Trainee Research Projects: Research Ethics and GDPR Guidance

Last updated August 2021

- GDPR has implications for all activities in general practice, including audit and research as both involve 'processing' of data and GDPR does refer to requirements in this regard.

- The Department of Health issued the Health Research Regulations on August 7th 2018 which outline how data protection applies to health research. They will also be issuing regulations relating to audit but we do not have a publication date for these yet. Therefore, currently there are no specific additional requirements for audit that is used only for internal practice quality improvement, if already applying best practice in terms of data handling/processing, etc. However, please see Appendix 1 for further information.

- **For research**—In order to comply with GDPR and the Health Research Regulations, please note the following:

    - All research (even if a health professional survey only) now must have ethical approval.
    - Consent is required for all research and data processing – no research ethics committee (REC) can give a waiver of consent anymore. If you believe obtaining consent is not possible and that the public interest of doing the research significantly outweighs the need for explicit consent, you can apply to the HRCDC for a consent declaration.
    - The ICGP will not give retrospective approval for research already commenced/completed.

- **For audits**—The situation regarding what requires REC review has not changed. If the audit is for internal practice consumption (such as for quality improvement in the practice) then no ethical approval is required as of now. If the audit is for external use (such as intention to publish) it requires REC review. Important points to consider when undertaking any audit are as follows:

    - Whether patients have been advised or would accept that such processing of their data occurs - it is advisable that the practice at a minimum has a notice in the practice stating that they are a training practice and that audit for quality improvement is undertaken by the GPs and trainees in the practice (Transparency requirement). A sample notice can be found on the ICGP website here.
    - Data extraction/review is undertaken by a member of the treating team (which the trainee is while in training in the practice).
    - No identifying information is extracted from the system and stored elsewhere – all data should be anonymous.
    - The ICGP will not give retrospective approval for an audit already commenced/completed.

- **Indemnity for trainee research:** The ICGP have taken on board to have trainees covered for research that is undertaken as part of the training requirements and involve activities not outside the scope of general practice. This was in the absence of cover being confirmed by the CIS scheme for research activity undertaken by trainees.

  If a member of the Programme Directing Team is listed as an academic supervisor, as this can be considered as part of their ICGP educational activities then they are covered under ICGP indemnity. However, if they are listed as a PI, co-investigator or project data controller, as this implies a role beyond academic supervision, they must notify what indemnity they are covered under – depending on the auspices under which they are participating in this role, this may be under University, HSE or their own clinical indemnity.

- **Retrospective Chart Reviews:** A 'retrospective chart review study' means:
  - a low risk research study carried out by a controller (a controller can be a hospital, GP practice, etc.)
  - on personal data only (which can include medical images), if the study is, for example, linked in any way to bio-samples then it is not covered
  - where that personal data has already been obtained by that controller for the purposes of the provision of health care to an individual by the controller.

  The requirement for explicit consent will not apply in relation to such a retrospective chart review study where:

  - it has been approved by a REC
  - where the REC, as part of that approval, is satisfied and states in writing that the required data protection risk assessment carried out by the controller indicates a low risk to the rights and freedoms of the data subjects whose data will be accessed and used in the study.

  This study can only be carried out by a health practitioner employed by the controller or a person studying to be a health practitioner who is under the direction and control of the controller, OR an employee of the controller who would ordinarily have access to the personal data of individuals held by the controller.

  In addition, transparency requirements must be in place including notices and posters on display in public areas (see minimum requirements here).

  See further information from the HRCDC here.

- **DPIA and DPO guidance** - The DPIA is a process for building and demonstrating compliance. Please note that the ICGP REC do not ask to see the full DPIA - only confirmation that is has been completed and discussed with your DPO. This is because we consider the DPIA as a live document that is reviewed and updated throughout the process and therefore not a final document at REC application stage.

  Currently, it is not considered appropriate for the ICGP DPO to act as DPO for trainee projects. Given that these projects are being conducted as part of training and are often the trainee's first exposure to being a PI/data controller/co-investigator, it would also not be considered appropriate that a trainee could act as DPO, given that purpose here is to ensure the researcher(s) are informed and advised of their data protection obligations under the GDPR;

compliance with the GDPR, other data protection legislation and internal data protection policies and procedures. In general, a project's PI/data controller cannot be the project DPO for the same reason.

Appointing a DPO - It is not mandatory for the scheme to appoint a DPO, however, it is advisable that someone is supervising and advising trainees on their obligations under GDPR and compliance during the project. This can be documented on the DPIA screening form i.e. named person is taking on this role although not a DPO.

Purpose of a health research DPIA – the purpose of the DPIA is to help researchers identify and minimise the data protection risks of the research project. It often raises issues that were not previously considered. While for example, a questionnaire might be fully anonymous, the process of identifying those to be sent the questionnaire may involve potential data protection issues if individuals are identifiable that stage. Some RECs do not use a DPIA screening form (only a full DPIA) – the ICGP REC uses the screening form to help researchers. If any question on this is a YES or if the researcher is unsure, then a DPIA should be completed to fully consider if there any aspect of the process shows a potential data protection or privacy risk to the individual.

- **The ICGP Research Department** is aware of the time pressure trainees are under to meet CSCST, and therefore we have detailed guidance on the website to assist trainees to complete all relevant documents so that there will not be delays due to errors, missing documents, etc. This guidance includes:

    - Instructions on how to complete each question in the standard application form (please refer to 'Additional Reference Materials' on this page)
    - Frequently made mistakes (please see this page)
    - Toolkit for audits (here)

- **The ICGP Research Ethics Committee** will continue to have an additional and dedicated trainee-only meeting in October each year. Trainees can, of course, apply to any other regular REC meeting. Deadline for submission is four weeks before each meeting. The details are on the website by December for the previous year. Application steps are as follows:

    1. All trainees should complete a non-clinical trials research ethics application form which is available on the ICGP's Research Ethics site here. Guidance on how to complete the form and template forms such as consent forms and participant information leaflets are also available from this link.
    2. This form and a project proposal (and all necessary supplementary material) should be submitted electronically (as one document) to your local programme administrator. The timeframe for this should be agreed with the programme but should be no later than the second Friday of September.
    3. The assigned person(s) from the programme team should initially review the submissions using the checklist and guidance supplied by the ICGP, and then sign under the 'Academic Supervisor' section of the Local Committee Declaration and Signatory page (also available via the link above) to acknowledge s/he has reviewed the application in full.

4. The complete application material should then be forwarded to the ICGP by 5pm on the application deadline (Tuesday, 21 September for the October 2021 mtg). Please note that at this time, only one soft copy (by email to research@icgp.ie) needs to be submitted.
5. The ICGP Research Ethics Committee will review submitted applications at the dedicated trainee meeting in October and alert applicants regarding the results thereafter.
6. If changes are required, they should be submitted within two weeks by the trainee using the appropriate ICGP Clarifications Response form and will then be reconsidered by the ICGP Research Ethics Committee.

- It is acknowledged that some programmes require the research project to be completed in 3rd year while others do so in 4th year. The entire process will likely take one year and the timelines should be adapted to the programme requirements in terms of reporting etc. The below is an indicative timeframe:

Month 1	Discussion of possible topics; initial fact-finding
Month 2	Selection of topic; Literature Review; Research Question developed
Month 3-4	Methodology decided; Research proposal and Research Ethics application completed including development of all necessary documents. Submission to REC
Month 5	Literature Review continued
Month 6	Respond to any REC clarifications; Arrange necessary access if relevant
Month 7	Data collection; Commence data entry/collation
Month 8	Continuation of data collection. Data entry/collation finalised; Commence data analysis
Month 9	Data analysis continued; Write-up; Consider options for presentation at meetings/conferences and prepare abstracts
Month 10	Write-up continued
Month 11	Report submission to scheme
Month 12	Prepare and deliver presentation to scheme
After	Additional Presentations and Papers

Appendix 1: Time to start thinking about your PCS audit for 2019-2020 – GDPR does not prevent you undertaking an audit

FORUM Article – September 2019

Claire Collins

GDPR is the EU's new General Data Protection Regulation (EU) 2016/679. It came into force across all of Europe on **25th May 2018**. It replaced the EU's previous Data Protection Directive (95/46/EC). GDPR governs the collection, use and storage of all personal data of living individuals. The Data Protection Act 2018 is the Irish legislation that gives effect to certain aspects of the EU's GDPR in Ireland and repeals, for the most part, the previous Data Protection Acts 1998 and 2013. **If you collect, use or store personal data in digital, manual, handwritten or any type of record, then GDPR affects you.**

Given these changes, the Medical Council has published advice in relation to conducting your audit:

- *All registered medical practitioners are legally required to maintain their professional competence. This means that as well as undertaking 50 CPD credits, they also need to complete and record one clinical/practice audit annually. Employers are legally required to facilitate the maintenance of professional competence of registered medical practitioners.*
- *During the clinical/practice audit process, health data is processed. Even if the health data is anonymised shortly after it is retrieved from patient records for the purpose of clinical/practice audit, that retrieval process in itself amounts to processing. Health data is defined under the GDPR as special category data. Such data can be processed in situations where it is necessary to do so for reasons of public interest in the area of public health, such as ensuring high standards of quality and safety of healthcare (Article 9(2) of the GDPR).*
- *Medical practitioners can lawfully process special category data for the purposes of clinical/practice audit. However, in doing so, they must ensure that they adopt suitable and specific measures to safeguard the fundamental rights and freedoms of the data subjects concerned.*
- *Consent is just one of the legal bases upon which data controllers can rely in order to lawfully process special category data.*
- *Given the high threshold for consent and the fact that it can be withdrawn at any time, and in circumstances where there is another legal basis available to the practitioner to lawfully process a patient's special category data (Part 11 of the Medical Practitioners Act 2007), it is not recommended to rely on consent as the legal basis for the processing of special category personal data for the purpose of clinical/practice audit. This means that medical practitioners (and their employers) are not required to seek consent before processing special category data for the purposes of undertaking a clinical/practice audit.*
- *However medical practitioners (and employers) should ensure that they are compliant with the transparency obligation in the GDPR Article 5(1)(a) by ensuring that comprehensive privacy notices are provided to their patients. Further details on what privacy notices constitute can be found in the GDPR.*
- *Each medical practitioner is either a data controller in their own right, or is employed by a data controller (for example a hospital). Every data controller is responsible for ensuring that they are compliant with the GDPR. The Medical Council can only give guidance in this regard.*

In light of this, medical practitioners should liaise with their data protection officer or seek their own legal advice on this issue. Further information and resources on data protection is available at https://www.medicalcouncil.ie/FOI-Data-Protection/

The National Office of Clinical Audit (NOCA) has advised that national clinical audit should not rely on consent as the lawful basis but instead apply the public health lawful basis of Articles 6(1)(e) and 9(2)(h). The collection of data, validation of data, and review of outliers for national clinical audit does not require consent. However, patients should be informed that their data may be used as part of a national clinical audit.

In summary, during a clinical/practice audit, health data is processed and the process of data retrieval/extraction from the patient record in itself amounts to processing. However, such data can be processed in situations where is it necessary to do so for reasons of public interest in the area of public health, such as ensuring high standards of quality and safety of healthcare (Article 9(2) of the GDPR). Hence, you can lawfully process special category data for the purposes of clinical/practice audit, however you must ensure that you adopt suitable and specific measures to safeguard the fundamental rights and freedoms of the data subjects concerned. You, therefore, are not required to seek consent before processing special category data for the purposes of undertaking a clinical/practice audit once you ensure that you are compliant with the transparency obligation in the GDPR Article 5(1)(a) by ensuring that comprehensive privacy notices are provided to your patients.

It is important to inform patients that the practice may use data for internal audit. This can be included in a patient information leaflet, in a privacy statement, on patient registration forms or on the practice website. It is not acceptable for external research staff to trawl through individual patient records without informed patient consent. It is also not acceptable to release the contact details of patients to researchers without informed patient consent. Identifiable data should not be used – only anonymous data should be extracted/compiled for the audit.

Audit is not research however and different and additional rules apply. You cannot personally use your patients' health data or share their health data with a third party individual or organisation, for research purposes, without the patient's explicit consent, unless the research has obtained a consent declaration under the new Health Research Regulations 2018. Clinical audits usually involve looking at information already collected about a patient or treatment and do not usually involve gathering new information. In addition, the data is mainly gathered for internal (practice) consumption in one practice for the improvement of care/services in that practice and is completed by the caregiver or a member of his/her team. Hence, audit does not usually require ethical approval. However, if you intend to gather new data, to interview/test patients, to permit access to files to an individual not in your employ, to transfer non-anonymous data outside the practice or to use the data for research, you should obtain additional advice regarding the ethical review requirements.

More information and sample audits are available on www.icgp.ie/audit

Queries can be sent to ProfessionalCompetence@icgp.ie