



IPCOR 1

EXTERNAL DATA ACCESS POLICY



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1. Document Control

Version	Date	Author	Summary of changes
0.1	19-Oct-22	Cara Dooley	Internal draft for discussion
0.2	21-Jun-23	Áine Murphy	Updated internal draft for discussion
1.0	23-May-24	Noa Gordon	First version

2. Purpose of the Policy

2.1 Project Background

The Irish Prostate Cancer Outcomes Research (IPCOR) Study funded by Movember in partnership with the Irish Cancer Society began in February 2014. The study was carried out by a collaborative research partnership involving the National Cancer Registry Ireland, the Health Research Board Clinical Research Facility in Galway, the National Cancer Control Program and the major national academic institutions represented by Clinical Research Development Ireland. IPCOR collected clinical data from 6816 men and PROMs data from 873 men diagnosed with prostate cancer in Ireland between 2016 and 2020. The data was collected in 16 hospitals and men from all 26 counties were registered in the study. The IPCOR study is now hosted by University College Dublin (UCD) and UCD is the sole data controller of the IPCOR 1 pseudonymised dataset.

2.2 Policy Background

This policy applies to all external researchers who apply to use the data from the IPCOR 1 project in UCD. This policy refers to the IPCOR 1 dataset which is held on the IPCOR 1 area on the Novell server in UCD.

The IPCOR 1 dataset is a pseudonymised dataset, and is subject to a conditional consent declaration from the Health Research Consent Declaration Committee (HRCDC). The HRCDC consent declaration only applies to IPCOR team members and does not apply to external

researchers. This data access policy negates the need for external researchers to apply for their own HRCDC consent declaration to access IPCOR 1 data. The policy also ensures that proposed analyses are pre-registered which mitigates the chance of “p-value hacking or fishing”, making the research process transparent and reproducible. It also increases data security as the data never leaves UCD.

3. External Access Policy

3.1 General Guidelines

When publishing results from the IPCOR 1 dataset there are a number of conditions which must be considered:

- No cell counts of <5 will be published - these will be removed before issuing the results of analyses to external data requesters. Instead it will be indicated that the cell count is “<5”.
- No hospital or consultant should ever be named in a publicly available report – these will be removed before issuing the results of analyses to external data requesters. Instead a running number will be indicated.
- External researchers may have to pay costs that are associated with utilising the IPCOR 1 dataset. The IPCOR Data Access Committee will evaluate the research proposal and determine costs, if applicable. In some circumstances, costs may be waived at the discretion of the IPCOR Data Access Committee.

3.2 Accessing the Data

- External researchers will access a comprehensive data dictionary which outlines the data available in the IPCOR 1 dataset and use it to prepare their research proposal which they will submit to the IPCOR Data Access Committee.

- The IPCOR Data Access Committee in ~~IPCOR~~ will review the research proposal and determine if the proposal aligns with IPCOR research objectives and has not been previously carried out or is currently being carried out by IPCOR or other researchers. If the research proposal is deemed appropriate, the research proposal will be sent to the IPCOR Steering Committee for final approval. If the application to access IPCOR 1 data is unsuccessful, the IPCOR Data Access Committee will provide feedback and external researchers will have the opportunity to resubmit an updated research proposal.
- ~~Upon receipt of research proposal approval from the IPCOR Steering Committee,~~ the external researcher will apply for ethical approval for their research in their home institution.
- Once ethical approval is obtained and evidence is submitted to IPCOR, the researcher can request dummy datasets and the necessary information to prepare their code for analysis. This code will be preferably written in R and be in RMarkdown format. However, the IPCOR team will try to facilitate users of other software packages if the expertise is available in the project to support this.
- The code will be run by the IPCOR staff member and the results will be provided to the external researcher. The IPCOR staff member will make no changes to the code except to correct obvious spelling mistakes, but they will work with the external researchers to identify any errors. The output will only be edited to remove any results which contravene

the IPCOR data policy, e.g., cell counts less than 5. These edits will be clearly labelled for the external researchers.

- The researchers will include the following acknowledgement in their final publication: “The [research/result] is [based on or derived from] the IPCOR 1 dataset. Collection of the IPCOR 1 dataset was funded by Movember, in partnership with the Irish Cancer Society. Any opinions, findings, conclusions or recommendations expressed are those of the author(s) and not necessarily those of IPCOR, Movember or the Irish Cancer Society.”
- The researchers will include the following reference in their final publication :

Galvin D, Dooley C, Murphy A, Sharp L, McDermott R, Sullivan F. Mp19-09 establishment of a national cancer specific outcomes registry and initial data. *J Urol.* 2021;206(Supplement 3). doi:10.1097/JU.0000000000002004.09

4. Data Analysis Plan Template

When submitting a request to access the IPCOR 1 dataset, a data analysis plan should be submitted.

The minimal items to be included in the analysis plan are:

- Research objectives
- Hypotheses
- Inclusion and exclusion criteria, if using a subset of IPCOR 1 data
- Research variables, according to the IPCOR 1 data dictionary
- Statistical methods used to test the hypotheses
- Software used for the analysis including supporting software packages

5. External Researcher Acknowledgement Form

I acknowledge that I have read and understand the IPCOR 1 external data access policy.

I agree to be bound by the terms and conditions outlined within this policy including the following:

(Please tick)

- Acknowledge that this policy only refers to the IPCOR 1 data set.
- Results will be used only for purposes specified in the research proposal, unless otherwise agreed by the IPCOR Data Access Committee
- Report all security breaches to IPCOR Data Access Committee.
- Never publish any cell counts less than 5.
- Never identify hospitals or doctors in any publication
- Acknowledge IPCOR in any publication (print, online, limited circulation or otherwise).
Acknowledgement wording will be signed off by the IPCOR Data Access Committee.

Name (printed): _____

Signed: _____

(External researcher)

Signed: _____

(IPCOR Staff member)

Date: _____

Date: _____