**N0N-THERAPEUTIC INTERVENTIONAL TEMPLATE - PROTOCOL TITLE HERE**

**Who should use this template?**

*This template has been created to assist in the development of a behavioral sciences interventional investigator-initiated trial (IIT) protocols that are cancer-relevant and thus require Scientific Review Committee (SRC) approval. Use this template if your study will assign Individuals prospectively based on a protocol to receive specific interventions. These studies have the following characteristics:*

* *They may be single or multi-arm studies*
* *Participants may receive diagnostic, treatment, behavioral, or other types of interventions*
* *Assignment may or may not be random*
* *Participants are followed and biomedical and/or health outcomes are assessed.*

*In contrast, your study may be “observational”; that is, it may not involve prospective intervention or alteration in the status of the participants. An observational study may assess biomedical and/or health outcome(s) in pre-defined groups of participants. The participants may receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study. If your study is observational (non-interventional), use the Behavioral Sciences Non-Interventional Study template.*

**Other important instructions**

***The Protocol Title****: For grant-funded work, use the grant’s title. If the project does not already have an established title, create one that includes study phase, design descriptors (e.g., randomized, double-blind, placebo-controlled, multi-center, etc.), the intervention(s), the target population (disease(s) or condition(s), stage, and the setting (e.g. front-line, adjuvant, etc.). Acronyms should be spelled out.*

***Using this Template****: Titles and order presented in this template are not mandatory, however, the specified information should be present. Instructions and helper language in blue should be deleted before submission. Any language in black is suggested language to be used.*

***Be Clear and Concise to Facilitate a Quick, Smooth Review Process****: Please keep information concise, clear, and well-organized to facilitate SRC review of scientific rigor and significance. We discourage cutting and pasting large chunks of text from a grant. You may want to ask one of the SRC’s medical writers to review the application before it goes in to ensure efficient, effective evaluation by the SRC.*

***Initial SRC/IRB Review****: The initial protocol should be submitted and approved by SRC prior to IRB submission. If this template is being used, this template version should be submitted to the IRB (there should never be an SRC protocol version and IRB protocol version).*

***NOTE: This template is geared towards minimal risk studies. However, please note that the level of risk will be determined by SRC at the initial SRC review****. If the study is determined to be moderate or high risk by SRC, extra details and processes will need to be provided. Please see the DSMP for more information.*

***Protocol Updates and Changes Require SRC Review****: Each update or change to the protocol should be accompanied by a new version date and tracked changes within the protocol, and it must be reviewed by the SRC as well as by the IRB. Ideally there should be a summary of changes at the end of the protocol with rational for each change made within the protocol. SRC and IRB submission may be completed in tandem (after initial SRC/IRB approval)*

**PRINCIPAL INVESTIGATOR**: Name/Credentials

 Institution/Department or Division

 Address

 City, State, Zip

 Phone: [Here]

 Fax: [Here]

 Email: [Here]

**CO-INVESTIGATORS**: Name

 Department/Division *(may group individuals together from same)*

*List Northwestern University co-investigators first, then list co-Is from external sites*

**PARTICIPATING SITES**:*Indicate lead site and include the following information or each site:*

 Name/Credentials

 Institution

 Address, City, State, Zip

 Phone: [Here]

 Fax: [Here]

 Email: [Here]

**STATISTICIAN/ANALYST:** *Can be the PI or a Co-I, but should have expertise relevant to the type(s) of analyses to be conducted (e.g., quantitative and/or qualitative). Complete following request for a statistician to be assigned:* <https://redcap.nubic.northwestern.edu/redcap/surveys/?s=7YAAR3YFHJ>

 Name/Credentials

 Institution

 Email: [Here]

**INTENDED STATISTICAL \_\_\_** Not fully powered (e.g., pilot, feasibility, or other type not

**POWER**: intended to have sufficient power to detect specified effects)

**(check all that apply)** *Requires justification for sample size but not power analysis*

**\_\_\_** Fully powered (e.g., efficacy, effectiveness, or other trial type intended to have sufficient power to detect specified effects)

*Requires power analysis*

**METHODS USED: \_\_\_** Quantitative only (e.g., questionnaires) *Requires biostatistician*

**(check all that apply):** **\_\_\_** Qualitative only (e.g., interviews, focus groups) *Requires analyst*

**\_\_\_** Mixed methods, or both quantitative and qualitative *Requires both biostatistician and analyst (or someone with the capability to do both)*

**FUNDING SOURCE**: **\_\_\_** U.S. Federal government via direct award or sub-award

**(check one)** (e.g., NIH, AHRQ, other federal agencies and departments) (Grant number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 **\_\_\_** Other extramural funder (describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 **\_\_\_** Industry

 **\_\_\_** Not funded/investigator funds

 **\_\_\_** Other (describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

**JUST IN TIME**: **\_\_\_** This application is part of a “just in time” process (i.e., SRC

**(check one)** and IRB applications are being submitted to enable issuance of a notice of award)

 **\_\_\_** This application is not part of a “just in time” process

**VERSION DATE:** MM.DD.YYYY

*Each draft should have its own version date for clarity.*

**AMENDMENT NUMBER:** *X.X*

**COORDINATING CENTER:** *Consider providing this information or delete if not applicable*

**RELATED STUDIES:** *If there any related studies that provide context for the activities covered by this IRB submission, please explain and provide the IRB study numbers for those related applications. (For example, if you plan to use samples or data collected by another study, recruit participants from a registry established by a colleague’s research activity, or conduct a continuation of a prior study.)*

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# List of Abbreviations

*It may be helpful to include a list of frequently-used abbreviations. Some examples commonly used in oncology research include (please delete those that are N/A):*

|  |  |
| --- | --- |
| AE | Adverse Event |
| CAB | Community Advisory Board |
| CBPR | Community-Based Participatory Research  |
| CER | Community Engaged Research |
| CI | Confidence Interval |
| CNS | Central Nervous System |
| CRF | Case Report Form |
| CTCAE | Common Terminology Criteria for Adverse Events |
| CTEP-AERS | Cancer Therapy Evaluation Program Adverse Event Reporting System |
| CTO | Clinical Trials Office |
| DSMB | Data and Safety Monitoring Board  |
| DSMP | Data and Safety Monitoring Plan |
| ECOG | Eastern Cooperative Oncology Group |
| EDW | Enterprise Data Warehouse |
| GCP | Good Clinical Practice |
| HIPAA | Health Insurance Portability and Accountability Act of 1996 |
| HIV | Human Immunodeficiency Virus |
| ICF | Informed Consent Form |
| IRB | Institutional Review Board |
| IQR | Interquartile Range |
| M | Mean |
| MOP | Manual of Operations and Procedures |
| MOST | Multiphase Optimization Strategy Trial |
| MRI | Magnetic Resonance Imaging |
| NCI | National Cancer Institute |
| NCORP | NCI Community Oncology Research Program |
| PRO | Patient-reported Outcomes |
| QAM | Quality Assurance Monitor |
| RCT | Randomized Controlled Trial |
| SAE | Serious Adverse Event |
| SD | Standard Deviation |
| SMART | Sequential Multiple Assignment Randomized Trial |
| WBC | White Blood Cells |

# Study Schema

*The schema should be a diagram or pictorial representation of your study design. For example:*

Population to be recruited

Event (e.g., Screening, Baseline)

Randomize

Arm B: Name

Brief Description

Arm A: Name

Brief Description

Assessment [TIME, e.g., weeks, months]

Assessment [TIME, e.g., weeks, months]

Assessment [TIME, e.g., weeks, months]

# Study Summary

|  |  |
| --- | --- |
| **Title** | Full title of protocol |
| **Version** | Include date & amendment number. |
| **Study Design** | Study phase & design attributes such as 2 arm, parallel groups, randomized, assessor blinded, usual care control; cross-over design, etc. |
| **Study Center(s)** | If multi-center, list all projected centers to be involved and indicate the lead site. If a single IRB will be used, name which site will serve in this role. Participating sites should be established at time of application. If sites are not known, should be listed as “single-center” until sites are identified. |
| **Objectives** | At a minimum list all primary & secondary objectives (can refer to body of protocol for any exploratory objectives if applicable). Objectives may be the same as study aims, as long as they meet the criteria in section 2.0. |
| **Sample Size** | Number of participants projected for entire study. Justification of the sample size (e.g., power calculation for studies meant to be fully powered, or other justification for studies not mean to be fully powered or for qualitative studies). |
| **Study Duration** | Describe how long it will take to reach sample size. Also describe the duration of participation in the study. |
| **Diagnosis & Key Eligibility Criteria** | Note the main clinical disease state under study and some of the main inclusion or exclusion criteria (do not list all criteria here). |
| **Treatment Plan** | Brief overview of treatment plan including study intervention(s) or other description of therapy. Also state overall intervention timeframe.  |
| **Statistical Methodology** | A very brief description of the main elements of the statistical/analytic methodology to be used in the study. Include primary and secondary endpoints and summary of power analysis, if applicable. |

Check **any** **applicable** boxes in the table below – you will be asked for further detail on these topics later in the protocol form:

|  |  |
| --- | --- |
| Indicate Vulnerable Population(s) to be Enrolled | [ ]  Children (you must **complete Appendix A** in addition to this protocol document if you plan to enroll children)[ ]  Cognitively Impaired Adults [ ]  Pregnant Women (IF the research activities will affect the pregnancy or the fetus)[ ]  Prisoners (or other detained/paroled individuals)  |
| International Research (check this box if you will collect data from individuals located outside the United States) | [ ]  |
| Research involving external collaborators (some research activities will be carried out by individuals not employed by Northwestern or NU affiliates) | [ ]  |
| Research has US Federal government funding via direct award or a sub-award (e.g., NIH, AHRC, other federal agencies or departments) | [ ]  |

# Introduction - Background and Rationale

*Please provide background information particularly relevant to you study, including references. Discuss the reasoning for conducting the study in light of the background information already presented. This information should be brief and it should provide clear and concise information about the background and rationale. Consider providing rationale for each of the following:*

* + *The study design being used, including the primary endpoints.*
	+ *The participant population being studied*
	+ *Rationale for current study*

# OBJECTIVES

*Primary objectives of study – listed and numbered individually. Objectives should always be tied to the planned analyses. If there are primary and secondary objectives, or primary and secondary outcomes within the objectives, please indicate them. Objectives may be the same as study aims.*

## Objective 1

## Objective 2

## Objective 3

## Exploratory Aim(s)

*Delete if not applicable*

# Participant Eligiblity

The target population for this study is participants with [insert description]. This will be a [multicenter or single-center] trial conducted at [insert name of site or clinic] of Northwestern University. Remove or revise the following as appropriate: Northwestern University will serve as the lead site and coordinating center for this study. Participating sites will include [list additional sites].

Potential participants may be referred to the Principal Investigator (PI) at Northwestern University, or to the local PI at each participating site.

*Please consider including information on any pre-screening using the enterprise Data Warehouse (EDW) or another resource (e.g., the electronic medical record (EMR)) to identify participants and any information relevant in determining a potential participant is eligible.*

## Inclusion Criteria

*Consider including the following, if applicable:*

* *Diagnosis required, i.e. “Histologically confirmed…”*
* *Extent or stage of disease required if applicable*
* *Prior therapies or medical history*
* *Age range or other demographic characteristics*
* *Any fitness ranges, or health statuses that should be met by the participant*
* *All participants must have given signed, informed consent prior to registration on study*
* *Access to internet or cellular connectivity and sufficient bandwidth to participate in videoconferences (HIPAA-Compliant zoom).*
* *Include a statement about the eligibility of pregnant/lactating females, participants who are sexually active and/or of childbearing potential and the eligibility of any other vulnerable populations (children, prisoners, cognitively impaired adults).*

*Note: If the study will enroll participants who are considered to be of a vulnerable population (children, prisoners, cognitively impaired adults and pregnant women) please include extra measures put in place to safeguard during recruitment, consenting, and data collection in the relevant sections.*

## Exclusion Criteria

*List any criteria which would specifically exclude individuals from the study, consider the following, or remove this section as applicable.*

* *Psychosocial or medical criteria that would make a patient ineligible and how these criteria would be measured or established.*
* *Any medications which should be avoided during intervention and how the use of these medications would be measured or established, if applicable.*
* *Individuals who have a limited level of oral and written English (please use if due to funding you do not intend to have consents and other patient facing documents translated and use a translator).*
* *Individuals, in the opinion of the investigator, with psychiatric illness/social situations that would limit compliance with study requirements. Please include how this would be determined (e.g., a validated measure or clinical judgement)*

# Participant (Randomization and) Registration

*If participants are to be randomized, include specific details and process to be used. For instance, talk about the randomization ratio, method (e.g., permuted blocks and their sizes), variables to be used for stratification, concealment, and blinding.*

*Important note: Participants should be registered in NOTIS by the clinic study team, once eligibility has been confirmed and (ideally) before participating in the study. In accordance with the National Cancer Institute (NCI) requirements, the Lurie Cancer Center (LCC) must report participant demographic and registration data for all cancer relevant interventional research studies. LCC uses NOTIS to capture this information. Language describing this process is provided below. This language is required by the SRC for minimal risk interventions and the data points mentioned in the text are those that LCC must report to NCI.*

*Note: If the protocol is determined to be moderate or high risk, a prospective registration process will need to be put in place.*

At the time of registration, the research team will assign participants a participant ID, which is a unique identifying code. Registered participants will be tracked in the Northwestern Oncology Trial Information System (NOTIS), along with their participant ID, date of registration, date of birth (month and year at a minimum must be collected), gender, race, ethnicity and zip code.

# Waiver of Consent (delete if not applicable)

*If you plan to not consent participants or you plan a modified consent, then a section titled “waiver of consent” or “alterations of consent information” should be included here. If waiver of consent or alterations of consent information are not applicable, please delete this section.*

*If included, this section must include justification for your proposed approach.*

*Justification should include the following information:*

* *Why no consent or a modified consent will be requested*
* *Research involves no more than minimal risk to participants*
* *Research could not be carried out practicably without the waiver or alteration*
* *The waiver or alteration will not adversely affect the rights and welfare of the participants; and,*
* *Where appropriate, the participants will be provided with additional information about their participation.*

*.*

# Study Intervention and Procedures

*Describe the study intervention and/or procedures for participants on study. Please be concise and very clear. Include information needed to evaluate rigor.*

## Data to be Collected

*Consider including a section with what data points will be collected in the study, when they will be collected (timepoints and any windows to these timepoints) and where/how data will be stored. For urine and blood samples, in addition to including timepoints and windows for collection, consider including amounts and collection tubes/containers as applicable, and any processing, shipping and/or storage details. Add a diagram or table if that will help reviewers.*

## Procedures Involving Human Subjects

*Briefly describe procedures involving participants including identifying them, approaching them for recruitment, screening, enrollment/consent, and subsequent study activities. Please make this section as clear as possible and add a table or diagram if that will help reviewers.*

## Duration of Participation

*Consider including information about how long participants will be considered on study. Parameters for participants being taken off study prior to study completion.*

## Removal of Participants from Study Prior to Study Completion

*Describe the parameters for participants being taken off study prior to study completion.*

# Study Activities Table

*Please modify the below table as appropriate to fit the study plan. Column headings may be changed, added, removed, or combined. Procedures and activities should be listed in the far left column. Use of footnotes to provide clarity and detail is encouraged. The table below provides an example. Please consider providing completion windows for study events where appropriate (e.g., to let reviewers know that follow up assessment #1 will occur 1 week after the intervention period but can be completed within a window of 7 days before and after that date). When completing this section think about what assessments are required to be collected at a minimum to ensure study endpoints are met. Please include all study procedures that will be conducted at screening and during the study, including (but not limited to) interviews, focus groups, questionnaires/surveys, EMR data collection, procedures (EEG, EKG, MUGA, ECHO, MRI, CT etc.), biospecimen collections (blood, saliva, hair etc.), mobile applications/wearable devices (e.g., Fitbits, actigraphs, etc.), behavioral decision making tasks (e.g., puzzles, interactive games, etc.), physical activities (e.g., walking, exercise activities etc.), completion of eHealth/mHealth activities. If participants are randomized and will receive different interventions, consider using two tables.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Time Period** | **Screening** | **Baseline** | **Week 1** | **Week 2** | **Week 3** | **Follow Up #1** | **Follow Up #2** |
| **Timing and Window for Completion** | **Prior to enrollment** | **Within 28 days of informed consent** | **Intervention period activities, weeks after baseline, ± 7 days** | **4 weeks after baseline, ± 7 days** | **3 months after baseline, ± 7 days** |
| **Study Activity** |  |  |  |  |  |
| Screening Interview Cognitive Function | X |  |  |  |  |  |  |
|  Exercise <90 min/week | X |  |  |  |  |  |  |
| Informed Consent |  | X |  |  |  |  |  |
| Sociodemographic Data1 |  | X |  |  |  |  |  |
| Medical Data2 |  | X |  |  |  |  | X |
| Questionnaires3 |  | X |  |  |  | X | X |
|  Health-rel. quality of life |  | X |  |  |  | X | X |
|  Depressive symptoms |  | X |  |  |  | X | X |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Time Period** | **Screening** | **Baseline** | **Week 1** | **Week 2** | **Week 3** | **Follow Up #1** | **Follow Up #2** |
| Intervention Arm Online Training Sessions |  |  | X | X | X |  |  |
| Interview4 |  |  |  |  |  | X |  |
| EKG5 |  | X |  |  |  |  |  |
| Blood Sample6 |  | X |  |  |  |  |  |
| Accelerometer7 |  |  | X |  |  |
| Adverse Event Assessment8 |  |  |

1. Sociodemographic data will include *XXX;* all sociodemographic data will be self-reported.
2. Medical data will include XXX and will be abstracted from the medical record
3. Questionnaire will be completed electronically via REDCap at the indicated times. They need to be completed within 24 hours (Note: list domains in this table on separate lines, such as “health-related quality of life” or “depressive symptoms,” and provide information about specific measures in Section 8.9.)
4. Interview, implemented with a semi-structured interview guide, will last approximately 90 minutes and will be conducted by a trained interviewer in person/via videoconference sessions using WebEx and/or HIPAA-compliant Zoom*.* Interviews will be scheduled around participants’ availability.
5. Note: List any measure of physiological/functional data that will be gathered or used (e.g., an EKG) and criteria for its use (e.g., We will use any standard of care measure of EKG gathered at NM within 3 months prior to the start of the intervention may be used)
6. Note: If applicable, provide information about biospecimen collection, such as “Blood will be collected for cfDNA/ctDNA analysis.”
7. Note: Provide information about data collection using monitors such as “Wrist-worn accelerometer validated for research (Actigraph wGT3x-BT) will be worn by participants in both study arms daily during waking hours, except during water activities, for the duration of the intervention period.”
8. Adverse events will be assessed through responses to validated measures completed at baseline and follow-up and by trained staff during patient contacts. Refer to Section XX for more details.

# Assessments and Outcomes

*List measures, being sure to indicate primary and secondary outcomes. This list should correspond to domains listed under “assessments” in the table in Section 7.0, and with study objectives (aims) described in Section 2.0. Be sure to include what will be measured (the domain), how (the measure), and when (the assessments/timepoints).*

*For example, for health-related quality of life (the domain), specify the measure to be used (with relevant citations) and briefly describe it (e.g., relevant information about its development, citation, number of items, response scale, scoring, its scale of measurement [categorical/ordinal/continuous]), Indicate whether it has been validated in a relevant population and describe the assessments/timepoints at which it will be measured.*

## Primary outcome

### Measure 1

*For the primary measure, consider identifying the primary timepoint of interest (e.g., follow-up #1).*

## Secondary outcomes

### Measure 2

### Measure 3

### Measure 4

## Exploratory outcomes

### Measure 5

# Statistical Considerations

## Study Design/Study Endpoints

*This must be written/reviewed by a statistician or analyst prior to SRC submission. Please consider including any definitions relating to objectives (aims) and their respective outcomes. Please consider defining which participants will be considered evaluable for each outcome and if data collected for participants who do not complete study intervention will be used.*

## Sample Size and Justification

*This section must include proposed sample size for each part of your study and justification for it. It should include a statement of feasibility and powering of the study, if applicable. For studies that do not need to be fully statistically powered (e.g., a feasibility trial), describe how you can be sure that the selected sample size will provide meaningful data that can be used to advance the research, ideally providing citations. For qualitative methods, describe how you can be sure that your sample size will sufficient for achieving study objectives (aims), providing citations where possible. This section should be organized by each objective (aim).*

## Data Analysis Plan

*This section must include proposed analyses that correspond directly to the stated aims of the study. For studies that do not need to be fully statistically powered (e.g., a feasibility trial. It should be organized by objective (aim) and refer to domains/measures described in Sections 7.0 and 8.0*

# Adverse Events

## Adverse Events

### Adverse Event Monitoring

Adverse event (AE) data collection and reporting, which are required as part of every clinical trial, are done to ensure the safety of patients enrolled in the studies as well as those who will enroll in future studies using similar agents or interventions. Adverse events are reported in a routine manner at scheduled times during a trial. In addition, certain adverse events must be reported in an expedited manner to allow for optimal monitoring and participant safety and care.

### Adverse Event Definitions & Collection

An adverse event (AE) is any untoward medical occurrence in a participant or clinical investigation participant administered a pharmaceutical product or undergoing an experimental intervention, and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, disease, or medical/psychological/psychiatric event temporally associated with the use of an investigational product or experimental intervention, whether or not related to the investigational product or intervention.

This is a [insert risk level – this is determined at SRC] risk behavioral intervention study.

*Consider providing information on the following:*

* *Timeframe and timepoints that AEs will be monitored and assessed*
* *How AEs will be assessed, CTCAE, patient report, QOL etc.*
* *What will determine an AE for this study*
* *Definition of Serious Adverse Events (SAEs)*
* *Timeframe for monitoring SAEs*

*The higher the risk the more detail and information will be required in this section. If this is more likely to be a high risk protocol consider using AE language from the interventional template for non-behavioral research, modifying as appropriate. When completing this section, consider potential for: physical,*

*psychological, social, and legal risks as well as potential loss of participant confidentiality. If this is determined to be a moderate risk study per the DSMP, be aware that the DSMC will need to see adverse event data every 6 months. In this case, you may want to use an electronic CRF (eCRF) system that can capture these data in NOTIS. For studies determined to be high risk by SRC more oversight by the DSMC and frequent monitoring by the Cancer Center Quality Assurance Team will be required.*

*An example of minimal risk language is:*

*“This is a minimal risk behavioral intervention study with no physical, social, or legal risks and only minimal psychological risk. There are not expected to be many, if any, adverse events reported. Any event that is reported by the participant and determined to be related or possibly related to the intervention of the study will be entered into the EMR, or data management system (e.g., the study’s REDCap database. See Section 10 for details on specific potential risks to participants which will be monitored.*

*Serious Adverse events (SAEs), for the purpose of this study, will be defined as any death or any hospitalization for an event that is determined by the PI to be at least possibly related to the study intervention.*

*Participants will be monitored for psychological adverse events during Visit X through Visit Y through evaluation of scores on self-report measures of XXX and in study contacts that trained staff have with participants throughout the study. Participants will also be instructed to contact the study team to report any adverse events experienced outside intervention sessions.”*

### Reporting to Northwestern University IRB

*Please modify this language as needed*

All serious adverse events (SAEs) which meet criteria defined in Section 10.1.2 that are experienced by a participant will be reported to the Northwestern University IRB in accordance with the IRB’s policies and procedures. Similarly, the PI will inform the IRB of any unanticipated problems or unexpected risks to participants or others that may occur as determined by the PI.

# Potential Risks to Participants

*Consider including/listing any physical, psychological, social, or legal risks to participants and potential loss of participant confidentiality.*

# Potential Benefits to Participants

*Please consider adding any direct benefits to participants, any future benefits to the participant population or this field.*

# Financial Compensation

*Provide any financial compensation that participants will be provided with including any reimbursement for travel etc. include amounts, methods and timing of payment. Delete section or insert n/a, if not applicable to your study.*

# Study Management

## Institutional Review Board (IRB) Approval and Consent

*For studies obtaining consent by phone (e.g., with waiver of signed consent), documenting signed consent with electronic signatures, or other consent procedures, review Northwestern standard operating procedures on the Northwestern eIRB website and revise the text in this section as needed:* [SOPs – Institutional Review Board (IRB) Office (northwestern.edu)](https://www.irb.northwestern.edu/sops/)

*For studies seeking to recruit participants with little or no English proficiency, you may considering adding text such as the following: “For potential study participants with limited proficiency in English, a short form consent document (written in the language understood by the patient) will be used during the initial consent process. In addition, the services of an interpreter who is fluent in both English and the language understood by the potential study participant will be used to explain the contents of the long form consent document (written in English). If the patient enrolls, they will be reconsented using an IRB-approved long form consent document that has been translated to the language understood by the patient, when it is available. The process will be conducted in accordance with guidelines and policies of the IRB of record.”*

It is expected that the IRB will have the proper representation and function in accordance with federally mandated regulations. The IRB should approve the consent form and protocol.

In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s) and should adhere to Good Clinical Practice (GCP) and to ethical principles that have their origin in the Declaration of Helsinki.

Before recruitment and enrollment onto this study, the participant will be given a full explanation of the study and will be given the opportunity to review the consent form. Each consent form must include all the relevant elements currently required by the FDA Regulations and local or state regulations. Once this essential information has been provided to the participant and the investigator is assured that the participant understands the implications of participating in the study, the participant will be asked to give consent to participate in the study by signing an IRB approved consent form.

Prior to participation in the trial, participants should sign the informed consent form and personally date it. The person who conducted the informed consent discussion should also sign and date the form.

## Instructions for Participating Sites

*Remove this language if no additional sites are planned.*

Before the study can be initiated at any site, the following documentation must be provided to the PI and team (as applicable):

* Completed feasibility assessment(s) to verify site’s capacity to support a Northwestern sponsored trial
* Signed copy of Northwestern University’s Data Participating Site Acknowledgement which details data submission guidelines
* Draft consent form for review and approval prior to submission to the local IRB
* A copy of the official IRB approval letter for the protocol and informed consent
* A copy of the IRB approved informed consent
* Pertinent credentials (CVs, MLs, CITI & GCP Training and FDFs) for the local PI and any sub-investigators who will be involved in the study at the site
* Form FDA 1572 appropriately filled out and signed with appropriate supporting certifications

Additional activities may be required prior to site activation (i.e. contract execution, study-specific training, and delegation of authority log). Full requirements will be outlined in the study start-up packet upon successful completion of a feasibility assessment.

### Northwestern University acting as single IRB in Multi-center Research

*Remove this language if NU will not be acting sIRB for multi-center research.*

The Sponsor-Investigator will be responsible for ensuring that all local site investigators conduct the study in accordance with applicable federal regulations and local laws. No study-related activities will happen at relying sites until reliance agreements are fully executed.

Prior to implementing the protocol at each participating site, the current version of the protocol, informed consent form, HIPAA authorization and other relevant documents, as applicable, must be first approved by the Northwestern University Institutional Review Board (IRB) at Northwestern University. In addition, each participating site must be added to the NU IRB study application and IRB approved. The Sponsor-Investigator also will be responsible for the distribution of the most current version of the protocol, consent document, HIPAA authorization, and other relevant study documents, as applicable, to each participating site, in accordance with local regulations.

The Sponsor-Investigator will be responsible for the distribution of relevant safety information and problems (inclusive of reportable events), interim results, and the closure of the study, where relevant, to participating sites in accordance with local regulations. The Sponsor-Investigator will be responsible for ensuring that all IRB-approved modifications to the protocol, consent document, HIPAA authorization, and other applicable materials have been communicated to sites. The Sponsor investigation will be responsible for ensuring that all required approvals (initial, continuing review and modifications) have been obtained by the single IRB.

Upon receipt of all required documents and approvals, the PI and/or team at Northwestern University will formally contact the site and grant permission to proceed with enrollment.

Participants will be recruited according to local site recruitment methods, as described in the protocol and local policies. Recruitment methods not under the control of the local site will not be used.

The Sponsor-Investigator will be responsible for ensuring that non-compliance with the study protocol or applicable requirements will be reported in accordance with the policies of the single IRB.

The Sponsor-Investigator will be responsible for ensuring that all engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.

## Confidentiality of Participants and the Research Data

The confidentiality and privacy rights of participants enrolled in the study will be fully protected and HIPAA regulations will be strictly enforced.

*Please provide mitigation steps to ensure every measure is taken to protect participant confidentiality.*

## Long-term Data Storage & Sharing

*Please consider including length of time that data will be stored and how and when it will be shared.*

*An example of language is “Records for the study will be retained for at least [insert number of years] years after the investigation is completed and accessible only to study personnel. Upon completion of the study, the data files will be fully anonymized and the links between participants and the codes will be deleted. Final data will be shared in accordance with NIH policy. All identifiable information will be removed from the data.” The policy for closing studies and retaining records is described here* [*https://cpb-us-e1.wpmucdn.com/sites.northwestern.edu/dist/2/2819/files/2020/01/Study-Closure-GENERAL-1901.pdf*](https://cpb-us-e1.wpmucdn.com/sites.northwestern.edu/dist/2/2819/files/2020/01/Study-Closure-GENERAL-1901.pdf)*. As it states: “Research records (including IRB applications) must be retained for three years. Records retention must also comply with all other applicable regulations governing the study, including NU Records Retention Schedules… There may be additional records retention requirements associated with the funding agency or other agencies involved in the research – it is the researcher’s responsibility to be aware of any additional records retention requirements associated with sponsors or other agencies involved in the research.” See the NU Policy on Retention of University Records here: https://policies.northwestern.edu/docs/Retention\_of\_University\_Records\_030410.pdf.*

## Data Management and Monitoring/Auditing

This study will be conducted in compliance with the Data Safety Monitoring Plan (DSMP) of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University (please refer to the CTO website for additional information). The level of risk attributed to this study requires [level of intensity determined at SRC review] intensity monitoring, as outlined in the DSMP. In addition, the study will abide by all safety reporting regulations, as set forth in the Code of Federal Regulations.

## Investigator Obligations

The Principal Investigator is responsible for the conduct of the clinical study at the site in accordance with Title 21 of the Code of Federal Regulations and/or the Declaration of Helsinki. The PI is responsible for personally overseeing the treatment of all study participants. The PI must assure that all study site personnel, including sub-investigators and other study staff members, adhere to the study protocol and all FDA/GCP/NCI regulations and guidelines regarding clinical trials both during and after study completion.

# References

*Please begin on separate page*

# Appendices

*Please begin on separate page. May include data collection forms, detailed specimen processing procedures, participant tools (i.e. questionnaires), etc. Please bear in mind that if these tools are modified in some way the protocol will have to undergo an amendment. Questionnaires etc. may remain stand alone supporting documents.*

# Summary of Changes

*Please begin on a separate page. Please consider including a summary of changes for each amendment/version that is submitted to SRC/IRB.*

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| **Amendment X – MM.DD.YYYY** |
| ***Section(s) Affected*** | ***Prior Version*** | ***Changes*** | ***Rationale*** |
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