BRITISH WOMEN'S HEART & HEALTH STUDY

PROTOCOL FOR BASELINE SCREENING 1999-2001

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1.0 BACKGROUND

1.1 Who is invited to take part?

The British Women's Heart & Health Study is based on the British Regional Heart Study which recruited men aged 40-59 years in 1978-80 from 24 towns throughout Britain. The women's study will use similar methods and will be able to make comparisons between men and women in each of the towns. A study was carried out in two towns (Dewsbury & Maidstone) in 1996 so these towns will not be included in the current study. In each town a sample of women (approximately 300) will be invited to take part in the study. We anticipate that the response rate will be around 66% resulting in about 200 women taking part in each town, a total of 4,400.

1.2 Liaison with Practices

The study will focus on the single Practice in each town which was originally involved in the men's study. A parallel re-screening exercise is currently underway and the survivors of the original cohort are having a similar battery of tests performed. The re-screening is running about a year ahead of the women's field work.

By the time the Study Team visits a particular town, the town Practice will already have been visited and a meeting held with the Practice Staff to confirm the survey arrangements in the town. The survey will take place either within the Practice or (where this is not possible) in a local Health Clinic or other Health Authority premises.

1.3 Invitations to subjects

The subjects have received a letter inviting them to take part in the study one month in advance. The invitation letter is signed by the Practice partners. A copy of the letter is attached in the Appendix.

The package received by the study subjects will include:-

-the main invitation letter

-an appointment card (with tear-off reply slip)

-a questionnaire on diet

-an information sheet

-a reply paid envelope

The subjects are asked to return:-

-the reply slip confirming, changing or declining their appointment

-the self administered questionnaire, which aims to provide detailed information on the dietary patterns of the subjects,

In preparation for the survey visit they are asked:-

-to fast overnight or (in the case of appointments at or after 11.20) for about five and a half hours;

-to wear clothing which is easily adjustable;

-to bring reading glasses and their medications or a prescription list.

1.4 Framework of assessments being made:-

The subjects will proceed from the receptionist to Research Nurse 1 then to Research Nurse 2 in order, returning to the Receptionist before departure:-

With the receptionist, each subject will:-

-be logged in and have documentation prepared

-prepare for assessment (dressing gown etc)

-receive the self-completed questionnaire and data sheet on a clipboard (all labelled)

With Research Nurse 1, each subject will:

- complete an interview covering current health, diagnosed diseases, disabilities, cardiovascular and respiratory symptoms, medication, smoking and alcohol use, physical activity, diet, social background, pregnancies and family history.

With Research Nurse 2, each subject will:-

-have measurements of height, weight, blood pressure and lung function

-have a resting electrocardiogram

-provide a blood sample

(Research Nurse 3 is reponsible for processing blood samples)

2.0 RECEPTIONIST PROCEDURES

2.1 Subject arrival

As each subject arrives at the centre, the receptionist will:-

-check the identity of each subject on arrival at the centre, including name, date of birth, address and G.P.

-log arrival time and any change of address/G.P.

(S)he will then ask the subject:-

-to undress on top (blouse) but leave bra on and put on a dressing gown. Heavy or bulky objects should be removed from pockets and placed in a shoulder bag provided

-to p.u. if needs to do so before being measured (we are not planning to test urine in the protocol)

She will then direct the subject to Research Nurse 1, issuing the subject with a clipboard with the questionaire and data sheet attached to it.

2.2 Subject return and departure

As each subject returns at the end of assessment, the receptionist will:-

- check the questionnaire has been completed

-book a return appointment, in the case of duplicate subjects

-check that dietary questionnaire was returned, issuing duplicate if necessary

-record the time at the end of assessment

-offer the subject food and drink

2.3 Other duties during the day:-

-Preparation and labelling of questionnaire, data sheets on clipboard

-Maintaining food and drink supplies

-Sorting all material in serial number order at the end of each day.

3.0 RESEARCH NURSE 1 PROCEDURES

Nurse 1 is responsible for administering the questionnaire. She will have the set of cards available.

Procedures for each subject will be as follows:-

- greet patient, checking identity on arrival and ask the subject to put on reading glasses if worn

- read the explanation on the front page of the questionnaire

- ask each question, using the cards as indicated

- check completeness of all items

- thank subject for their help

3.1 At the end of the day

- coding of questionnaires

- general help with tidying up

4.0 RESEARCH NURSE 2 PROCEDURES

4.1 On arrival in the morning

Nurse 2 will be responsible for setting up and calibrating measurement equipment.

Procedures with each subject will be as follows:-

- greet patient, checking identity on arrival and taking the clipboard with Q and data sheet.

-subjects should be asked to remove shoes and to remove any heavy or bulky item from pockets and place in a bowl

4.2 Measurements

These will be taken in order as follows:-

4.2.1 Height

Subjects will be asked to stand on the stadiometer. The Research Nurse should check for the following points:-

- FEET: ankles should be together and resting on the bar at the back,
- ARMS: should be resting by sides, not behind or in front,
- HEAD: subject should be looking straight ahead (i.e. lower edge of orbit is in line with external auditory meatus [earhole])

The index fingers of both hands should then be placed below the mastoid process on each side. During inspiration the increase in height should be maintained and during expiration gentle stretch should be applied. The measurement is recorded at the end of expiration. Care is needed to ensure that the subject does not stand on tiptoe.

Record any problems which the patient has which may lead to underestimation of height in the 'adequate?' box. Reasons may include problem with balance/standing, problem with posture, spinal curvature

The subject should then be asked to sit down and the measurement of height repeated using the same procedure to extend the neck, as described above.

Record any problems which the patient has which may lead to underestimation of sitting height in the 'adequate' box. Reasons may include problems with posture, spinal curvature.

4.2.2 Weight

Weight is recorded on the Soehnle scales. Press button before asking subject to step on.

Subject should stand reasonably straight if possible - leaning to one side (or forwards) can affect the weight recorded.

If the weight registered is between two 0.1 kg marks, take the lower one.

4.2.3 Estimated age and life expectancy

Estimate the approximate age of the participant with reference to their face, general posture, skin and hair. Estimate the number of years of life expectancy the subject might expect. As a reference, a 65 year old woman will live, on average, for another 20 years.

4.2.4 Arm circumference (right arm)

With the subject's right arm flexed to 90º, identify the acromial process and the lower tip of the olecranon. Using the Holtain steel tape measure, identify the midpoint of the upper arm and mark with a felt tip pen. With the arm hanging loosely at the side the arm circumference should be measured at this point to the last completed millimetre.

4.2.45 Blood Pressure (right arm)

The subject should sit down at the measurement table and rest their right arm on the table. This will ensure that the subject is sitting with their upper arm at chest level.

Select the cuff size in accordance with arm circumference. Between 28.0 and 35.0 use standard adult cuff. Less than 28.0 -> small adult cuff, more than 35.0 -> large adult cuff. The cuff should be placed around the upper arm with the bladder centre over the artery.

Check that subject is familiar with having his blood pressure taken. Explain that

-you plan to take 4 measurements one minute apart, the first two sitting and the second two standing

-the cuff will inflate and slowly deflate automatically

-encourage the subject to keep the arm still and not to talk during measurement

The Dinamap should have been set to take repeated measurements at one minute intervals. To take two measurements at one minute intervals, switch the AUTO/MANUAL switch to AUTO. The machine will immediately inflate the cuff and the first reading will begin.

- the measurements of SBP, DBP, MAP and PULSE should be recorded from the Dinamap display while waiting for the second measurement to be made.
- enter room temperature, ethnic origin and the presence of obvious dementia where appropriate

The second measurement will be made after a one minute interval on the Dinamap's automatic cycle.

- record the second measurements from the Dinamap display

Once the second reading is complete, ask the subject to stand up, allowing the right arm to rest loosely by his side. Allow the instrument to continue with two additional measurements and record these.

4.2.6 Waist circumference

This should be measured with the subject standing with feet one foot apart on a marked template.

If the subject is wearing a corset or similar garment this should be removed for these measurements.

The waist should be identified as the mid point between the iliac crest below and the lower edge of the ribs above, i.e. measured at the sides.

Pass the tape around the waist (for large subjects, ask them to help passing the tape around) and reinsert at front, positioning level at the waist.

Ask subject to breathe out gently and record measurement at the end of expiration to the last completed millimetre.

If you are not satisfied about the accuracy of your measurement, record a 1 in the appropriate coding box.

Repeat the measurement

4.2.7 Hip circumference

This is measured by placing the tape measure around the hips at the point of maximum circumference.

The tape should be horizontal and the gluteal muscles not contracted. Record to the last completed millimetre. If you are not satisfied about the accuracy of your measurement, record a 1 in the appropriate coding box.

Repeat the measurement

4.2.8 Spirometry

Preliminary explanation to subject. "This machine measures the size of the lungs. What I want you to do is to take a very big breath in and to blow out as hard and as long as you can, until your lungs are empty. Watch me."

(Demonstration by nurse)

Subject then practices: ensure that:-

full breath in
lips tightly around mouthpiece
long hard blow right to the end

Before measurements made check about use of inhaler and about the time of previous inhaler use.

Before starting the test enter the subject's 4 digit serial number and press the 'enter' key in order to proceed.

On the main menu press 'FVC test'. The machine will then say 'perform test', indicating that it is ready for the first blow.
We want to record three definitive blows.

Please ensure that you encourage the subject during the blow, particularly towards the end, by saying `blow…blow…blow'.

After each blow, press 'end test' to expedite results and then 'retest' to go on to the next test.

The machine takes a short period to calculate results, after which FVC, FEVI and PEF figures will then be displayed on the screen. Once the results of each of the first two blows are displayed press 'retest' and the machine will display 'perform test' to indicate readiness for the next reading.

Once the result of the third reading is recorded, check the `best test variation' which is recorded on the screen. If best test variation is more than 5% after 3 readings, please take an additional reading by pressing 'retest' again.

If you are not satisfied that subject has done an adequate blow on at least one of the readings, please enter 1 in the `problem' box.

Once the 3 (4) readings are complete, press 'end test' to return to the main menu. Press 'print' and then 'selected' to print out the results. The printed output should be stapled onto the front of the data sheet in the space provided. Then press the 'new patient' category and agree to delete old patient's results. This will leave the machine waiting for the next subject's serial number to be entered in due course.

In the event of Vitalograph printer failure

Please record the number of readings and the best test variation directly from the screen before leaving the test screen. Then on main menu press option 5, display results, and write down the other parameters on the data sheet.

- Ask the subject time of last meal and record on datasheet

4.2.9 Electrocardiogram

- Explain that you will perform a heart tracing (ECG) and this is not uncomfortable

- Help the subject to get on to the couch, using the steps if necessary

- Encourage the subject to relax and lie as flat as possible, though a pillow is quite acceptable.

- Place ECG electrodes and record electrocardiogram

- Check quality of tracing and repeat if poor

- Remove the ECG electrodes

4.2.10 Other measurements

-Check for presence of ankle oedema and for presence/absence of all four foot pulses.

4.3 Blood sampling

The blood sample will be taken at the end of the examination, after the electrocardiogram is completed. The blood sample should be taken with the subject lying down.

Check whether the subject has had previous problems with blood sampling.

It is not necessary to clean skin with an alcohol swab unless the area is obviously dirty. If a swab is used, allow skin to dry after use.

A tourniquet may be used throughout. Wear the rubber gloves provided for taking the sample. A 21 gauge butterfly needle (or Sarsted needle) should generally be used; a small supply of 23 gauge needles will also be supplied for exceptional use.

If blood is not obtained at the first attempt, a single further attempt may be made in the opposite arm if the subject consents. No further attempt to obtain blood should be made.

Each subject's blood collection tubes will be prepared in advance by the nurse in a polythene bag with an identification label on the front and individual tube labels throughout. Please check the label against the data sheet. The tube labels will have the subject's full serial number for identification.

The first priority tubes are:-

green	citrate tube	code AE	9.0 ml	
red	EDTA tube	code FJ	9.0 ml	
yellow	fluoride tube	code K	2.7 ml	
white	serum tube	code LP		9.0 ml

The second priority tubes are:

red	EDTA tube	code T	2.7 ml
white	serum tube	code QR	9.0 ml

After venepuncture, raise subject's arm and encourage subject to press firmly on cotton wool pad to avoid bruising. Plasters are provided. Please check for elastoplast allergy - if present, use cotton wool and tape.

After venepuncture the tubes should be gently agitated and placed in a rack. Please record:-

- the time of venepuncture
- the full success/partial success/failure of sampling
- if partial success, which of the ` primary' collection tubes have no blood in them

Samples can then be allowed to sit for at least 30 minutes before centrifuging and separtion and aliquoting.

If the subject is seen during the first week of the study, she should ask whether she would be prepared to return for a further check during the second week of the study (measurements only, no questionnaire).

Possible text

` I wonder whether you would be willing to help us with our quality control procedures and return next week for a repeat measurement. This helps us to find out how much the measurements we are doing vary from day to day and helps us to assess how important the different factors are in relation to heart disease. Is there any possibility that you would be prepared to come back next week for a repeat check up (measurements and blood test, but no questionnaire)?'

Nurse 2 will mark on her appointment list those subjects invited for repeat and whether they agree. If the subject agrees, Nurse 2 will give her a card to take to the receptionist. The receptionist will record the name of each subject in the log book and provide a new appointment card with fasting time recorded. A maximum of 12 subjects per town should be recruited.

4.5 On completion

- pass blood specimens and datasheet to Nurse 3

- thank the subject for their cooperation and praise them for their performance

- ask them to go to the receptionist and hand in their questionnaire and clipboard

- tell them they will then be free to get dressed, half some refreshments and go home

4.4 At the end of the day

- transmit ECGs to Glasgow

5.0 RESEARCH NURSE 3 PROCEDURES

Research Nurse 3 has sole responsibility for the organisation and handling of blood samples. Gloves and an apron should be worn.

5.1 On arrival

-Set up relevant equipment

-Prepare blood syringes and collection tubes for the morning and (if possible) afternoon session, following the appointment list for the day

-to label sample tubes for the day

-to prime tube F with metaphosphoric acid. 1 ml of metaphosphoric acid is placed in the tube, using the accurate manual pipette. (The mixture is made up fresh for each town, 10 grams of metaphosphoric acid to 100 ml of deionized water).

-to collect dry ice for use during the day

5.2 Handling of samples for each subject

5.2.1 Small EDTA (pink) tubes T

-Tube T will be set aside, as this is a whole blood samples which does not require additional preparation. They should be stored in serial number order in a cool place (**not** frozen!) for collection later in the day.

5.2.2 Citrate tube (A-E), EDTA tube (F-J)

-Special priority should be given to the handling of the citrate tube (A-E), which is for coagulation factors. However, the handling of the EDTA tube (F-J) and the glucose tube (K) can take place alongside this one.

Centrifuging After each pair of subjects, the citrate tubes (A-E), the EDTA tube (F-J) and the glucose tube (K) should be spun at 3500 rpm for 5 minutes and then aliquotted. Ideally this will be completed within an hour of collection.

Aliquotting Citrate tube A-E is aliquotted into 5 equal 1 ml aliquots A 1.0 ml, B 1.0 ml, C 1.0 ml, D 1.0 ml, E 1.0 ml [any extra to tube E] (use electronic pipette, discard pipette after use). Take particular care with this tube to ensure the buffy coat layer is untouched.

EDTA tube F-J is aliquotted as follows:-

Into F 0.5 ml using accurate manual pipette

Into G 0.5 ml, H 0.5 ml, I 2.0 ml, J 1.5 ml [any extra to tube J] (using electronic pipette, discard pipette after use)

Freezing These aliquot tubes should be snap-frozen in dry ice once separated. Once snap frozen, they can then be placed in the separate boxes labelled A-J in the -20ºC freezers in serial number order.

Residues The cell residues of the original citrate tube A-E and the EDTA tube F-J should be kept and placed in the freezer at convenience in bags of seven.

5.2.3 Glucose tube (K)

The glucose tube K should be aliquotted using the hand bulb pipette into tube K (1.2 ml or so - tube slightly more than half full). They can then be transferred twice daily to the boxes labelled K in the -20°C freezer in serial number order; no snap freezing is needed. The residue of the first tube K can be discarded.

5.2.4 Serum tubes L-P and Q-R

As time permits, the serum tubes L-P and Q-R should be dealt with. They should be allowed a minimum of 30 minutes to settle before centrifuging.

Centrifuging They should be centrifuged at 3500 rpm for 10 minutes. A small number of tubes may not separate well and require recentrifuging at 4000 rpm for a further 5-10 minutes.

Aliquotting After centrifugation they should be sorted into pairs for each individual; each pair should be aliqotted in turn. The allocation of the two tubes should be sorted in order as follows; do L-P tube first, and aliquot as far as it will go. Serum from L-P and Q-R is interchangeable - can be used for top ups if needed. Both of these can be done with one electronic pipette.

Serum tube L-P into Monovet tube W 1.5 ml, L 0.5 ml, M 0.5 ml, N 0.5 ml

Serum tube Q-R into aliquot tube O 1.0 ml, P 1.0ml, Q 1.0ml R 1.0ml [any extra to tube R].

Freezing These aliquots should be transferred into the appropriate boxes L to O and placed in the -20 freezer and placed in batch number order; there is no need to snap freeze the samples.

Residues The cell residues of the serum tubes L-P and Q-R can be discarded.

5.3 Documentation of blood sampling

5.3.1 Paper printouts

For the tubes which will be most rapidly analysed, which are:-

-tube T (full blood count)
-tube W (biochemistry)
-tube K (biochemistry)

it will be necessary to mark on a paper printout which samples are not present. For tube T (FBC) this will need to be updated regularly and checked before samples collected at 2.00 p.m. The listing will need to be cut at the collection point and later afternoon samples will go with the following day's material.

A summary for each of tubes W and K will be needed for the whole town.

5.3.2 Data sheet blood sample documentation

It is very important that we are aware of any tubes which have **not** been filled. These should be recorded on the data sheet as soon as possible. It will not be possible to make a final data sheet entry

for each subject until **all** that subject's tubes are dealt with.

The default code will be ` all tubes filled? yes = 1' No other entry will then be needed.

If all tubes filled? no = 2 we then need to mark the individual aliquot tubes which have **not** been filled. Tubes which have blood in, even if short, should be considered as filled for this purpose.

5.4 Problems

Insufficient sample Simply fill as many aliquot tubes as possible from what has been collected, in the usual order.

Blood into the wrong tubes The samples should be left in and the aliquot tubes relabelled in biro (not felt-tip) - (spare blank labels might be helpful).

5.5 At the end of the day

Clean out centrifuges as needed

Ensure that samples are all packed appropriately into their receiving boxes (tube A, tube B etc) and that no samples are still on dry ice.

Set pipette buoys to charge

6.0 CALIBRATION AND CHECKING OF INSTRUMENTS (Research Nurse 2)

6.1 MORNING SESSION

The following calibration steps should be undertaken:-

6.1.1 Stadiometer

Please check recorded height of standard 1 metre rule once instrument set up, and record result. (This ensures that recorder has not become displaced)

6.1.2 Scales

The zero setting on the scales should be checked by pressing the reset button with the scales empty. This should be 00.0. The result should be recorded. If there is a problem:-

- check that correct adapter voltage (9.0 volts) is being used
- if persists, please discuss with base at earliest convenience

6.1.3 Spirometer

Please ensure that spirometer is turned on early and left to warm up before testing.

Check paper supply.

Enter 'set up' mode and go to 1 'accuracy + calibration'. when the machine invites you to blow air through the flowhead to equilibrate temperatures, please blow 3 litres through slowly,
then 'continue'.

Set ambient (room temperature) consulting the electronic thermometer.

Pump 5 litres of air slowly (each litre must take more than 1 second) through the flowhead to calibrate and then 'exit'.

Read in 5.00 as reference volume and enter.

Update calibration if error is 1% or greater.

'Retest' by putting a further 5 litres of air through the flowhead. If error is 1% or greater update calibration again and retest one more time.

If calibration will not settle, raise threshold for correction to 3%.

When you have finished, move to main menu and to FVC test, and when the machine says 'perform blow', blow 1 litre through calibration syringe and record the result.

6.1.4 Dinamap blood pressure recorder

- put machine in auto mode and use set button to set interval between readings at one minute

The calibration procedure is as follows:-

(I) Set up the instrument with the adult cuff to be used in place. Insert the calibration kit on one of the

cuff connector leads. Turn the instrument on with the SET button held in. The CYCLE display should show 88, and will continue to do so while the instrument is in calibration mode.

The machine is now in calibration mode 1.

Display read:- CYCLE 88
MAP 0
All others blank

Inflate the cuff until the mercury column reads 200mm Hg (top of the mercury meniscus). RECORD the MAP result. Check that there are no leaks (pressure remains above 190mmHg for at least 10 seconds).

Check MAP readings at 150, 100, 50, 0mmHg on the mercury column, RECORDING the result each time.

If leaks in system:-
- try replacing cuff with reserve
- try replacing blue cable with spare

If problem not solved discuss instrument servicing/replacement with Peter at earliest opportunity

6.2 AFTERNOON SESSION

Recalibrate the Vitalograph as before.

7.0 REPEAT MEASUREMENTS

A subset of non-migrant subjects seen in the first week of the study will be asked to return for a repeat measurement during the second week of the study. The aim is to obtain remeasurements in about 5% of the total. This will involve 10 subjects per town (suggest we attempt to recruit 12).

These subjects will be recruited by RN2 from the outset. Need to be clear about who invited and who agreed. The Receptionist will book them an appointment at the end of the survey. For their second visit they will be provided with one of a pre-prepared list of supplementary serial numbers, which will be allocated by the Receptionist at the time of booking.

On the return visit, the subject will skip the questionnaire, but will go through the remaining aspects of the measurement and blood taking procedure as before.

8.0 FEEDBACK OF RESULTS

When the subject agrees, results will be fed back to the subject's G.P. including:-

Height

Weight

Body mass index with cutoffs as a comment, viz:-

20 or less	=	underweight
> 20-25	=	acceptable
> 25-30	=	overweight
> 30	=	obese

Systolic BP (mean of 2 readings, minus 8 mm)

Diastolic BP (mean of 2 readings)

Blood results

From biochemistry

include

Total, LDL, HDL cholesterol and triglycerides

Blood glucose

urea k na creatinine urate

tprotein alb bili alk phos ast = aspart transam alt = alanin transam ggt = gamma gt

(exclude mg ca corr ca po4)

From haematology

include wbc, hb, platelets, rbc, hct, mcv, mch, mchc only

Abnormal values as defined by the laboratory will be indicated with a star next to the abnormal parameter. A copy of the ECG with report will be attached to this output. Abnormal values requiring more urgent attention are summarized on the next page.

9.0 MARKEDLY ABNORMAL RESULTS

9.1 During study measurements

The only abnormalities which are likely to be identified during the study measurements are a high blood pressure reading or an abnormal electrocardiogram.

9.1.1 Action for high blood pressure readings

Comparability issue

Bear in mind that the Dinamap records systolic pressure about 8mm Hg higher than the mercury

sphygmomanometer; diastolic readings are virtually identical. This is taken into account in the following recommendations, which refer to actual DINAMAP readings.

Diastolic pressure readings

Average 120mm Hg or more: severely raised

Average 100-119mm Hg: moderately raised

Systolic blood pressure readings

Average 210mm Hg or more: severely raised

Average 180-209mm Hg: moderately raised

If either systolic or diastolic pressure is **severely** raised, should tell the patient:-

`Your blood pressure is **high** today. Has your blood pressure been high before, or have you received treatment for high blood pressure?'

(If no), `Blood pressure can vary from day to day, so that one high reading does not necessarily mean that you have high blood pressure.'

(All) `You would be well advised to arrange to see your doctor **within a week** to have a further check on your blood pressure. I will give you a card with a note of your blood readings today to give to your doctor'

If either systolic or diastolic pressure is **moderately** raised, should tell the patient:-

`Your blood pressure is **on the high side** today. Has your blood pressure been high before, or have you received treatment for high blood pressure?'

(If no), `Blood pressure can vary from day to day, so that one high reading does not necessarily mean that you have high blood pressure.'

(All) `You would be well advised to arrange to see your doctor **during the next two or three weeks** to have a further check on your blood pressure. I will give you a card with a note of your blood readings today to give to your doctor'

Direct notification of GP - to be discussed **

9.1.2 Electrocardiograms

Always consider the state of the subject first in interpretation. If the subject is well and symptom-free, threshold for rapid action on the ECG will be higher.

If the ECG specifies `acute myocardial infarction' ask the patient about recent chest pain,

breathlessness or other symptoms of ill-health and about any previous history of heart trouble. Irrespective of answers to these questions, should refer patient directly to G.P.

If the ECG specifies digoxin toxicity and the subject is taking digoxin or any other cardioac glycoside, he should be referred to the G.P. directly.

9.2 Abnormalities on biochemical/haematological tests

Results which should be phoned through to the General Practitioner directly would include:-

blood glucose above 15 mmol/L (provide urea and electrolytes also)

blood urea above 20 mmol/L

serum potassium below 2.5 mmol/L or above 6.0 mmol/L
serum sodium below 120 mmol/L

Haemoglobin below 8.0 g/dl; acute leukemia

10.0 PROTOCOL VIOLATIONS/DEPARTURES FROM PLAN

These will need to be dealt with as they arise. Details should be recorded in the study log book.

If a member of staff is ill:-

-please phone base so that a replacement can be found as soon as possible and any other arrangements made

-if one nurse is out of action without replacement:-

-Research Nurse 1 proceed as usual with questionnaire

-Research Nurse 2 should do physical measurements and venesection, but omitting waist-hip ratio and ECG. Aliquoting of bloods to be done as time permits

11.0 ANSWERING QUESTIONS ABOUT THE STUDY

What is the study for?

What has the study shown so far?

Will you want to see me again?

Will these results be seen by my doctor?

What happens if my tests are abnormal?

Dear Doctor_____,

British Regional Heart Study

Your patient_____ attended our survey examination. Her sitting blood pressure readings were:-

SBP*_____DBP_____

SBP*_____DBP_____

We recommended that he should attend your surgery for a further blood pressure measurement within a week/within two-three weeks.

Thank you for your attention.

British Regional Heart Study

* These measurements were made with a Dinamap instrument, which overestimates systolic blood pressure by about 8 mmHg compared with a mercury sphygmomanometer.

For attention of study receptionist

This study participant has kindly agreed to return for a further set of survey measurements during the next few days. Please book her another appointment to attend at her convenience.

<<Name>>
<<Address1>>
<<Town>> <<Postcode>>

Dear <<name>>

We are writing to invite you to take part in the **British Women's Heart & Health Study.** The purpose of this study is to find out how common heart disease is among women living in different parts of Britain. We also want to find out more about the causes of heart disease in women, as this will help us to prevent heart problems in the future. Finally, we want to know more about how women with heart disease are treated in Britain so that we can improve health services for women.

To take part in the study, which is funded by the Department of Health, a study team of trained nurses will see you for a health check at the John Milton clinic for an appointment during the two weeks beginning April 19th. The examination will include a questionnaire on past medical history and lifestyle, height, weight and waist measurement, an assessment of your heart (electrocardiogram), blood pressure, lung capacity and a blood sample.

We hope that you will be willing to have this check up, whether or not you have heart trouble, as we believe it will provide valuable new information about the health of British women and will also be in your own interest. However, should you choose not to take part in the study, it will have no effect on your usual medical care.
Enclosed with this letter is a dietary questionnaire and an appointment invitation offering a date and time for you to attend. Please tick a box either:

1. Accepting the appointment offered
2. Choosing another date and time on the calendar provided
3. Declining to take part

or 4. Providing your telephone number if you require further information or help.

Please return the reply slip and completed questionnaire in the enclosed pre-paid envelope even if you are unable to accept the appointment. No stamp is needed. Further information about the study can be obtained directly from the research team at the Department of Social Medicine, Bristol University on 0117 928 7327 who will call you back if you leave your number.
With our best wishes

Yours sincerely