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| **FOR EMBRACE USE ONLY** |
| **Concept No:** |  |
| **Approval Code:** |  |

**Epidemiological Study of Familial Breast Cancer (EMBRACE)**

**Analysis Concept Form**

Please provide the following information on the analyses you wish to perform and then send it to EMBRACE team by email at embrace@medschl.cam.ac.uk. This will be reviewed by the EMBRACE Principal Investigators, and Data for approved concepts will be sent only to the investigators listed below. For investigators outside University of Cambridge a standard Data Transfer Agreement will have to be signed before any data are shared.

|  |  |
| --- | --- |
| **Date:** |  |

**Section A. Principal Investigator Contact Information:**

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| **Title of Proposed Project:** |  |

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| **Is this an amendment?** | Yes [ ]  No [ ]  | If yes, provide Concept Number of the original form:  |

|  |  |
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| **Contact Investigator(s):** |  |
| **Institution:** |  |
| **Contact E-mail:** |  |
| **Collaborator of EMBRACE:** | Yes [ ]  No [ ]  |

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| **OTHER Investigators and their institutions:** | Yes [ ]   |
| **Please list individually all Investigators (and their institutions) who will require access to the data requested:** |  |
| **Please confirm that all the named investigators have read AND agreed to be named on this proposal?** | Yes [ ]   |

**Section B: Study Description**

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| **Concept Description:** *Please provide a concise description of Background/Aims* |

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| **Primary Endpoint** *(please check box)***:** |
| Breast cancer  | [ ]  |  |
| Subtype of breast cancerOvarian cancerOther cancer, non-breast/ovarian | [ ] [ ] [ ]  | Specify: Specify: |
| Survival | [ ]  |  |
| Other | [ ]  | Specify:  |

**Section C: Data**

Information about EMBRACE study can be found on the website (<https://ccge.medschl.cam.ac.uk/embrace/>). The data requested will be sent in excel file, or other required format. Due to data protection legislation, no dates (e.g. date at recruitment, date at cancer diagnosis etc.) can be sent.

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| **Data** | Check if applies | Baseline data only | Baseline andprospectivefollow-up data | Specify Details(please check with questionnaires and list the variables being requested) |
| **Phenotype Data** |  |  |  |  |
|  Personal information* Ethnicity, weight, height etc.
 | [ ]  | [ ]  | [ ]  |  |
| Menstrual History | [ ]  | [ ]  | [ ]  |  |
| Previous Pregnancies | [ ]  | [ ]  | [ ]  |  |
| Other Medical History | [ ]  | [ ]  | [ ]  |  |
|  Cancers --Breast, Ovarian and other cancers | [ ]  | [ ]  | [ ]  |  |
|  Operations/Surgeries--BPO, BPM | [ ]  | [ ]  | [ ]  |  |
| Mutation Status--Carrier/Non-Carrier | [ ]  |  |  |  |
| **Genotype Data** |  |  |  |  |
| Mutation--BRCA1, BRCA2, PALB2, BRIP1, RAD51C, RAD51D, ATM, CHEK2, BARD1, PTEN, TP53, CDH1 | [ ]  |  |  |  |
| GWAS data: iCOGS OncoArray CONFLUENCE | [ ] [ ] [ ]  |  |  |  |
| **Pathology**--Please contact study team for more information | [ ]  |  |  |  |
| **Death** | [ ]  |  |  |  |
| **Samples** |  |  |  |  |
| Blood Samples: EDTA Serum PAX DNA | [ ] [ ] [ ] [ ]  | [ ] [ ] [ ] [ ]  | [ ] [ ] [ ] [ ]  |  |
| Tumor Samples | [ ]  |  |  |  |
| Other tissue Samples --Please specify | [ ]  |  |  |  |

**Section D: Additional Information**

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| **i. Analysis Plan:** |

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| **ii. Timeline:** |

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| **iii. Any other considerations you would like the EMBRACE to be aware of:** |

**Section E: Publication and dissemination of data**

Please identify how you will publicise and disseminate the findings of your proposed study with deadlines.

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| --- | --- |
| Submit papers to academic journal(s) -give details: |  |
| Submit findings to a report – please specify:  |  |
| Present work at conference/seminar – give details: |  |
| Books or contributions to them – please specify: |  |

**Section F: Terms and Conditions**

1. The data will be used solely for the purposes of the research study outlined in the protocol and will be used only by those named in the application (or researchers working under the direction of the named individuals).

2. The dataset cannot be exchanged between institutions, and data cannot be passed to another user without the written permission of EMBRACE.

3. The applicant outside University of Cambridge must agree with Data Transfer Agreement and Sample Transfer Agreement.

4. The applicant must provide a draft manuscript to the EMBRACE principal investigators ahead of publication and discuss authorship options. The contribution of EMBRACE should be acknowledged in all publications resulting from the data.