

## Deliverable D9.1 POPD – Ethics Requirement No.1

PIONEER commenced in early 2018 when the relevant principal data privacy legislation was the Data Protection Directive, as implemented into the laws of each member state. GDPR came into force on 25 May 2018, after the commencement of PIONEER. Because GDPR represents a very significant change to data protection law, with very many aspects being substantially different to the position under the Data Protection Directive, we are still in a transitional state. Although GDPR is in force, it has still not been implemented into national legislation by all EU member states and, as noted above, the ability of member states to derogate from GDPR means that we do not yet have a fully clear view of how GDPR will eventually be implemented across the different countries. There is also a significant amount of work to be done by national data privacy authorities and by the European Data Protection Board (the body which provides central guidance on interpretation of GDPR and issues arising from it) in providing guidance on how GDPR should be understood, interpreted and applied in various circumstances. We also anticipate guidance on healthcare data, big data and research from the European Data Protection Board, national authorities (both regulators of data privacy and regulators of research and healthcare) and also professional bodies such as clinician organisations.

We have also assessed the challenges arising from data protection legislation (particularly following GDPR) where data is personally identifiable patient data and PIONEER's conclusion has been to go forward on the basis of a Federated Database Model (where the "analysis goes to the data" rather than vice versa) with a tailored de facto anonymised Centralised Database Model also being utilised which, again, does not involve the processing of personal data. Thus PIONEER will not be processing personal data and thus falls outside of the GDPR regime, but will still continue to carry out its activities in compliance with legal, regulatory and ethical requirements and legally binds itself, and data set providers, to this.

## Deliverable D9.2 NEC – Ethics requirement No. 2

- The Project has not yet reached the stage of exporting/importing personal data to/from the EEA
- The Project has a step-wise process for ensuring that any such export/import will be carried out in compliance with the legal/regulatory/ethical framework and pursuant to binding contracts
- The proposed research is compatible with EU and international regulation

## Deliverable D9.3 GEN – Ethics requirement No. 4

PIONEER is an ambitious 5-year programme of work and the consortium firmly believes that to be successful it is necessary to ensure that a structure is in place to render timely independent advice on the complex scientific and ethical issues that PIONEER will encounter. To facilitate this PIONEER has established two Advisory Boards: scientific and ethical. This report outlines the formation of PIONEER's Ethics Advisory Board (EAB) which has been established to ensure robust independent ethical advice

relating to PIONEER's data usage and infrastructure during the project and beyond. As independent members, the views of the EAB will be regarded by the consortium as unbiased, in the best interest of all Prostate Cancer stakeholders, and importantly, in the interest of the project being delivered to the highest ethical standard. PIONEER's Ethics Advisory Board members are Prof. Federico de Montalvo Jääskeläinen and Prof. Bartha Maria Knoppers.