce both nationally and within our urban multi-site academic health system (AHS). Over 4 million registered nurses live and work in the United States and over 9,000 nurses work in this multi-site AHS. Nurses work in modern environments of escalating complexity, facing significant time pressures, staffing challenges and increased patient acuity. They face a myriad of emotional and occupational challenges that affect the nursing workforce, contributing to a cascading crisis in the healthcare workplace through staffing turnover. High stress and nurse burnout result in lower quality and safety of patient care (Keykaleh 2018). It is incumbent upon healthcare organizations to mitigate burnout by supporting overall employee wellbeing. While there are many approaches to activating employee engagement, this program specifically utilizes techniques of engaged observation through visual arts instructional techniques to help nurses hone their skills of perception and to reconnect to their practice. The World Health Organization defines stress to be the “body's response to anything that requires attention or action” (WHO 2022) and clinical workplaces are stressful environments of interruption, urgency and shifting attention. More than ever, nurses need proficiency using in techniques, skills and interventions supporting personal health behaviors and wellness.

1.2 Rationale

The overall goal of this project is to enhance engagement, resilience and cultural competence by introducing nurses to skills drawn from a visual arts pedagogical framework. Through reflective, experiential approaches nurses will be introduced to museum works by an expert educator and guided through interactive exercises and discussions. Though many academic papers describe visual arts frameworks used among nursing students, few describe using this format among nurses in practice with a validated cultural competence instrument.

1.3 Potential Risks & Benefits

1.3.1 Known Potential Risks

The risk of being identified as participating in the study will be minimized by not collecting participant names. All collected information will be placed in REDCap. Once the study is complete emails and cell phone numbers will be destroyed. All de-identified data will be analyzed and reported in aggregate to decrease the chance of being identified. Participants can choose to withdraw from the study at any point.

1.3.2 Known Potential Benefits

Participants may or may not develop increased self-reflective skills that benefit performance and awareness of connections in nursing practice. The results of this study will help to guide future interventions to assist nurses in developing self-reflective and cultural competency skills that translate to the workplace setting.

2 Objectives and Purpose

2.1 Primary Objective

The main objective is to determine if a visual arts educational intervention impacts nurse cultural competency and personal reflection skills.

2.2 Secondary Objectives

The secondary objective is to understand if nurses believe training in the visual arts impacts their clinical practice and whether it can be widely applied to pedagogical nursing practice.

3 Study Design and Endpoints

3.1 Description of Study Design

This is a single-site mixed methods longitudinal cohort with a pre-post measurement design. All NYULH registered nurses will be invited to participate. The purpose of this study is to enhance engagement, coping and self-reflection by attuning nurses to creative and observational skills drawn from a visual arts pedagogical framework. To fulfill this goal, we will cultivate an existing relationship between NYULH Nursing, the NYU Health Sciences Library, and museum educators at The Met to design and deliver an intervention of museum educator-led workshops that introduce nurses to arts appreciation skills to improve their practice and overall wellbeing.

Participants will be asked to complete two surveys, pre- and post-intervention, the Cultural Awareness Scale, which measures cultural awareness, sensitivity, knowledge and skills, and the Interpersonal Reactivity Index, which measures four separate aspects of empathy and its relationships with measures of social functioning, self-esteem, emotionality, and sensitivity to others. We will also solicit qualitative feedback via REDCap survey at the end of the intervention to gain insight into nurse's experiences of the art immersion program. All data will be analyzed in aggregate by the research coordinator and therefore no identifiable information will be available.

Descriptive and inferential statistics will be used to analyze the data. Descriptive statistics will be used to describe the sample demographics. Dependent samples t-tests will be used to assess correlations and

differences pre- and post-intervention for the CAS and IRI surveys. Convergent analytic techniques will be used to link qualitative feedback to the quantitative survey results.

4 Study Enrollment and Withdrawal

4.1 Inclusion Criteria

To be eligible to participate in this study, an individual must meet all the following criteria:

1. A Registered Nurse at NYULH
2. Willing to provide an email address or cell phone number of choice
3. Willing to attend one workshop in person at The MET and one virtually via WebEx
4. Willing and able to provide consent
5. Age 18 years of age or older

4.2 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Not a Registered Nurse at NYULH
2. Not willing to provide an email address or cell phone number of choice
3. Not willing to attend one workshop in person at The MET and one virtually via WebEx

4.3 Vulnerable Subjects

The subjects in this study will be employees at NYULH. The study will only include the subject's email or phone number (for SMS texting only) of choice and no other identifiable information will be collected. All results will be analyzed and reported in aggregate and once the data is collected emails will be destroyed by the PI. Study team members are not direct supervisors of any potential participants. One of the art immersion program workshops will be held at the MET, the other session will be held virtually over WebEx. Research will be conducted outside of work hours where possible and appropriate to minimize the risk of breach of confidentiality. No data will be collected at The MET or any virtual session. All research data will be collected via REDCap survey that will be sent as a link in an email or text message depending on the participants preference. The goal of this nursing study is to study the impact of an art immersion program on nurses and therefore the subjects must be nurses.

Participation is voluntary. Decision whether or not to take part in this study will have no impact on the participants' employment status, salary, or perfornance evaluation at NYU Langone Health.

4.4 Strategies for Recruitment and Retention

Passive recruitment strategies will be used to minimize any coercion/undue influence. Recruitment will be conducted so to ensure employees initiate contact with the study's investigators and to self-identify as an interested participant in a way that maintains their confidentiality, rather than methods by which an investigator approaches or solicits specific employees.

All subjects will be recruited through a recruitment email to specific nursing lists that Kathleen Zavotsky is the administrator over (# PhD-EdD Nursing Council <#PhD-EdDNursingCouncil@nyulangone.org>, #EdD/PhD council # DNP Council <#DNPCouncil@nyulangone.org> and campus specific Research Councils# Research Council <#ResearchCommittee@nyulangone.org>) and study flyers will be available in person at staff meetings and other professional nursing forums that include Annual Nursing Science Day, Nurse Week Events Competency Training sessions). Recruitment email will be sent up to 3 times over a month to maximize participation. No direct supervisors of any potential subject will be involved in recruitment to minimize coercion. The PI Lita Anglin will be responsible for sending recruitment emails.

An additional recruitment email will be sent via #_All_Nurses_ to all NYU Langone Health nurses in month 7 of the study, due to low enrollment in previous recruitment attempts. The email will be sent on behalf of the PI, Lita Anglin, who has no supervisory role over any nurses at NYU Langone Health.

To increase enrollment, Lita Anglin will add the sessions and a link to the REDCap as posted classes in the Health Sciences Library calendar of classes and events. The sessions will also be posted on nursing websites and in the CIAC newsletter.

Approval from Department of Human Resources will be obtained recruitment of employees.

4.5 Duration of Study Participation

The duration of the study for participants will not exceed 6 months.

4.6 Total Number of Participants and Sites

Up to 60 participants will be enrolled from different campuses of NYU Langone Health.

4.7 Participant Withdrawal or Termination

4.7.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from participation in the study at any time.

4.7.2 Handling of Participant Withdrawals or Termination

Participants who wish to withdraw may do so at any time with no consequence to their employment. There is no need to notify the PI, they may cease participation in the program or decline to complete surveys at their own discretion.

4.7.3 Premature Termination or Suspension of Study

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the IRB. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable

Study may resume once concerns about protocol compliance and data quality are addressed and satisfy the IRB.

5 Study Schedule

Activity	Enrollment and Baseline Month 0	Month 1.5	Month 3	Month 6
Informed Consent	X			
Demographic Survey	X			
Cultural Assessment Survey	X			X
Interpersonal Reactivity Index	X			X
Art Workshop 1		X		

Optional Self-directed Activity			X	
Art Workshop 2				X
Post-Intervention Qualitative Survey				X
Additional Art workshops, due to low enrollment (1 in person, 1 online)				x

5.1 Screening

There is no official screening by study staff.

5.2 Enrollment/Baseline

Enrollment/Baseline Collection (Day 0)

- Obtain signed electronic consent from participant via REDCap.
- Participant will complete demographic information, baseline CAS and IRI surveys

5.3 Intermediate Visits

Art Immersion Class 1 (1-2 months from baseline)

- In-person workshop at the MET

Optional Self-Directed Activity (1.5 months from baseline)

- Independent self-directed reflective exercise with art materials and prompts provided by the MET.

Art Immersion Class 2 (3-4 months from baseline)

- Virtual workshop with MET staff via WebEx

Art Immersion Class 3

- Additional in-person workshop at the MET, added due to low enrollment in previous sessions

Art immersion Class 4

- Additional virtual workshop with MET staff via WebEx, for same reason as above

5.4 Final Study Visit

Final Data Collection (6 months from baseline)

- 6-month CAS and IRI surveys
- Post-program qualitative evaluation survey

5.5 Withdrawal Visit

No visit is required for withdrawal, participant may cease participation at any time

5.6 Unscheduled Visit

N/A

6 Study Procedures/Evaluations

6.1 Procedures/Evaluations

After consent has been obtained, the following will take place:

- Participants will be asked to provide their email or cell phone of choice so we may communicate study information, reminders, and surveys via email or text message.

- Participants will then be asked to complete a demographic survey, the Interpersonal Reactivity Index (IRI) and the Cultural Assessment Survey (CAS).
    - The demographic survey contains questions about age, race/ethnicity, gender, years of nursing experience, NYULH campus, specialty, shift time, and role (clinical or nurse leader).
    - CAS measures cultural awareness, sensitivity, knowledge and skills.
    - IRI measures four separate aspects of empathy and its relationships with measures of social functioning, self-esteem, emotionality, and sensitivity to others.

- Following completion of the surveys, participants will be asked to sign up for 2 art immersion classes. Participants will be offered 4 dates to sign up for the art immersion classes. An additional set of one in-person class and one virtual class will be added due to low enrollment. The first class will be an in-person class at the Metropolitan Museum of Art (MET) located on 5th Ave and 86th New York, NY. The second class will be virtual via WebEx. Each class will last 60 minutes.

- There will also be an optional independent self-directed reflective exercise with art materials and prompts provided by the MET.

- At 7 months (after second class), participants will be asked to complete the IRI and the CAS surveys again. Participants will also be asked to complete a short qualitative survey about the overall impact of the art immersion program on your work and life.

Museum educators from The MET will be providing the curriculum that will include an art immersion program that will select specific works/art in the museum as well as virtually that will help to stimulate self-reflection and prompt connection to their nursing practice. MET staff will be conducting workshops as part of their paid job and will not be engaged in human subjects research as researchers.

7 Adverse Events

7.1 Definitions

Unanticipated Problems Involving Risk to Subjects or Others
Any incident, experience, or outcome that meets <u>all</u> of the following criteria:

- <u>Unexpected in nature, severity, or frequency</u> (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc)
- <u>Related or possibly related to participation in the research</u> (i.e. possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research)

- Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm).

Adverse Event
An ***adverse event*** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study.

Serious Adverse Event
Adverse events are classified as serious or non-serious. A ***serious adverse event*** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***.

Post-study Adverse Event
All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained.

7.2 Recording of Adverse Events

At each contact with the subject, the investigator must seek information on adverse events by specific questioning and, as appropriate, by examination. Information on all adverse events should be recorded immediately in the source document, and also in the appropriate adverse event module of the case report form (CRF). All clearly related signs, symptoms, and abnormal diagnostic procedures results should recorded in the source document, though should be grouped under one diagnosis.

All adverse events occurring during the study period must be recorded. The clinical course of each event should be followed until resolution, stabilization, or until it has been determined that the study treatment or participation is not the cause. Serious adverse events that are still ongoing at the end of the study period must be followed up to determine the final outcome. Any serious adverse event that occurs after the study period and is considered to be possibly related to study participation should be recorded and reported immediately.

7.3 Reporting of Serious Adverse Events and Unanticipated Problems

For Narrative Reports of Safety Events
If the report is supplied as a narrative, the minimum necessary information to be provided at the time of the initial report includes:

- Study identifier
- Study Center
- Subject number
- A description of the event
- Date of onset
- Current status
- Whether study treatment was discontinued
- The reason why the event is classified as serious
- Investigator assessment of the association between the event and study treatment

7.3.1 Investigator reporting: notifying the IRB

Federal regulations require timely reporting by investigators to their local IRB of unanticipated problems posing risks to subjects or others. The following describes the NYULMC IRB reporting requirements, though Investigators at participating sites are responsible for meeting the specific requirements of their IRB of record.

Report Promptly, but no later than 5 working days:
Researchers are required to submit reports of the following problems promptly but no later than 5 working days from the time the investigator becomes aware of the event:

- ***Unanticipated problems including adverse events*** **that are unexpected and related**
  - *Unexpected: An event is "unexpected" when its specificity and severity are not accurately reflected in the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document and other relevant sources of information, such as product labeling and package inserts.*
  - *Related to the research procedures: An event is related to the research procedures if in the opinion of the principal investigator or sponsor, the event was more likely than not to be caused by the research procedures.*
  - *Harmful: either caused harm to subjects or others, or placed them at increased risk*

Other Reportable events:
The following events also require prompt reporting to the IRB, though ***no later than 5 working days***:

- ***Complaint of a research subject*** when the complaint indicates unexpected risks or the complaint cannot be resolved by the research team.
- ***Protocol deviations or violations*** (includes intentional and accidental/unintentional deviations from the IRB approved protocol) for any of the following situations:
  - *one or more participants were placed at increased risk of harm*
  - *the event has the potential to occur again*
  - *the deviation was necessary to protect a subject from immediate harm*
- ***Breach of confidentiality***
- ***Incarceration of a participant*** when the research was not previously approved under Subpart C and the investigator believes it is in the best interest of the subject to remain on the study.
- ***New Information indicating a change to the risks or potential benefits*** of the research, in terms of severity or frequency. (e.g. analysis indicates lower-than-expected response rate or a more severe or frequent side effect; Other research finds arm of study has no therapeutic value; FDA labeling change or withdrawal from market)

Reporting Process
The reportable events noted above will be reported to the IRB using a Reportable New Information submission and will include a description of the event with information regarding its fulfillment of the above criteria, follow-up/resolution, and need for revision to consent form and/or other study documentation. Copies of each report and documentation of IRB notification and receipt will be kept in the Clinical Investigator's study file.

8 Study Oversight

It is the responsibility of the Principal Investigator to oversee the safety of the study at her site. This monitoring will include careful assessment and appropriate reporting of adverse events as noted above, as well as the construction and implementation of a data monitoring plan. The PI has experience in leading art immersion programs in collaboration with The MET and will have the support needed by Kathleen Zavotsky, PhD, RN, who is the System Senior Director of Nursing Research to ensure that the integrity of the research protocol is maintained across the campuses.

9 Statistical Considerations

9.1 Study Hypotheses

Primary: Visual arts training by museum educators is associated with increased skills in cultural competency and personal reflection among nurses in clinical practice in an academic health system.

Secondary: Nurses believe training in the visual arts impacts their clinical practice and whether it can be widely applied to pedagogical nursing practice in an academic health system.

9.2 Sample Size Determination

The target sample size is 60 NYULH nurses. Sample size calculations were performed in G*Power with the following parameters

- Test statistic: Dependent samples t-test
- Effect size estimation=0.4
- Type I error probability=0.90
- Type II error probability=0.05

9.3 Statistical Methods

Demographics will be reported with descriptive statistics including means and frequency counts.

The main objective, to determine whether visual arts training by museum educators increases nurses' skill in cultural competency and personal reflection, will be assessed with a dependent samples t-test. We will compare CAS and IRI at baseline and post-program to find if there is a significant difference in mean scores.

The secondary objective, to understand nurse beliefs about the pedagogical value of visual arts education to nursing practice, will be explored via qualitative survey (attached as separate document) and thematically analyzed.

10 Source Documents and Access to Source Data/Documents

REDcap will be the primary data collection instrument for the study.

Access to study records will be limited to IRB-approved members of the study team. The PI will permit study-related monitoring, audits, and inspections by the IRB, the sponsor, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The PI will ensure the capability for inspections of applicable study-related facilities.

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

11 Ethics/Protection of Human Subjects

11.1 Ethical Standard

The PI will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46.

11.2 Institutional Review Board

The protocol, key information sheet, informed consent form, recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval from NYU Langone Health IRB must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

MET staff will be conducting workshops as part of their paid job and will not be engaged in human subjects' research as researchers.

11.3 Informed Consent Process

11.3.1 Consent and Other Informational Documents Provided to Participants

Participants will be given information describing in detail the study intervention, study procedures, and risks prior to starting the intervention. The following consent materials are submitted with this protocol: Key Information Sheet and Informed Consent Form.

11.3.2 Consent Procedures and Documentation

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. The informed consent process will begin with a concise and focused presentation of the key information using an IRB-approved *Key Information Sheet*. Extensive description of risks and possible benefits of participation will be provided to potential participants. If the potential participant is still interested in participating after reading the key information form, they will continue to the consent form and select "yes" or "no" to participating in the study. Should potential participants have any questions or concerns about the study before consenting, they may contact the PI, Lita Anglin, or Sub-I, Kathleen Zavotsky by phone. Phone numbers and emails for the PI and Sub-I will be provided on the REDCap e-consent form. Their participation is voluntary and confidential and neither the PI nor the Sub-I are in supervisory roles for any potential participants and are not responsible for terms of employment. The rights and welfare of the participants will be protected by emphasizing to them that their employment status, salary, or performance evaluation will not be adversely affected if they decline to participate in this study.

Following a selection of "yes" on the consent, participants will continue to the surveys. A waiver of documentation of consent will be applied for as this study is minimal risk and research procedures do not involve procedures for which written consent is normally required outside of research. In addition, this waiver would further minimize the risk of a breach of confidentiality for employees. The updated electronic consent form in REDCap will be submitted to the IRB for review in Research Navigator via Modification before use in the study. Language consistency with the IRB-approved consent materials will be reviewed and approved by the IRB before use.

11.4 Participant and Data Confidentiality

Participant emails will be the only identifiers attached to the data. Data will be stored in REDCap, only accessible to IRB-approved research staff members. Participant emails will be deleted upon completion of the study. Participant data will be kept confidential and not be accessible to anyone outside of the study team. No one on the study team is a supervisor of any participants.

Data will be analyzed and reported in aggregate. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and Institutional regulations.

The study monitor, or representatives of the IRB may inspect all documents and records required to be maintained by the investigator.

11.5 Future Use of Stored Data

Data collected as part of this study will not be stored for future research.

12 Data Handling and Record Keeping

12.1 Data Collection and Management Responsibilities

Data collection is the responsibility of the study staff at the site under the supervision of the PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All data will be collected and stored in REDCap, accessed exclusively by research staff.

12.2 Study Records Retention

Study documents and data will be retained for the longer of 3 years after close out or 5 years after final reporting/publication. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

12.3 Protocol Deviations

A protocol deviation is any noncompliance with the study protocol or MOP requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the site to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation, or within 5 working days of the scheduled protocol-required activity. All deviations must be addressed in study source documents, reported to the IRB. Protocol deviations must be reported to the local IRB per their guidelines. The site PI/study staff is responsible for knowing and adhering to their IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

12.4 Publication and Data Sharing Policy

N/A

13 Study Finances

13.1 Funding Source

13.2 Costs to the Participant

There will be no costs to participants.

13.3 Participant Reimbursements or Payments

Each participant will receive a travel stipend of $50, complimentary entry to the museum to participate in the class, plus an additional complimentary ticket to be used at any other time that you wish. Participants will also be provided with a bag of art supplies for them to keep. Screen shots of selected art supplies will be attached in research navigator.

14 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this study will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the study. The study leadership has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by the NYU Langone Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All NYULH investigators will follow the applicable conflict of interest policies.

15 References

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