**Arnot Ogden Medical Center**

**(In affiliation with the**

**Lake Erie College of Osteopathic Medicine)**

**Research Proposal A-21-01**

**Sample of a retrospective**

**study proposal**

**(Edited to serve as an example)**

**Part 1 - Cover Material**

1. Title of project: *The impact of cardiac rehabilitation on risk factor reduction in patients with known cardiovascular disease.*
2. Names of authors with institutional affiliation:
	1. **Principal Investigator:** Neha Ghalib. ArnotHealth, Dept of Internal Medicine. neha.ghalib@arnothealth.org
	2. **Additional Investigators:** Dr. Ravi Akula (faculty). ArnotHealth, Dept of Cardiology.
	3. **Research Coordinator:** Dr. Sowmya Srinivas, ArnotHealth.

All investigators have current CITI training certificates on file.

1. IRB status: IRB exemption applied for per 45 CFR 46.104(d)(4).

**Part 2 – Nature of the project**

* + - 1. Research question: To evaluate the relative risk reduction in patients recovering from acute coronary syndrome (ACS), coronary artery bypass graft surgery (CABG), percutaneous coronary intervention (PCI), and heart failure who participated in cardiac rehabilitations (CR) versus those who did not participate in CR.
			2. Study design: Retrospective data analysis via chart review.
			3. Interventions: N/A
			4. Inclusion criteria: Patients between the age of 18 and 65 years who had ACS, CABG, PCI and heart failure, with and without CR from Arnot Ogden Medical Center, between January 2015 and December 2020.
			5. Exclusion criteria: No exclusion criteria other than those who did not follow up within the ArnotHealth system.
			6. Primary outcome measures: We will retrospectively analyze markers of cardiac disease risk to include HbA1c, weight, LDL. HDL and blood pressure, etc. in CR patients versus those who did not receive CR.
			7. Description of data collection: Data will be collected via a Quadramed/ECW/outpatient chart review of patients during the specified period.

**Part 3 – Literature Background**

Cardiac rehabilitation (CR) is an intervention program that incorporates an integrated approach to constructively influence the cause of cardiovascular disease and provide the best physical, social, and mental conditions for participating patients. CR aims to deliver patients the ability to improve their optimal functioning and even reverse the progression of disease. The main component of CR is exercise training. Other aspects of CR include providing risk factor and lifestyle education, counselling and psychosocial support. Combining the knowledge and skills of physicians and other allied healthcare professionals, nutritionists, and cardiac rehabilitation specialists can help enhance cardiovascular outcomes.(1)(2)

In order to assess the benefits of CR, it is important to evaluate the risk factors involved in determining the outcomes. The risk factors that need to be assessed in CR can be classified into traditional and nontradional. Traditional factors include age, family history, hypertension, diabetes, dyslipidemia, and obesity. Nontradional factors are psychosocial stressors, air pollution, and inflammation. One such study, Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION), showed that patients in exercise training programs showed significant improvements in quality of life at a 3-year follow-up. They also had a decreased risk of hospital admissions as compared to the control group that received usual care.(1)(3)

In addition, a study showed supervised CR for a time period of 8 weeks was effective in improving hemodynamic responses and exercise capacity in coronary artery bypass graft (CABG) patients(8). CR programs for the elderly diabetic population showed that weight loss was related to better glycemic control. Weight loss of more than 5% was associated with improved glycemic control. (9) Furthermore, muscle strength has shown to be increased with the help of CR.(10)

**Part 4- Risks/Benefits**

The only risk involved in this study is the potential for breaches of patient privacy. This will be carefully guarded against, as described below. Benefits include the fact that the data gathered from this study will enhance our understanding of the potential risk reductions to be obtained through patient engagement in cardiac rehabilitation programs. If substantial benefits are shown, greater efforts can be made to increase patient participation in CR.

**Part 5 – Privacy Considerations**

Data will be transferred completely deidentified onto a spreadsheet. The spreadsheet will be kept by the investigators on an encrypted and password protected drive to which only the investigators will have the password. Patient information will be deidentified through the scrubbing of name, date of birth, medical record number, and dates of service. The PI will randomize all lines of the excel sheet to minimize the ability to identify a patient based on their relative position in the list and identifying information will be scrubbed from the stored data. There will be no contact with the subjects through surveys or questionnaires. Any paper forms that were used to collect data will be destroyed once the information is recorded on the encrypted drive.

**Part 6 – Additional Forms – N/A**

**Part 7 -- Financial Considerations – N/A**

This project will require no funding.

**Part 8 – Consent process, if applicable: N/A**

**Part 9 –** **Waiver of informed consent requests, if applicable: N/A**

**References**

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