

Primary Care Reimbursement Service (PCRS)

Information Requests

Date Updated: 10.08.2022

Introduction

The Primary Care Reimbursement Service (PCRS) collects a large volume of data in relation to reimbursements arising from claims in respect of medical card usage and national primary care schemes. Data is processed in accordance with GDPR regulations.

Access to information

Access to summary statistical data is made available through the PCRS website & the eHealth Open Data portal. Requests for information in respect of data held by PCRS which is not publically available can be made to PCRS using the form provided on the PCRS Publications web page.

Acknowledgements

An acknowledgement will be sent to the requester by e-mail within 10 working days of a request being received and any necessary clarifications sought. Whilst every effort will be made to adhere to the requester's timeframe for response, this is not guaranteed. Priority will be given to requests from the government, the Department of Health and the HSE. Depending on the resources required to extract the information sought, if it is not be possible to allocate the resources required to provide a response within the timeframe requested, PCRS will reengage with the requester to close out the request or set a new timeframe for response.

Guidelines for requesters

Sufficient particulars should be supplied to enable a record to be identified if it already exists. Where records have to be created, a draft template of how the final report might appear would be helpful to submit with the request. Supplying definitions of terms used and clear parameters will help to avoid any confusion.

Please note that high level summary data is more readily accessible and that requests for granular level data, particularly if the information could identify an individual, may not be releasable due to GDPR regulations, even where pseudoanonymisation is applied to the data. Claim data, which has been received by PCRS from Community Pharmacists, GPs, Dentists and Opticians only includes items reimbursed by PCRS. Data in relation to clinical diagnosis is not available.

Research requests involving personal data

The Health Research Regulations 2018 (S.I. No. 314 of 2018), which came into effect on 8 August 2018, govern what is permitted in terms of secondary uses of data in Ireland. These regulations state that explicit consent is the lawful basis to use a patient's personal data in research, unless a consent exemption is sought.

Consent (c.f. Art 4 GDPR) to be valid and lawful must be voluntary, informed and appropriately recorded (thereby making it explicit). It must also allow for the withdrawal of consent.

Article 9 of GDPR specifically deals with the processing of special categories of personal data, including data concerning health. However, if the data has been anonymised and can no longer be linked back to an identifiable individual, it is not considered personal data and is not subject to the GDPR.

Any research involving personal sensitive data requires ethical approval. This would normally be a requirement within a research institute, but the HSE has its own research ethics committees to approve research. For PCRS as a national body, approval must come through the Research Ethics Committee (REC) of CHO 8 (cf. hseresearch.ie).

The Health Research Regulations also provide for certain circumstances where the public interest of doing research significantly outweighs the need for explicit consent. In such circumstances, applications can be made to the Health Research Consent Declaration Committee (HRCDC) for a consent declaration, which, if granted, means that individual consent is not required to use personal information in the research.

Before PCRS will agree to share personal data, it is necessary that the research has undertaken a risk assessment and that a Data Privacy Impact Assessment (DPIA) is completed. This will set out the parameters for the research, its objectives, how the research will be conducted and what measures will be taken to mitigate data privacy risks. The HSE has a template DPIA, (June 2019, version 2.0), that should be used. Once submitted, PCRS will send it to the HSE Data Protection Officer (DDO) or Deputy DDPO for an opinion as to whether the data processing in question is GDPR compliant or not.

Both DPIA and ethical approval are necessary before making an application to the HRCDC. Consideration should also be given to PPI (Public and Patient Involvement) in the research and the involvement of

patient advocacy groups in order to better inform the research being undertaken.

A data sharing agreement between PCRS and the researcher/ research institute can then be entered into and, building on the DPIA, will include some of the technical information around how the data will be shared, who will be responsible for it and what safeguards will be put in place to protect the data (using data minimisation and anonymisation where possible). The agreement will be signed off by the head of PCRS.

Addendum

All correspondence with PCRS is subject to FOI. To protect information from going to the wrong person, the information requested will normally be sent by encrypted email.

Given that there are ongoing changes in the regulatory environment and that the HSE and HIQA are actively updating requirements in this area, these guidelines are subject to change.

Further advice and information on health research can be obtained from the Health Research Board (HRB).

Contact e-mails

PCRS: PCRS.ReportQueries@hse.ie

HRCDC: <u>secretariat@hrcdc.ie</u>

HRB: hrb@hrb.ie

 $REC: \underline{REC.B.CorporateMidlands@hse.ie}$