Access to data and/or samples from the ProtecT study
(implemented January 2014)

Applications to access data and/or samples\* from the [ProtecT study](http://www.bris.ac.uk/social-community-medicine/projects/protect/about/) for research related to prostate cancer are welcome. Applications will be reviewed by the PIs and study co-ordinator, and we aim to respond within one month.

Please indicate the particular data/samples you wish to access on this page for research related to prostate cancer, and then complete the relevant sections indicated overleaf.

Return form to info-protect@bristol.ac.uk (tel: 0117 9287272)

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| --- | --- | --- |
| 1. | Do you wish to access ProtecT baseline (pre-randomisation) data (e.g. clinical diagnostic data, epidemiological and other questionnaire data completed by study participants (e.g. urinary symptoms, diet and lifestyle issues etc.)? | Yes: complete Section A overleaf |
| 2. | Do you wish to access baseline (diagnostic) biological samples from ProtecT or ProMPT participants, and/or data related to these samples?  | Yes: complete Section B overleaf |
| 3. | Do you wish to access post-randomisation or outcome data/ samples from ProtecT participants (including those not randomised)?*NB The majority of these data are embargoed until 2016.*  | Yes: complete Section C overleaf |
| 4. | Do you wish to collect new data by contacting the ProtecT participants? | Yes: contact info-protect@bristol.ac.uk |
| 5. | Do you wish to investigate issues other than prostate cancer? | Yes: contact info-protect@bristol.ac.ukfor details of the HELPP study |

All applicants must complete the following:

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| Do you agree to comply with the ProtecT study publication and authorship policy? A mark in the box will be taken as agreement if submitted by email.  Forms will not be considered without this agreement. |  |

Now turn over and complete ALL relevant sections.

\* All biological samples collected in the ProtecT study fall under the ethics and governance procedures for the ProMPT study (Trent MREC). Access to ProMPT clinical samples – contact freddie.hamdy@nds.ox.ac.uk, den22@medschl.cam.ac.uk, Rajeev.Kumar@nds.ox.ac.uk

Section A: Access to ProtecT baseline data

Please complete all boxes

|  |  |
| --- | --- |
| **1. Lead applicant:**  Title, name Institution  Email address: |  |
| **2. Title of proposed analysis/publication:** |  |
| **3. Structured summary of proposed analysis** (one side of A4/350 words): | Background (including scientific justification and the novelty of your proposal)Aims/objectives:Methods:Key scientific references: |
| **4. Details of ProtecT data requested:**Indicate whether socio-demographic, diagnostic, other clinical, epidemiology.Itemise variables where possible.Specify clearly the numbers and types of ProtecT participants required. |  |
| **5. Which member of the ProtecT team have you discussed this analysis with?** Give name.  |  |
| **7. What funding do you have available to cover data extraction costs?** |  |

Section B: Access to baseline biological samples from ProtecT participants

Please complete all boxes

|  |  |
| --- | --- |
| **1. Lead applicant:** Title, name Institution  Email address: |  |
| **2. Title of proposed analysis/publication:** |  |
| **3. Details of samples requested:**Specify whether serum, plasma, genomic DNA, type of TMA, FFPE tissue, urine.Specify and justify exact volumes requested. Specify exact numbers and types of ProtecT participants for each sample type requested. |  |
| **4. Details of data requested:**Indicate whether socio-demographic, diagnostic, pathological, other clinical, epidemiological.Itemise variables where possible.Specify exact numbers and types of ProtecT participants requested. |  |
| **5. Structured summary of proposed analysis, including justification for use of samples:** (one side of A4/350 words): | Background (including scientific justification and novelty of your proposal)Aims/objectives:Methods:Key scientific references: |
| **6. Which member of the ProtecT team have you discussed this analysis with?** Give name  |  |
| **7. What funding do you have available to cover sample and data extraction costs?**Give details |  |

Section C: Access to ProtecT post-randomisation and outcome data or samples

These data are mostly embargoed until 2016. You are strongly advised to contact one of the ProtecT PIs before making this request. Please complete all boxes

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| --- | --- |
| **1. Lead applicant:**  Title, name Institution  Email address: |  |
| **2. Title of proposed analysis/publication:** |  |
| **3. Structured summary of proposed analysis:** (one side of A4/350 words): | Background (including scientific justification and the novelty of your proposal)Aims/objectives:Methods:Key scientific references: |
| **4. Details of ProtecT data/samples requested:**Specify exactly what outcome or post-randomised data or samples are requested.Itemise variables where possible.Specify exact numbers and types of ProtecT participants requested. |  |
| **5. Which member of the ProtecT team have you discussed this analysis with?** Give name.  |  |

**For office use only: Approval process**

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| --- | --- |
| Date received by ProtecT co-ordinator |  |
| Date sent to by ProtecT PIs: |  |
| Decision by Protect PIs: Approved, or Preliminary approval subject to specified conditions, or Rejected |  |
| Date of decision: |  |

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| --- | --- |
| Id no. allocated by ProtecT study: |  |
| Date decision sent to applicants: |  |