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# Manual of Operations

## Contents



## Operational Manual

## 1. Introduction

The purpose of this document is to provide a manual of operating procedures (MOP) for the principal investigator and other team members of the research project to study the medical and lifestyle determinants of presymptomatic intracranial atherosclerotic disease in two tertiary care centers through a cross-section-center-based study. The role of this document is to facilitate consistency in protocol implementation for recruiting participants of study, implementing the desired tools, collecting data, and analyzing the data. Following the guidelines in OM will assure that the results of the study will be scientifically credible.

## 2. Study Protocol

The detailed study protocol is available in Appendix 1.

## 3. Study Organization

### 3.1 Research Team

The study will be coordinated by a research coordinating committee. The committee will be composed of a principal investigator (PI), Dr. Farzin Majeed, a research supervisor, Dr. Ayeesha Kamal, and the committee members, including Dr. Omrana Pasha and Mr. Mohammad Islam.

Two data collectors, one for each study site, and one data entry officer will be recruited. Data collectors will be recruited for a period of three months, while data entry officer will be recruited for a period of one month. The PI will coordinate all the activities at both the research sites. She will also be responsible for safekeeping and confidentiality of all the data as well for editing and cleaning of the data.

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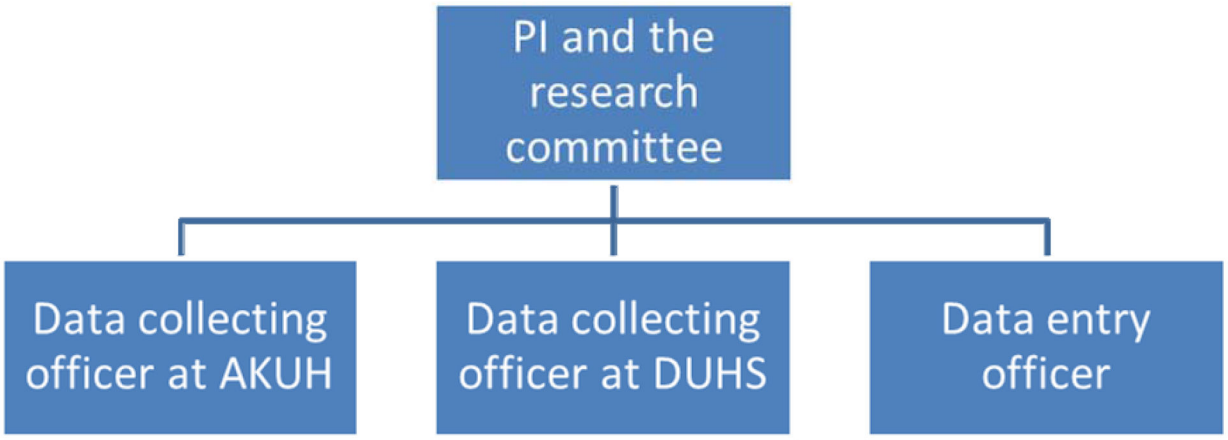



**Fig. 1.**

### 3.2 Operational Organogram

### 3.3 Qualification of the Staff Members

The data collectors recruited for this specific study should have a minimal qualification of bachelors in science. They will be recruited two weeks before the start of the study and will be given a formal training in interviewing for two weeks.

The data entry office should have a bachelor's degree in computer sciences with at least one year of relevant experience. The staff members will be recruited after advertisement through the community health sciences in Aga Khan University.

### 3.4 Coordinating Center

This research project will be coordinated from the office of the PI located in student's area in the department of community health sciences (CHS), Aga Khan University, Karachi, Pakistan. The data collectors would be required to submit all the filled forms to the PI at the end of the day.

The data entry officer will be working from the office of the PI.

### 3.5 Staff Roster

A roster will be maintained containing the names, roles, addresses, phone numbers (landline and mobile phone), and e-mail addresses of the members of research coordinating committee and all other staff members working in the project. This document will have detailed information about who should be contacted in different situations. One copy of this roster will be present at all times in the coordinating office as well as with each data collecting officer. In addition to this, all the members of the research coordinating committee will be provided with one copy of this roster.

### 3.6 Study Settings

This study will have two settings.

**3.6.1 Aga Khan University Hospital—**Patients will be recruited from those who present for getting MRI brain in the radiology department of Aga Khan University Hospital (AKUH) and fulfill the inclusion criteria. The recruitment will be done on a daily basis for all patients presenting between 9 a.m. and 5 p.m. To be able to assess the extent to which enrolled patients represent all potential subjects, clinical study coordinators at each site will keep logs of every eligible patient who will be offered participation in the study, whether or not they chose to enroll. The logs will contain initials and date of birth of the eligible stroke patients, date of screening, sex, and race/ethnicity.

**3.6.2 Dow International (DUHS)—**Patients will also be recruited from the radiology department of Dow university health sciences in the same manner as at AKUH. The recruitment will be done in the same way as elaborated in the previous section.

## 4. Training Plan

### 4.1 Training of the Data Collectors

Before the start of the data collection process, training will be given to the data collectors. The training will be given through a two-day-long workshop conducted by the PI. The training will consist of lectures on communication skills focusing on how the data collectors should

communicate with the study participants as well other team members. They will also be given training on how to perform anthropometric measurements .The specific job descriptions communicated to the data collectors at the time of the recruitment will be elaborated in this lecture. They will also be introduced to different tools that they will be using in this study. The second day will be a practice session. This session will be composed of two exercises. In the first exercise, each one of the data collector will administer all the data collection tools to the PI, and the rest of the data collectors will be watching the whole exercise. The PI will identify the common communication mistakes. In the second exercise, the tools will be administered by all the data collectors to different subjects under the observation of the PI. The two exercises will be followed by a session in which the PI will identify important communication mistakes and importance of avoiding them. A standard method of data reporting would be communicated. Particular emphasis will be given on the color of the pen used for reporting and clear writing to avoid confusion while interpreting the data. The data collectors will mark all forms in blue pen, which will be provided by the PI.

The data collectors will also be trained on how to take informed consent and get it signed by the person himself. In case of refusal, they should not force the participant and ensure that the environment remains cordial.

In the subsequent sessions, the data collectors will be educated about the pattern of communication as specified in the communication section of this document. Manual of operations will be introduced to the data collectors. The sections of the manual of operations relevant to the data collection process would be specified. The data collectors will also be an overview of the study. Training will also include a visit to the specified settings to orient the data collectors to the place and introduce them to the relevant people whom they might encounter during the data collection process. The data collectors will be introduced to all the members of research coordinating committee. One roster containing the contact information will be given to the data collectors. The data collectors need to keep records of all patients they approach, whether they then are enrolled in the study or not. No box or space in the form has to be left blank. If left blank, the reason has to be specified on the right-hand corner.

All data forms coming from the field will be checked by the PI in red pen and discrepant or unfilled forms will be returned for completion.

### 4.2 Training of the Data Entry Officer

Data entry officer will also be trained by the PI. He will be given training on how to read the filled data forms. Codebook will be introduced to the data entry officer. An SPSS spreadsheet made by PI will be given to the data entry officer. The officer will be trained on how to enter the data from the filled forms into the spreadsheet. The PI will request the data entry officer to enter the data for five study participants in front of the PI. The mistakes done in this process by the data entry officer will be communicated to him/her.

## 5. Communication Plan

For ensuring the smooth running of the project, a specified communication plan will be followed. The plan will be composed of a specified number of meetings among the members of the team. The research officer posted at DUHS will be given a mobile card to communicate with the PI in case of any query.

The PI will arrange weekly meetings with the two data collectors to give them feedback regarding the data collection procedure.

The PI will also make random checks at the data collection sites to ensure that data collection procedures are performed according to the SOP.

### 5.1. Between the Members of the Research Coordinating Committee Members

One meeting per month will take place between the members of the research coordinating committee. This meeting will review the progress of the entire research project.

### 5.2. Between the PI and the Data Collection Officer

The PI and the data collection officers will meet once in a week. In this meeting, the field supervisor will check all the forms filled on that day in the presence of data collectors. Any writing mistakes that are difficult to interpret will be identified in the presence of the data collector. If possible, these mistakes will be interpreted and corrected with the help of the data collector. If any data are found missing, the relevant data collector will contact the participant to fill in the missing information. In addition to this, the data collectors will mention any problems that they have encountered during the day in front of the PI. The PI will try to solve the problems as soon as possible.

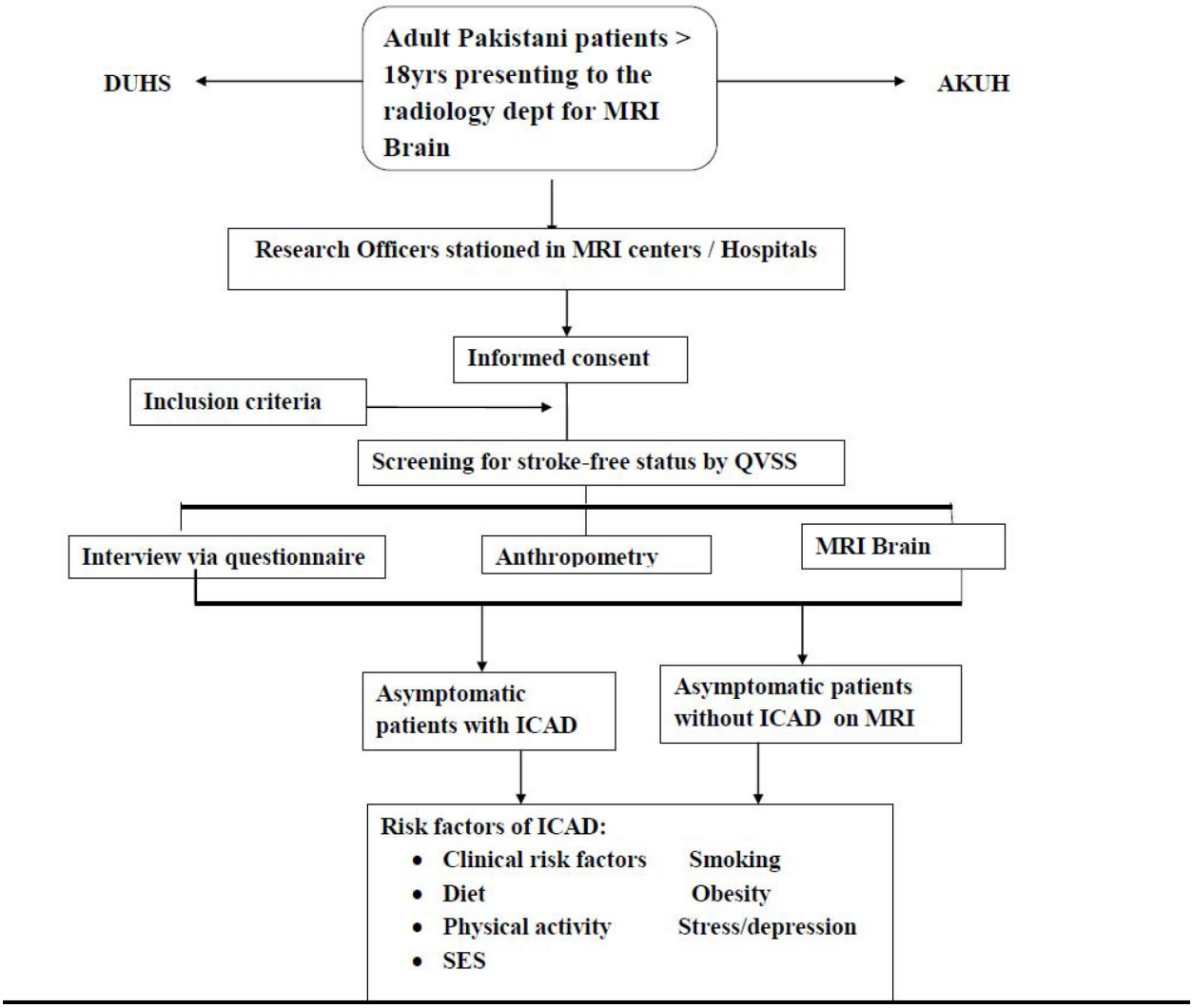



**Fig. 2.**

### 5.3 Between PI and Data Entry Officer

The PI will regularly monitor the data entry process by meeting the data entry officer at least once a day. In this meeting, the PI will monitor the way the data are entered and ask the data entry officer for any problem in the data entry process.

## 6. Study Flow

## 7. Informed Consent

Informed consent will be obtained by the data collectors. They will be instructed to first explain the objectives of the study to the participants and then read the consent form to the anticipated participant in Urdu and make sure that he/she understands the content of the informed consent. If the person agrees to participate in the study then participant will note the name of the participant with the help of blue pen on the consent form. If the subject is able to sign the consent form, his sign will be taken on the consent form. In case of illiterate participants, the thumb mark of the left thumb will be used to indicate the agreement of the participant.

The data collector will make two copies of the consent form. One copy will be given to the study participant. The original consent form will be saved in the office of the research supervisor. Two copies of the consent form will be kept at two different places in the office of PI. The detailed consent form is appended.

## 8. Study Measurements and Procedures

Different tools would be used to collect the needed information. Within each tool, the instructions have been clearly mentioned below each question.

### 8.1 General Guidelines for Data Collectors

All the data collectors will be instructed to write in a clear writing. All writing should be done in capital letters, with adequate space between the two letters. Where tick marks are required, they should be properly marked within the given block. Data collectors will use blue pen. The PI will use red pen for any correction or writing something on the data collection tools. After completing the data collection from each study participant, the data collectors need to review to ensure that all tolls have been administered.

**a.** This can be ensured by using the checklist of the list of tools given the Appendix 2.

**b.** Check for any missing information on each page of all the tools

**c.** Check for the number of pages of all the tools to ensure that none of the information is missing.

**d.** Make sure that the document related to a single participant is stapled together to avoid mixing of documents.

**e.** Before going to the next participant, the documents related to the last participant should be kept in a locked place to ensure the confidentiality.

**f.** Make sure that the number of the study participant is properly written on each page of the questionnaire in clear numbers.

### 8.2. Data Collection Tools

All data collection tools will be translated into Urdu and pretested before the start of the study.

### 8.3. Anthropometric Measurements

For body mass index (BMI) calculation, weight and height will be measured.

**8.3.1. Height measurement—**For height measurement, data collectors will be provided with a measuring tape and a small box.

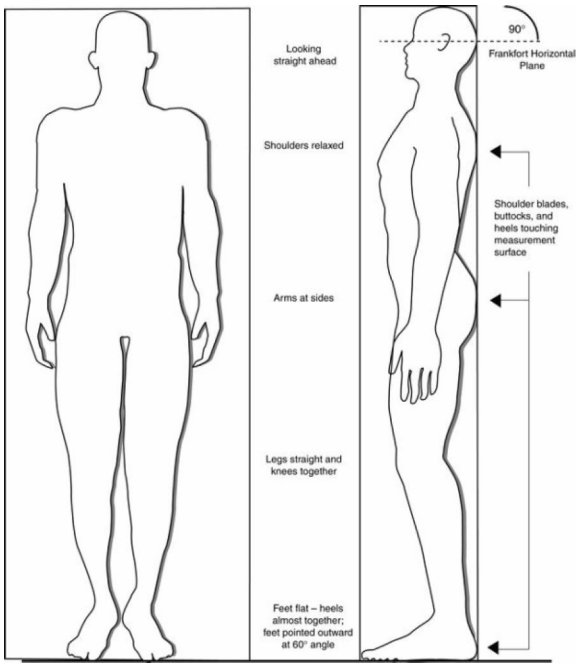



**Fig. 3.**

**PROTOCOL FOR TAKING HEIGHT MEASUREMENT:** (Please see Fig. 3 for proper position)

**1.** Ask the patient to take off his/her shoes and anything on the head (hat, head ornaments, buns, and braids) that would inflate the height (besides hair).

**2.** Make the patient stand with his back against the wall straight with heels together, feet angled at about 60°and hands by the side.

**3.** The back of the feet, butt, shoulders, and the back of the head should be touching the wall. Ask the patient to look straight ahead with the chin tucked in. This ensures that the body is as straight as possible.

**4.** The subject should look straight ahead.

**5.** The data collector needs to have the box in one hand and pencil in the other before he/she starts measuring. Once in good position, raise the box to the top of the patients head, push it against the wall, and make sure that the box is **horizontal.** ***A slight tilt could mean a few inches of difference.***

**6.** Use the measuring tape from the ground up to the mark, and record the height in centimeters. Make extra effort to make sure the tape is

Fig. 4.

straight. This is where a door hinge or a corner comes in handy as they can serve as a guide for the tape.

**8.3.2. Weight measurement—**For measuring weight, a calibrated weighing scale will be provided.

**PROTOCOL FOR MEASURING WEIGHT:** (Please see Fig. 4 for proper position)

1. Set the scale at zero reading.
2. Have the patient remove shoes, heavy outer clothing (jacket, vest, sweater, hat), and empty pockets (cell phones, iPods) to extent possible
3. Have the student step on the scale platform, facing away from the scale read out, with both feet on the platform, and remain still with arms hanging naturally at side and looking forward
4. Read the weight value to the nearest 1/4 pound or 0.1 (1/10) kg

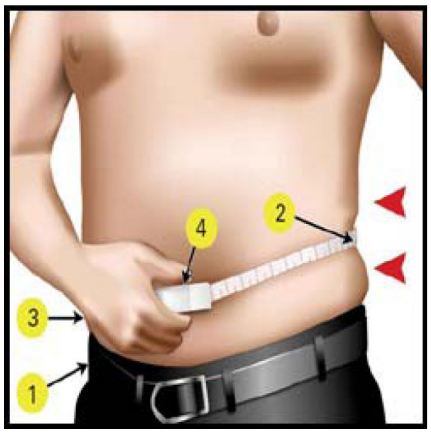



Fig. 5.

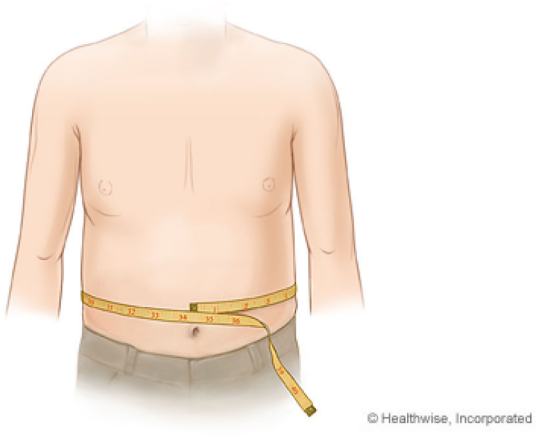
5. Have the patient step off the scale and take a second measurement, repeating the steps above (measurements should agree within 0.1 kg or 1/4 pound; if not, re-measure until this standard is met)
6. For confidentiality and to avoid stigma or harassment, do not call out weight value
7. Record the weight value immediately on the data log in kilograms.

**8.3.3. Waist measurement—**measuring tape will be used (please see Fig. 5 for proper position)

1. Take measurements under the clothes.
2. Position the tape mid-way between the top of the hip bone and the bottom of the rib cage
3. When taking measurement, the abdomen should be relaxed and the patient should be breathing out
4. Record the measurement in centimeters.

## 9.1 Data Management and Confidentiality

All questionnaires will be coded and the identity of the individual will be removed. All filled up questionnaires will be stored under lock and key in the PI's student desk and will be accessible only to the PI. Similarly, the CDs/DVDs containing the patients' MRA brain will also be given same code numbers and the identity of the patient will then be discarded. They will also be stored under lock and key with the PI. Any software taken for entering data will also be available only to the PI, with only the PI knowing the password.



## 10. Data Dissemination

Once the analysis is complete and results are prepared, they will be disseminated to the participants through seminars and workshops.

If an abnormal finding is found in the scans of any patient, they will be notified via post or telephonic communication, whichever is easily feasible. In addition, they will be given appropriate referrals for this.