**Academic Health Care Center - Scientific Advisory and Review Committee (SARC) Flow Chart**

Please complete these forms:

1. IRB Application
2. Standard Operating Procedure Form
3. Delegation Log

Procedure Form

Protocol is sent to 3 AHCC Staff if utilizing AHCC services

Protocol is sent to 3 reviewers (PhD and DO)

Reviewers will have one week to comment on protocol and return comments to the Chair and Co-Chair of the committee

Suggestions will be sent to the Principle Investigator within 10 days of submission or letter of approval with signature sheet to submit to the IRB with your application

Submit these forms to Chair and Co-Chair

Joanne Donoghue Arline Allera

[jdonoghu@nyit.edu](mailto:jdonoghu@nyit.edu) [aallera@nyit.edu](mailto:aallera@nyit.edu)

**Standard Operating Procedures Form**

**NYIT-COM Scientific Advisory Research and Review Committee**

Please complete this form and submit this with your IRB application and Delegation Log to the chair of the SARC committee prior to IRB submission. The chair will randomly assign your protocol to a SARC committee member for review. You will receive approval or recommendations within 10 days of submission.

Please forward to Joanne Donoghue

[jdonoghu@nyit.edu](mailto:jdonoghu@nyit.edu)

Please fill out all that apply. Leave areas blank that so not apply

Principle Investigator

Department: Click or tap here to enter text.

Study Title: Click or tap here to enter text.

Co-Investigators: Click or tap here to enter text.

**Where will the study be conducted? (**check all that apply) physical therapy  biomechanics lab

AHCC treatment room  DEXA Room Other Click or tap here to enter text.

**Who will be scheduling subjects**? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Blood Work: N/A**

1. Who will be drawing the blood? Click or tap here to enter text.
2. Will the subject be fasting? Yes  No
3. Who will document blood draw on sample log?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. What tubes will be used to collect samples?Click or tap here to enter text. (e.g. speckled, green top)
5. How will the blood be processed? (e.g. Spin for 15 minutes, separate serum into plastic transport tubes, frozen within 15 minutes or left at room temperature, how will tubes be labeled):

Click or tap here to enter text.

1. Will you be collecting plasma  serum  both
2. If you are using a Lab (e.g. Quest) please attach collection procedures from lab website.
3. Which colored tube will be centrifuged?\_\_Click or tap here to enter text.
4. How will each tube be labeled (3 identifiers)?Click or tap here to enter text.
5. How will samples be stored (where) or sent to lab? Click or tap here to enter text.
6. Who will be training co-investigators on sample procedures?

Click or tap here to enter text.

**Urine Collection:** N/A

1. Who will be collected and storing the urine?Click or tap here to enter text.
2. Will the urine be collected at home or in the clinic?Click or tap here to enter text.
3. Will you require clinic urine cups for collection? Yes  No 
   1. If yes, how many cups do you anticipate? Click or tap here to enter text.
   2. How will the urine be stored? Click or tap here to enter text.

**Saliva Collection:** N/A ☐

1. Who will be collected and storing the saliva?Click or tap here to enter text.
2. Will the saliva be collected at home or in the clinic?Click or tap here to enter text.

**Osteopathic Treatment N/A**

1. Who will be performing the OMM?Click or tap here to enter text.
2. Who will train each investigator on the protocol?Click or tap here to enter text.
3. How will the procedure be documented?Click or tap here to enter text.

**X-Ray or Radiology N/A**

1. Who will perform X-Ray or Radiology test?\_Click or tap here to enter text.
2. Who will train the technician on the protocol? Click or tap here to enter text.

**Exercise, OT, PT, interventions and testing N/A**

1. Who will be performing outcome measures?Click or tap here to enter text.
2. Who will be conducting the intervention?Click or tap here to enter text.

Click or tap here to enter text.

1. Who will train the co-PI’s on intervention/outcome measures?Click or tap here to enter text.
2. Who will document each subject visit?Click or tap here to enter text.

**Questionnaires and surveys**

1. How many surveys will you use? Click or tap here to enter text.
2. Will you use a preexisting survey or create one? Click or tap here to enter text.
3. Who will be creating the questionnaire?Click or tap here to enter text.
4. Who will the questionnaire target?Click or tap here to enter text.
5. How will the questionnaire be administered? (e.g. electronic, paper)Click or tap here to enter text.
6. How will data be stored from questionnaire? \_Click or tap here to enter text.

How will you recruit subjects? (Check all that apply) Flyer  social media  email  EMR  OtherClick or tap here to enter text.

**Protocol Details**

1. Please type in the type of study design your project will be: Click or tap here to enter text.
2. Please list your Inclusion criteria: Click or tap here to enter text.
3. Please list your exclusion criteria: Click or tap here to enter text.
4. Please list your primary outcome measure(s) Click or tap here to enter text.
5. Please list your secondary outcome measure(s) Click or tap here to enter text.
6. How was sample size determined? Click or tap here to enter text.
7. Will you be randomizing subjects yes/no If yes, how will you be randomizing? Click or tap here to enter text.
8. Please state statistical methods that will be used to compare groups for primary and secondary

outcomes

Click or tap here to enter text.

1. Please briefly state the potential clinical meaningfulness of the study?

Click or tap here to enter text.

1. Please attach your intake demographic forms or any documents you will be using to collect data with this form.

Please insert any comments here:

**Delegation of Responsibilities Log**

***Note: The PI is ultimately responsible for all aspects of the study.***

Study Title: Click or tap here to enter text.

Principal Investigator:Click or tap here to enter text.

Department/Campus: Click or tap here to enter text.

Responsibilities: Record staff responsibilities using the following codes, list **all** that apply.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study Personnel Printed** | **Title** | **Study Personnel Role (e.g. Pi, Co-PI, x-ray technician)** | **Responsibilities**  **(list all letters that apply)** | **Date** |
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***\*****Ensure that clinical responsibilities are only delegated to study personnel who can do so within the scope of their professional licensure and training, and a copy of their state license and training is on file.*

|  |  |  |  |
| --- | --- | --- | --- |
| A) Subject Recruitment | E) Assesses Subject for Adverse Events | H) Regulatory Reporting | |
| B) Obtains Informed Consent | F) Sample Collection | I) Packs/ships samples | |
| C) Performs Study Assessments | G) Data Management | K) Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| D) Completes CRFs |  | |  |