FORECEE (4C) and BRCA UNITE
Patient Information Sheet

You are invited to take part in the FORECEE and BRCA UNITE research study. FORECEE is a unique project investigating molecular (genetic and epigenetic) and bacterial/viral factors that may predict a woman's risk of developing breast, ovarian, womb and cervical cancer (the 4Cs).

The BRCA UNITE study aims to determine the key triggers and factors why a woman with a BRCA mutation will develop breast and/or ovarian cancer and, most importantly, identify new ways to prevent these cancers.

We hope that by identifying such risk factors, we will be able to give better advice to women about their options for staying healthy and preventing the development of breast, ovarian, womb and cervical cancer.

Do I have to take part?

Participation is entirely voluntary and whether you participate or not will not affect your medical care in any way. If you do join, you are free to withdraw at any time, without giving us any reason.

What will happen to me if I take part?

If you agree to take part, you will be invited to one of our dedicated research clinics. A research nurse or gynaecologist will explain the study to you in greater detail. You will be able to ask any questions, and you will also have the option of coming back at a later date should you wish to discuss your participation with family or friends first.

Once all your questions have been answered, you will be asked to sign a **consent form** and will be given a copy to keep. With your permission, we may contact your GP or other medical teams looking after you in order to acquire more information regarding your medical background.

You will also be asked to complete a **questionnaire** that will include questions about your medical, reproductive history and general health, history of cancer in the family and any symptoms that you may have experienced. You may also be asked to fill in an additional survey during your appointment that explores your expectations and emotions. This survey is not a required part of the study, and you can choose whether or not to partake in it.

In a private setting, and with the help of a trained research nurse or a gynaecologist, we will arrange for a **cervical smear** to be obtained, for research purposes only. This will be carried out in exactly the same way as smears done on the NHS national cervical screening programme. If this is your first smear, we will explain how the sample is obtained.

We would be grateful if you could also provide us with a **cheek swab** (one from the left and one from the right side of your mouth) and a 60mL **blood sample** at each of three visits during the course of one menstrual cycle.

In addition to these samples, you will be given a home collection kit and instructions on how to collect saliva, urine and fecal samples at home. If you are a BRCA carrier and decide in the future to have a prophylactic mastectomy or a removal of your fallopian tubes/ovaries, we will ask for a **small amount of tissue** that is removed in any case during the surgery and which is not required for diagnostic purposes. No extra tissue will be removed.

We are also looking to assess individual women's experience with genetic testing. To do this we intend to send online questionnaires to women who have undergone testing for a risk mutation. These surveys are optional and will not have influence on a participant's involvement in the rest of the study. It is hoped however that these additional studies will help us tailor interventions and communications in the future to the benefit of every women undergoing genetic testing.

Who will analyse the samples I provide?

The research involves national and international partners, several leading Universities as well as commercial companies. In order to ensure your anonymity, only coded data, with no personal identifiers, are used.

Do I have to stay enrolled in the study?

You are free to determine how long and for what purpose your samples will be used. You can also choose to withdraw from the study at any point. We would like your permission to store your samples after the initial study is completed, for a period of up to 25 years. You may ask for your samples to be withdrawn from the study at any point.

What tests will be carried out on the samples I give for this study?

Donated samples will be tested for small biological changes that may help us predict future health factors, including the risk of cancer. Tests include genetic, epigenetic, protein-based, viral, bacterial, hormonal, immunological, and other biological techniques. Individual results will not be released to participants of the study. Please ask the research team if you would like this to be explained further.

Will you be contacting me in the future?

We would like to contact you for information about your health for up to 25 years after you join the study. It would of course be entirely up to you whether you give further information at any of these future contacts. We would also give your personal details to the appropriate regulatory bodies, which will inform us of any change in your circumstances.

What will happen to the results of the research study?

The results will be reviewed by other medical scientists and published in the scientific press. If the results are significant, it is expected that they will be reported widely in the lay press. Preliminary results will probably be available within a two-year period. We aim to inform participants about the progress of our research, and will be available for questions at any time.

What are the possible disadvantages of taking part?

We are grateful to all research participants for the contribution to our work, and recognise that being part of a study like this can be a cause of distress. We aim to make the process as

open and supportive for you as possible. Additionally, there are small risks associated with donating biosamples, including bruising following the blood test and spotting/discomfort following the cervical smear. Again we will be on hand to ensure that these symptoms are as minimal as possible.

What are the possible benefits of the study?

By participating, you will make an important contribution to understand the causes of breast and ovarian cancer development and hence ways in which the disease can be prevented. The study is not intended to provide a diagnosis to individual patients, and participation is on a voluntary basis. As a research volunteer, you will not derive any immediate benefits from taking part. However, your participation will help us provide better ways of preventing women's cancers and your contribution to this work is vital.

How will the samples and my personal information be used in the future?

A portion of the material extracted from your samples and obtained during the course of the study will be coded for identification, frozen and stored in special containers for future use. The samples and information will be securely stored for as long as needed in order to enable the research to be completed. It is possible that new tests or scientific techniques may be developed that have commercial applications. You would not benefit financially in such circumstances.

Will my taking part in this study be kept confidential?

Yes, your participation will be strictly confidential. Only the members of the research team involved in the current study will have access to your personal details. All the samples and tissue you give will be coded and all information collected about you during the course of the research will be treated in the strictest confidence. Personal information will never be made available to anyone outside the study and no identifiable information will be published.

Who is organising and funding the research?

The study is being co-ordinated by the Department of Women's Cancer at the Institute for Women's Health, University College London, in collaboration with a number of European partners. The study is funded by a generous grant from the European Union (Horizon 2020/ERC), supported by The Eve Appeal charity and in future may also be funded by other grant bodies.

What if there is a problem or what happens if something goes wrong?

If you find that during the course of your participation in the research you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff then the National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information regarding and concerns you may have and the complaints mechanisms open to you.

Contact for further information

If there is anything that is not clear, or if you would like any further information or if you would like to discuss further any aspect of this project, please do not hesitate to contact:
Prof Martin Widschwendter, Department of Women's Cancer, UCL Institute for Women's Health, 72 Huntley Street, London WC1E 6BT, Tel: 020 3108 2002.