Preventing **O**varian Cancer **t**hrough early **E**x**c**ision of **T**ubes and late **O**varian **R**emoval (PROTECTOR) Study

Participant Information Sheet

Before you decide to take part in this study, it is important for you to understand its purpose and what it will involve. Please take time to read the following information carefully. Do discuss it with your family, friends, healthcare professional or others if you wish. Please ask if there is anything you do not understand or if you would like more information.

What is the PROTECTOR study?

PROTECTOR is a research study for women who are at an increased risk of developing ovarian cancer. Some women may carry a fault/alteration in their BRCA1 or BRCA2 gene making them high risk. Whilst, others may be at an increased risk due to a strong family history of cancer or a fault in another ovarian cancer causing gene like RAD51C, RAD51D or BRIP1. This study aims to assess the impact on women of a new two-step option to prevent ovarian cancer. This involves initially just having your tubes (fallopian tubes) removed to prevent ovarian cancer. This is followed by removing your ovaries in a separate operation at a later date of your choosing. The study assesses women's views and the impact of this approach to prevent ovarian cancer on sexual function, hormone levels, quality of life and overall satisfaction. Outcomes from this new approach are compared to the traditional approach of removal of both tubes and ovaries at the same operation. We also compared this to the well-being of women who do not have an operation.

Background information

Some women have an alteration or fault in their DNA sequence or genetic code which makes them high risk of developing ovarian cancer. Two such genes in which a fault may lie are known as the BRCA1 and BRCA2 genes. Pronounced '"brakka-1'" and '"brakka-2"'. Other examples of faulty genes which increase risk include RAD51C, RAD51D and BRIP1. Women with a strong family history of ovarian cancer or breast and ovarian cancer may also have a higher risk of developing ovarian cancer.

The currently advised practice is to offer an operation to remove both tubes **and** ovaries to prevent ovarian cancer in women at increased risk. This is undertaken after a woman has completed her family. It is called **R**isk **R**educing **S**alpingo **O**ophorectomy or **RRSO**. (Salpingo-oophorectomy = removal of tubes and ovaries). Removing both tubes and ovaries (RRSO) at present is the most effective or best way we have to prevent ovarian cancer in women who are at increased risk.

It involves undergoing a single operation to remove the 'tubes **and** ovaries' (Figure 1a). This is usually done through keyhole surgery under a general anaesthetic. This is available on the NHS (National Health Service). It is usually undertaken after the age of 35-40 years. Removal of the ovaries will lead to early menopause.

Early menopause is associated with side effects like hot flushes, sweats, mood changes, thinning of the bones, memory problems and a higher risk of heart disease. It may also reduce libido and impair sexual function. Taking hormone replacement therapy can minimise these side effects. A number of women choose to decline or delay this operation to avoid the potential symptoms or problems of early menopause.

The fallopian tube is the tube that is connected to the womb. It collects the egg from the ovary and transports it to the womb. Current research suggests that a significant number of cancers of the ovary actually start in the fallopian tube. It is important to understand that ovarian cancers may start outside of the tube too.

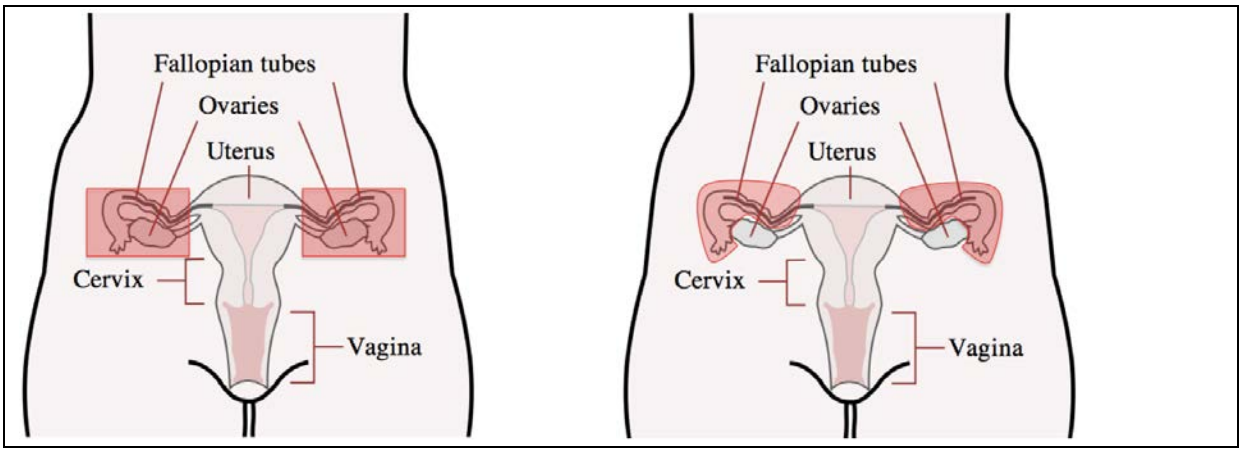

Figure 1a: Current procedure showing removal of tubes and ovaries (shaded in red).

Figure 1b: Proposed procedure showing removal of tubes alone (shaded in red)

It is now well established that a large proportion of ovarian cancers start in the tube. A number of experts believe that removing the tubes alone would provide some protection from getting ovarian cancer (Figure 1b). This 'first stage' is called **R**isk **R**educing **E**arly **S**alpingectomy (RRES). (Salpingectomy = removal of tubes). This may be particularly helpful for those women who wish to avoid or delay menopause. Women who just have their fallopian tubes removed will need to have a *second* operation at a later date to remove their ovaries. This 'second stage' can be undertaken once they reach the menopause or at a date closer to menopause whenever the woman wishes. This is called **D**elayed **O**ophorectomy (**DO**). (Oophorectomy = removal of ovaries). This is essential to provide optimal protection against ovarian cancer. Both operations are usually carried out by keyhole surgery (laparoscopy) under general anaesthesia. Each operation may involve an overnight stay in hospital and the recovery time is usually 1-2 weeks.

At present the 'precise' level of benefit obtained from removing the tubes alone is not known.

There are no research studies to show whether this 'two-stage procedure' is effective for preventing ovarian cancer.

In this study we are comparing outcomes of women undergoing this new two stage operation (**RRES + DO**) with the outcomes from women undergoing standard operation of removing both tubes and ovaries at the same time (**RRSO**). We are also interested in comparing outcomes with women who have no operation (**controls**). **You are free to choose whichever of the three options you prefer.**

What are the aims of the study?

- This study aims to assess the impact on sexual function, hormone levels, quality of life and satisfaction in women who have the new two stage operation to prevent ovarian cancer called **R**isk **R**educing **E**arly **S**alpingectomy and **D**elayed **O**ophorectomy (**RRESDO**).
- It will assess the impact on psychological well being
- It will assess the views of women and factors affecting decision making
- The project will evaluate the number of ovarian/fallopian tube/peritoneal/non-ovarian cancers developed in women who have RRESDO.
- It will assess the number of surgical complications.
- It will assess how cost effective this new procedure is in comparison to the routine operation currently performed (RRSO).
- The study will aim to develop a national register of women who have this new procedure to help with long term follow up.

Am I eligible to take part?

You may take part if you:

- Are at an increased risk of developing ovarian cancer. This is either because you carry an alteration/fault in one of the ovarian cancer genes like BRCA1, BRCA2, RAD51C, RAD51D, or BRIP1or you have a strong family history that puts you at higher risk of developing ovarian cancer.
- Are aged 30 years and over and have **not** gone through the menopause.
- Have completed your family - if you are choosing to undergo an operation to prevent ovarian cancer. You may also take part if you are not currently planning to have an operation to reduce your risk.

How do I take part?

- Your doctor will go through all the options available to you and you will be asked to read this patient information booklet.
- You will be given the opportunity to ask questions.

- Once you are satisfied that this is a study you would like to take part in, you will be asked to sign a consent form. Your doctor will go through the form with you.

What will happen if I decide to take part?

You will be given the choice of choosing which arm of the study you wish to be part of:

- **RRESDO**: the new, two staged operation to prevent ovarian cancer (initial removal of tubes followed by later removal of ovaries at a second operation).
- **RRSO**: the current operation which is standard of care on the NHS (removal of both tubes and ovaries at the same time).
- **Controls**: no operation involved.

What is subsequently involved depends on which of the above three options you choose.

RRESDO

- Before the operation, you will receive a baseline ultrasound scan to look at your ovaries. You will also have a blood test for an ovarian cancer marker called CA125 and a hormone called FSH. You will be asked to complete detailed questionnaires before the operation. This will ask about medical history, family history, quality of life, sexual function, cancer worry, psychological well-being and how satisfied you are with your decision.
- If your ultrasound scan shows abnormal ovaries or your CA125 is not normal you will be referred to your local gynaecologist/ gynaecological oncologist for review. It is possible your doctor may choose to do further tests. If after this, your doctor is satisfied that there is no suspicion of cancer, we will be able to proceed with the operation to remove both your tubes.
- The operation will often be performed laparoscopically (by key-hole). For a small number of women (less than 1 in 20) this will not be possible. In them the surgeon will need to make an incision (cut) to open your abdomen (tummy). This could be for any number of reasons such as, technical problems during surgery, obesity, scarring from previous operations, or bleeding during the procedure. Women who have had previous abdominal operations are also more likely to need an open incision. The operation will be performed under general anaesthesia.
- The average hospital stay associated with keyhole surgery is 1 day, compared with 5 days for open surgery. After keyhole surgery it is possible to return to normal activity in 1-2 weeks. With open surgery the average return to normal activity is 6 weeks.

- During the operation both your fallopian tubes will be removed. We will also collect some fluid (washings) from the abdomen (tummy) during the operation. These will be sent for examination to specialists called pathologists. The pathologist will carefully examine this under a microscope to look for any abnormal cells or signs of cancer/ pre-cancer.

- After the operation your doctor will be able to give you your results. This can take around 4 weeks. You will be seen in clinic for a check up to ensure your wound is healing well.
- At three months and then every year (for three years) after the operation, you will be posted follow up questionnaires. We will ask you to return this to us in a self-addressed freepost envelope we send you. You will also have a blood test for a hormone called FSH (3 months after the operation and then every year for three years). This will tell us how your ovaries are functioning. Your name will be added to a register of women who have had early salpingectomy. This will help the study team to follow your progress.
- It is important for you to have your second operation to remove both your ovaries at a later date. This may be done soon after menopause. You may also choose to have your ovaries removed before you reach the menopause. Again this is often done via key-hole surgery. Before this second operation, you will have another ultrasound scan to look at your ovaries and a blood test to check CA125. Within this study, you will have another blood test to check your FSH 3 months after this second operation. There will also be questionnaires to complete which will be posted to you. One year after your second operation (to remove the ovaries), you will be posted a final set of questionnaires to complete. If you decide not to wait until you reach menopause to have your second operation to remove your ovaries, please let your doctor know. He/ she will arrange for you to have the operation sooner.
- If you have pre-cancer or cancer cells detected (abnormal results) at histology, you will be referred to a gynaecological oncologist for review. The chance of this happening is up to 1 in 20 (5%). Further scans, blood tests or even surgery may be recommended depending on what abnormality is picked up.
- If you choose to have your second operation to remove your ovaries early before you reach menopause naturally, and you have not had breast cancer, hormone replacement therapy (HRT) will be recommended. This minimises the health risks of early menopause (hot flushes, sweats, thinning of the bones, memory problems, higher risk of heart disease, reduced libido/sexual function). If you have had breast cancer, your gynaecologist/gynaecological oncologist with your permission will speak to your breast doctor to determine if you can take HRT

RRSO

- Before the operation, you will receive a baseline ultrasound scan to look at your ovaries. You will also have a blood test for an ovarian cancer marker called CA125 and a hormone called FSH. You will also be asked to complete detailed questionnaires before surgery. This will ask about medical history, family history, quality of life, sexual function, cancer worry, psychological wellbeing and how satisfied you are with your decision.
- If your ultrasound scan shows abnormal ovaries or your CA125 is not normal you will be referred to your local gynaecologist/ gynaecological oncologist for review and further tests. If after this, your doctor is satisfied that there is no suspicion of cancer,

we will be able to proceed with the operation to remove both your tubes and ovaries.

- The operation will usually be performed laparoscopically (by key-hole). For a small number of women (less than 1 in 20) this will not be possible. In them the surgeon will need to make an incision (cut) to open your abdomen (tummy). This could be for any number of reasons such as, technical problems during surgery, obesity, scarring from previous operations, or bleeding during the procedure. Women who have had previous abdominal operations are also more likely to need an open incision. Surgery will be performed under general anaesthesia.
- The average hospital stay associated with keyhole surgery is 1 day, compared with 5 days for open surgery. After keyhole surgery it is possible to return to normal activity in 1-2 weeks. With open surgery the average return to normal activity is 6 weeks.
- During the operation both your fallopian tubes and ovaries will be removed. We will also collect some fluid (washings) from the abdomen (tummy) during the operation. These will be sent to a specialist called a pathologist. The pathologist will carefully examine the tissues under a microscope to look for any abnormal cells or signs of cancer or pre-cancer.
- After the operation your doctor will be able to give you your results. This can take around four weeks. You will be seen in clinic for a check up to ensure your wound is healing well.
- At three months and then every year (for three years) you will be posted follow up questionnaires. We will ask you to return these to us in the self-addressed freepost envelope we send you. You will also have a blood test at 3 months after the operation for the FSH hormone.
- If pre- cancer or cancer cells are found, you will be referred to a gynaecological oncologist for review. The chance of this happening is up to 1 in 20 (5%). Further scans, blood tests or surgery may be recommended depending on what abnormality was picked up.
- While RRSO can prevent tubal and ovarian cancer in the future, a small risk of primary peritoneal cancer remains. Peritoneum is the lining of the abdomen or tummy. This left over risk is reported to be around 2-4% in BRCA1/BRCA2 carriers.
- If your ovaries have been removed before the age of 50 and you have not had breast cancer, HRT will be recommended. This will minimise the health risks of early menopause. These health risks include: hot flushes, sweats, thinning of the bones, memory problems, higher risk of heart disease, reduced libido/ sexual function. If you have had breast cancer, your gynaecologist/gynaecological oncologist with your permission will speak to your breast doctor to determine if you can take HRT.

Controls

- If you want to have children in the future, would like to delay going through menopause or are just not ready to have an operation to prevent ovarian cancer, you can still take part in the study.
- Being a part of the control arm of the study, means no operation is involved.

- At baseline and every year for 3 years, you will be asked to have a blood test for a hormone called FSH. This will give us some information about how your ovaries are functioning. You will also be asked to complete detailed questionnaires. These will ask about your medical history, family history, quality of life, sexual function, cancer worry, psychological well-being and how satisfied you are with your decision. The questionnaires will be posted to you. We will ask you to return these to us in the self-addressed freepost envelope we send you. A final blood test and set of questionnaire will be posted 1 year after you have gone through menopause.

You can decide to have an operation to prevent ovarian cancer (RRESDO or RRSO) at any point. Let your study doctor know and he/ she will arrange this for you.

In Depth Interviews:

In addition to the above three options (RRESDO /RRSO /Controls), a small number of women will be approached to take part in an interview. Separate consent is sought for this. Interviews will explore views on acceptability, interest, factors influencing decision making and willingness to undergo the new two stage operation for preventing ovarian cancer. Interviews will last up to sixty minutes and will be recorded. Some women who go on to have an operation to prevent ovarian cancer (RRESDO/RRSO), will be contacted 1 year after their operation for a follow up interview to discuss their satisfaction with the process and their general health and wellbeing. The researcher will record the interview using an audio tape recorder. This allows the researcher to capture all the information discussed during the interview, which is important for them to analyse later. You will be asked to answer questions based on your personal experiences. However, you can refuse to answer any questions if they make you feel uncomfortable. You can also stop the interview at any time.

What are the disadvantages of Early Menopause?

Early menopause can lead to adverse health consequences. These include hot flushes, sweats, mood changes, thinning of the bones (called osteoporosis), memory problems (dementia) and a higher risk of heart disease and stroke. It may also reduce libido and impair sexual function. Taking hormone replacement therapy can minimise these side effects.

What are the advantages of taking part in the PROTECTOR study?

- You will be given the opportunity of having a two staged operation (RRESDO) to prevent ovarian cancer. The initial stage involves removal of tubes alone. This is not currently routinely available outside the study.
- Removal of the tubes alone will provide some protection against developing ovarian cancer and at the same time preserve ovarian function and delay or avoid early menopause. This will enable you to avoid the adverse health consequences of early menopause.
- You will be given the choice of deciding which arm of the study you wish to be apart

off: RRESDO (new procedure), RRSO (current practice), or controls (no surgery).
- You will be contributing to research into preventing ovarian cancer in women at increased risk. Results of this study will help us understand the impact of the new two stage procedure to prevent ovarian cancer and the views and opinions of women undergoing this. This will help us plan future care pathways for women who are at high risk of ovarian cancer.

What are disadvantages of taking part in the PROTECTOR study?

- Although there is evidence to suggest that removal of tubes alone will provide some protection against developing ovarian cancer, it is unclear what the precise extent of this protection is. There is the possibility of getting ovarian cancer despite removal of tubes.
- It was earlier thought that removal of ovaries before menopause reduces breast cancer risk in women. However, this has recently been questioned by some researchers who did not find such a benefit. Thus there remains some uncertainty if a potential benefit of reduced breast cancer risk is lost by not removing the ovaries before menopause.
- The two-stage option (RRESDO) involves two operations instead of undergoing just one (RRSO: removal of both tubes and ovaries). This may lead to more complications as women are having two operations instead of one.
- There is concern amongst clinicians that not all women who have their tubes removed initially will go on to have their ovaries removed in time at a later date. This would mean that these women who don't could still remain at an increased risk of developing ovarian cancer.

What are the surgical risks or complications from an operation for surgical prevention of ovarian cancer?

All operations carry the risk of minor complications. Minor complications include those that have no long-term effects but may delay recovery. Wound infections, urine infections and a chesty cough (chest infections) are among the more common examples. There is a very small chance that a woman might need a blood transfusion following the operation or develop a blood clot in the leg (deep vein thrombosis or DVT) or lungs (embolism).

Serious complications that can occur during the operation include damage to the bowel, bladder, ureter or a blood vessel. Should this happen during keyhole surgery, the operation may be converted to an open procedure in order to repair any damage. It is possible for injuries to go unnoticed at the time of surgery because the injury is so small or it has occurred outside of the field of vision or just presents later. Should this happen, a second operation might be required.

The overall risk of complications from this operation is around 3-5%. The list of possible complications that may occur during surgery is quite long, and so only the most common have been mentioned here. It is important to bear in mind that the vast majority of women do not experience any serious complications at all and have an uneventful operation and post-operative recovery. Your NHS doctor will explain the risks associated with your operation in detail as part of decision making before you consent to undergo an operation. If you are concerned about any complications, please speak to your doctor who will give you more information.

Can women die from this operation?

There is an extremely small risk of death from any operation including this one. This is extremely rare. This is more likely to occur in women who have medical or surgical problems before the operation.

Can I speak to anyone if I have any questions?

Yes. If you have any questions you can contact the PROTECTOR study team at Barts Cancer Institute, Queen Mary University of London, London by telephone/email/post. Our contact details are at the end of this information booklet.

Do I have to take part?

You do not have to participate in this study if you do not wish to. Your participation is entirely voluntary. If you do decide to take part, you may withdraw your consent at any time without giving a reason. This will not affect your current or future healthcare.

Is my participation in this study kept confidential?

Yes. Your participation in the study and the information you give us will be treated as confidential. This will not be released to anyone outside the study without your permission. Your GP and treating NHS doctors will be informed that you have agreed to take part with your permission. Any information you give us as part of the PROTECTOR study will be stored on a secure username/ password protected database at Barts Cancer Institute, Queen Mary University of London.

Storage of surgical tissue / blood samples

With your permission, a portion of your blood and tissue removed at the time of surgery will be stored in our tissue bank. It will be stored under the custodianship of Dr Ranjit Manchanda, at Barts Cancer Institute, Queen Mary University of London.

The stored samples may be used for future research studies. These studies will not be of direct benefit to you, but we hope these will benefit others in the future. In order to ensure that

your personal information remains confidential, samples will be coded. Only the PROTECTOR research team will be able to trace the sample back to you. Other researchers using your samples will not be able to tell from whom samples were obtained. If you are concerned about the use of your samples in any future research study, please do discuss this with the doctor/nurse recruiting you to the study or you can contact the PROTECTOR study team directly using the contact details at the end of this booklet.

Who are the researchers/doctors involved in the project?

The project will be run by health professionals under the leadership of Dr Ranjit Manchanda and co-ordinated by Dr Faiza Gaba QMUL. It is the result of collaborative work of a number of individuals. The study is also supported through the UK Cancer Genetics Group (CGG), National Cancer Research Institute (NCRI) ovarian cancer sub-group and British Association of Gynaecological Pathologists.

Investigators:

Dr Ranjit Manchanda (Chief Investigator)	Clinical Senior Lecturer, Barts Cancer Institute, Queen Mary University of London & Consultant Gynaecological Oncologist Barts Health NHS Trust
Dr Faiza Gaba	Clinical Research Fellow Gynaecological Oncology, Barts Cancer Institute, Queen Mary University of London & Barts Health NHS Trust
Professor Usha Menon	Professor of Gynaecological Oncology, University College London
Dr Naveena Singh	Consultant Histopathologist, Barts Health NHS Trust
Dr Matthew Burnell	Statistician, University College London
Mr Ertan Saridogan	Consultant Gynaecologist, University College London Hospital
Professor Gareth Evans	Professor of Medical Genetics and Cancer Epidemiology, University of Manchester
Professor Glenn McCluggage	Prof of Histopathology, Queen's University of Belfast
Dr Robin Crawford	Consultant Gynaecological Oncologist, Addenbrookes Hospital, Cambridge
Dr Marc Tischkowitz	Reader and Honorary Consultant, Department of Medical Genetics, Cambridge
Dr Rosa Legood	Assistant Professor, London School of Hygiene and Tropical Medicine

Study Collaborators include:
Dr Asma Faruqi, Mr Tom Ind, Mr Davor Jurkovic, Dr Ajith Kumar, Dr Munaza Ahmad, Dr Angela Brady, Ms Vishaka Tripathi, Dr Sudha Sundar, Mr Raj Naik**,** Professor Ahmed Ahmed, Dr Vivek Nama, Dr Nafisa Wilkinson, Professor Omer Devaja, Mr Tim Duncan, Dr Sonali Kaushik, Dr Anil Tailor, Dr Aarti Sharma, Dr Ian Hartley, Dr Supratik Chattopadhyay, Dr Robert Woolas, Dr Rema Iyer, Dr Mahalakshmi Gurumurthy, Dr Kalpana Ragupathy, Dr Wendy McMullen, Dr Sadaf Ghaem-Maghami, Dr Rekha Wuntakal, Dr Lucy Side, Mr Gautam Mehra,

Dr Raji Ganesan, Dr Ketan Gajjar, Mr Frederick Wilmott, Dr Dorothy Halliday, Dr Helen Hanson, Dr Katie Snape, Mr Kevin Hayes.

Who has reviewed the study?

The study has been reviewed by the London Bloomsbury Research Ethics Committee, the Health Research Authority and the Joint Research Management Office of Queen Mary University of London and Barts Health. It has also been reviewed by the large team of researchers and doctors involved.

Who is funding the project?

The project is funded by Barts and The London Charity.

What will happen to the results of the study?

The results of this study will not be known for some time. These will be made available using scientific/ medical publications and via charity support groups. These can be accessed by anyone. Results will also be presented at scientific conferences and meetings. You will not be personally identified in any such publications.

What happens when the research study stops?

Once the study stops, you will continue to have NHS based care at your local hospital under your gynaecologist/ gynaecological oncologist/ regional genetics team. The study team aims to establish a national register for anyone undergoing 'early salpingectomy' to facilitate long term follow up.

How will my data be collected and how will it be processed?

Queen Mary University of London is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Queen Mary University of London will keep identifiable information about you for 20 years after the study has finished.

Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

The NHS will collect information from you and/or your medical records for this research study in accordance with our instructions.

The research team will use your name, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from QMUL and regulatory organisations may look at your research records to check the accuracy of the research study. Your NHS site will pass these details to us (Queen Mary University of London) along with the information collected from you and/or your medical records. The only people in the research team at QMUL who will have access to information that identifies you will be people who need to contact you for the purpose of follow up or to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Queen Mary University of London will also collect information about you for research from national databases (e.g. Health and Social Care Information Centre, NHS Digital, ONS) and national cancer registries (e.g. National Cancer Intelligence Network NCIN) with your permission. This information will include health information, which is regarded as a special category of information. We will use this information for the purpose of long term follow up.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

You can find out more about how we use your information at http://www.jrmo.org.uk.

How will my personal information be stored?

Your personal details and all study data will be entered electronically onto a password protected customised study database. This will be based on a secure central server at Barts Cancer Institute, Queen Mary University of London. Only members of the research team will be able to access this information through a user−name/password protected computer. Unauthorised persons will not have access to this data. There is a special dedicated team of IT specialists to ensure and monitor data security for this study.

Paper copies of all documents (for example consent forms, completed questionnaires) that are completed by participants will be stored in a secured NHS/research facility. Unauthorised persons will not have access to these documents.

Data will be stored for 20 years after completion of the study. This is in accordance with policy and regulations of Queen Mary University of London.

What if something goes wrong?

If you have any concerns or questions you should initially contact the PROTECTOR study team. The team will do their best to answer your questions. The contact details are provided at the end of this information booklet. If there is something that you are unhappy with and wish to complain formally, you can do this through the Research Governance Sponsor of this study. Please write to: Joint QMUL/ Barts Health Biomedical Research Unit, R&D Directorate, Lower Ground Floor, 5 Walden Street, London, E1 2EF quoting reference 011893 QM. All communication will be treated in strict confidence. You may also contact the [Patient Advice & Liaison Service (PALS) / Patient Advice & Support Service (PASS)] on xxxxxxxx.

Every care will be taken to ensure your safety during the course of the study. However QMUL has no-fault insurance arrangements in place, in the *unlikely* event that something unforeseen goes wrong and you are harmed as a result of taking part in the research study. If you are harmed due to someone's negligence, then you may have grounds for a legal action. But you may have to pay for it. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms will be available to you.

How can I contact the PROTECTOR study team?

The PROTECTOR Study Research Team can be contacted as follows:

Email

bci-protector@qmul.ac.uk

Post

PROTECTOR Study Research Team

Barts Cancer Institute, ECMC, Queen Mary University of London

Charterhouse Square, London, EC1M 6BQ

Telephone

020 7882 8762

For further independent information or support please contact:

BRCA Umbrella

Website: www.brcaumbrella.ning.com

The Eve Appeal

Email: office@eveappeal.org.uk

Website: www.eveappeal.org.uk

Ovacome

Website: www.ovacome.org.uk