MATERIAL AND METHODS

3.1: Research Approach; Research Plan and Research Design:

This was programmed in advance, by meeting senior experts in the department.

The term “HOMEOSTENOSIS” was provided by one senior teacher who also provided motivation for study of elderly subjects.

By discussion with guide, it was resolved that such study of senior citizens of Vadodara city was not available, and hence such study can be meaningful as well as important for community.

From these suggestions, the research problem and related research hypothesis was developed that, there is increase in elderly population with increase in life expectancy, yet, in aging population, regrettably such study of heart, lung and blood parameters is on progressively diminishing functional reserve is scanty

Such study of homeostenosis in senior citizens of Vadodara by scientifically approved, valid parameters by equipments and gadgets which can give the results objectively [nullifying chances of personal / manual errors.] which are acceptable because of high specificity and sensitivity; is the need of the time.

Such study will critically address the need to evaluate the patho-physiologic realities of the aging in urban age specific population of Vadodara city.

Also, the outcome will assist in answering the need for the baseline study which can lay the foundation for further establishment of reference values of critical
parameters which are presently not existing or studied sparingly for elderly population of Vadodara city.

3.2: **Research Design:**

This was a partly qualitative [interrogative/history taking type,] and mainly quantitative assessment to determine state of homeostenosis in elderly of Vadodara city which was conducted in single session in two portions.

3.3: **Sample Size of Population:**

In the RAC [Research Advisory Committee] presentation, the guest expert gave a written suggestion that sample size should be determined by consultation of a statistician and as such the size is in accordance to it. As such formula, for the population size, given in literature is not used:

\[ n = \left( \frac{z^2 \times (p \times q)}{d^2} \right) \] [for large sample size]

It was also suggested by him to determine of CBC [Complete Blood Cell] count by automatic cell counter, and so here, the variables presented are as per the given suggestions.

A senior Professor of Physiology, Dr. G. K.Hathi who was constituent member of the RAC at the presentation of the pre Ph.D. Synopsis of this candidate, suggested that; control group of young normal adult individuals in age range of 17-20 years in ratio of 1:<4 [control: case] may suffice as the values in this age group will be suitable without influence of aging changes. The Case: Control sample size is taken accordingly.
3.4: *Research Plan:*

1] The sample size: 50 consecutively coming, community dwelling apparently healthy males and 50 community dwelling apparently healthy females in age group between 60-80 years residing in Vadodara for more than 5 years were studied. 15 young adults between age of 17 and 20 years living in similar region or environment, compared; in population ratio of [<4:1]

3.5: **Biological profile of Population [sample] of study:**

Community dwelling mainly middle class, of origin from Gujarat, largely Hindu, vegetarian, non smoking, non liquor consuming settled in Gujarat; for at least for 5 years staying in Vadodara city. Engaged in sedentary life activity, capable of taking self care, as unassisted daily living, adequate awareness and cognition, apparently healthy, with uncomplicated aging.

3.6: **Selection Bias:**

To avoid selection bias the critical population was selected in form of small groups of age specific clusters from different regions of residential areas like Chhani Jakat Naka to Kareli Baug area, Khande Rao Market area, Manjal Pur area etc.

3.7: **Observational Bias:**

To rectify the observational bias, only those gadgets and equipments which can give the result in objectively observable digital technology were used.
3.7: *Compliance and Co-/Assistant investigator:*

The assessment being single time study there were practically no issues of compliance; moreover, for clinical assistance and for ECG in females, one lady health care professional who is GNM reg. nurse, graduate Naturopathy qualified doctor, experienced in London for taking ECG had assisted.

2] **FOLLOWING DOMAINS WERE STUDIED:**

1) Hematology

2) Cardio-vascular system,

3) Respiratory system.

3] **FOLLOWING HEMATOLOGIC PARAMETERS WERE STUDIED.**

1) Hemoglobin Estimation

2) Total R.B.C. Count

3) Total W.B.C. Count

4) Determination of Blood Indices-

   MCH, MCV, MCHC, PCV, RDW


6) Platelet Count

7) ESR
4] FOLLOWING CARDIO-VASCULAR PARAMETERS WERE STUDIED.

1) Anthropometric Parameters:

   A. Weight in kg.

   B. Height in cm.

   C. BMI [Body Mass Index]

   D. SFT [Skin Fold Thickness]

2) Heart Rate

3) Blood Pressure

4) SpO2 And Radial Pulse tracing By Pulse Oxymeter

5) ECG[Electro Cardio Gram] with:

   - Bipolar Limb Leads: I; II; III;

   - Augmented Leads: aVL; aVR; aVF.

   - Chest Leads: V1; V2; V3; V4; V5; V6; also;

   - P; QRS; PQ; QT; QTc; QT/QTc %; QT/RR %;

   - Axis-P; Axis-QRS; Axis –T.

   - These electrocardiographic investigations were done in resting state by ISO STANDARD automatic read out giving ECG machine.
• Prior standardization was done by company engineer stationed at VADODARA.

5] **RESPIRATORY PARAMETERS STUDIED:**

1) FVC;

   % PREDICTED;

   M PREDICTED,

2) FEV1;

   % PRED.,

   M PREDICTED,

3) FVC PRED;

   % PRED;

   M PRED,

4) FEV1;

   FEV1 % PRED,

   FEV1 M PRED;

5) FEV1/ FVC;

   % PRED

   M PRED
A Spiro gram suggesting any alteration is included if required.

3.8: **PRE REQUISITES:-**

1) Mutual introduction and providing awareness of the Purpose and Procedure to the participant.

2) Adequate privacy, confidentiality.

3) Complete apprising of this investigation to patient.

4) Comfortable and cozy ambience.

5) Informing and providing of patient information sheet.

6) Signing of informed consent paper.

7) Adequate mental and physical rest when indicated.

8) Advices regarding positions in which test is to be done.

9) Providing opportunity to be familiar with gadget.

10) Where the biomarker is prone to have variation, if feasible at least 3 repeats at comprehensive intervals to be performed.

11) Preliminary clinical history including name, age, sex, address, next of kin, case / record no / date of examination / person examining and

12) Anthropometric parameters like height, weight, BMI [Body Mass Index], SFT [Skin Fold Thickness] etc. to be determined.

13) Critical search for exclusion / inclusion criteria.
14) Any information regarding cardiac procedures in past/application of/installation of cardiac prosthetic devices implantation/ cardio-or respiratory medication undergone in recent past/presently to be noted.

15) Data relevant to past hospitalization, blood transfusion etc. to be availed.

16) Any family history of hematologic/cardio-respiratory issue must be ruled out before selection as participant.

- Trained research assistant: The investigator is a trained and qualified doctor who studied /supervised the work of co-worker who was also an experienced medical professional.

- The study was undertaken after consent of subject, on IEC [INSTITUTIONAL ETHICAL COMMITTEE] suggested informed consent sheet.

- Mutual introduction and awareness and purpose and information regarding procedure were provided beforehand.

- Face to face interview or clinical case taking was undertaken. PIS [PARTICIPANT INFORMATION SHEET] with details in it were explained to participants.

- Eligibility of participants was determined by age factor and inclusion and exclusion criteria.

- Battery of investigations as seen in authentic research literature was used.

- The physical function/anthropometry was undertaken to cover demographic assessment.
• Basic assessment data and history was multi dimensional.

• For critical assessment of respiratory function by spirometry, approved protocol was followed.[ATS Protocol]

• The physical fitness level was taken for granted by relevant systems clinically examined and how the participant evaluated his state of health as “apparently healthy”. [not judged by MET by calculation ]

• For BMI ASSESSMENT, the prevalent value determinants were utilized-as under
  a] <18.5=under wt;
  b] 18.5-<25=normal;
  c] 25-<30=over wt.
  d] >30=obese

  [All values in Kg. /m²]

• The Statistical Assessment was done by standard MS Excel version.

• Fidelity/confidentiality-all investigations were done in strict confidential and safe environment, maintaining due care for human dignity and respect.

• Participant adherence /compliance was not the issue as it was a single time assessment.[two sessions]

• For Hematological study, strict aseptic care, approved norms for disposal of resultant waste, and single time sterile disposable kits were used. Also, they were done by qualified staff and by approved methods of Lab. Technology. Samples
collected empty stomach, and samples were studied as early as in 2-4 Hrs. in lab. Hematologic samples collected at similar time, so no diurnal variation could influence the value. The samples were stored at approved temperature.

- The usage of simple equipments were explained to participants, they were allowed to ask questions, and their queries were satisfied.

- Each investigation of spirometry was done by Clarity Company ISO 9001 grade Computerized Spiro Meter.

- ECG study was done by Clarity Company ISO 9001 GRADE digital automatically giving ECG read out type ECG machine, giving all 12 ECG leads at a time.

- SPO2 was studied by Omron Digital equipment displaying digitally the values of Heart Rate, and pulse wave continuously with SPO2 values.

- The Hematological parameters like CBC were studied on automatic cell counter in one 100 bed hospital having all ultra modern heath care facilities.

- Blood pressure was determined on Omron Digital Equipment-Tokyo, JAPAN brand.

- The typical case study sheet is given at end of this synopsis.
INCLUSION CRITERIA:

1) No. - 50 males and 50 females; parsons staying in Vadodara for about / more than 5 years

2) Age – 60 - 80 years.

3) Who gave consent for undergoing this study.

EXCLUSION CRITERIA:

1) Who have undergone a major hospitalization/cardiac surgery/respiratory operation/blood disease/have prosthetic device of heart, or who were taking medicines potentially influencing these critical parameters to be tested.

2) Serious medical / surgical illness / complication of blood / heart / respiratory disorder.

3) Who do not give consent for undergoing this study.