ANZFFR Data Access Policy

Purpose and Scope

Access to data collected and collated by Australia and New Zealand Fragility Fracture Registry (ANZFFR) is guided by privacy, confidentiality, and ethical principles. Provision of data to the Registry is governed by the study protocol, which has been approved by Human Research Ethics Committees in each jurisdiction, and the relevant Research Governance Offices of participating sites. This document outlines the principles that ANZFFR will apply to requests for access to registry data and the procedures for applicants to follow when making a request to access data.

Background

The ANZFFR holds identified data about people aged 50 years and older who have suffered a fragility fracture. The registry holds the data submitted by participating sites, and it is important that the privacy of this information is maintained. This policy is intended to protect the privacy and confidentiality when considering requests for access to the data from third parties.
The ANZFFR Steering Committee encourages the use of its accumulated data for appropriate academic research, clinical review, planning or scientific investigation of issues to do with fragility fractures. Parties interested in accessing ANZFFR data are encouraged to make informal enquires to the FFR National Manger in the first instance: FFRManager@osteoporosis.org.nz

Applicant Responsibilities

1. People accessing ANZFFR data are responsible for ensuring appropriate security for the storage of any material, confidential or otherwise, held in any format including on computing systems.
2. A date for data disposal must be included in any request for access to data.
3. In accessing de-identified data, no attempt will be made to re-identify individuals in the data provided by the ANZFFR.
4. For research proposals, ethics and governance approvals must be provided prior to the release of data. In New Zealand institutional ethics committee approvals will be accepted (University or Hospital) and applications to the National Health and Disability Ethics Committee will not be necessary.
5. For non-research proposals, compliance with relevant privacy and data governance legislation should be demonstrated.

6. For all proposals, a schedule for the reporting and dissemination of results must be included in the submitted project outline.
7. Applicants must provide an annual report on progress with data use and a final report when analysis completed.

Data Access

1. The ANZFFR Steering Committee shall be the final approver of data access requests except Basic Summary Data and Site Data.
2. Requests for data access will be referred to the ANZFFR Data Management Committee (DMC) which will consider each application in detail. This committee may request further information and clarification from the applicant. The Data Management Committee will forward a recommendation about each application to the Steering Committee for final review.
3. The Data Management Committee will consider:
    a. Whether the project meets appropriate standards of scientific merit and/or public health importance.
    b. Whether the ANZFFR data requested is of a sufficiently high level of quality as has previously been reported on as part of the annual reporting process.
4. All requests for data must take timeframes into account as data requests are considered along with other ANZFFR tasks. ANZFFR Steering Committee meetings are held quarterly, and data will not be extracted until Steering Committee approval has been given.
5. It is a condition of use of the data that the data source is acknowledged, with a statement that the analysis and interpretation of the data are those of the author(s) and not the ANZFFR.
6. The Steering Committee must review any results before submission for intended publication, presentation, or other public release. The Steering Committee should be given at 15 working days to comment on any material.
7. Data requests must be lodged in writing on the Registry application form.
8. Data is released for the specific purpose(s) set out in the submitted application. The use of the data for any other purpose without prior approval is not permitted.
9. Applicants will be required to complete a confidentiality undertaking prior to the release of data.

Specific Access Guidelines

1. Site data. Participating sites may have ad hoc access to their own patient level data and comparisons to ANZFFR benchmarks on demand. This may be used for quality improvement and other analysis but must not identify individual participants. This access does not require review by the Data Management or Steering Committees.
2. Basic summary data. This is data that is in an aggregated form and does not directly or indirectly disclose information concerning individual participant. Where this is requested, a formal application will still be required. This level of data access can be approved by the Data Management Committee. A record is kept of all applications, and this is reported to the Steering Committee.
3. Aggregate de-identified data. Requests by researchers or other third parties that include de-identified participant level data, are required to make a formal application, and this must be accompanied by ethics committee approval. (Note: in New Zealand an institutional (University or Hospital) ethics committee approval will be accepted.) Each application will be reviewed in detail by the Data Management Committee.
4. Identified data for linkage.
    a. Individually identifiable unit record data (such as name, address, date of birth, NHI) will not be provided directly to an applicant.
    b. Individually identifiable information would only be made available to third parties (such as data linkage centres) for the purpose of linkage to other data collection(s). No clinical or health information would be provided for the purpose of data linkage.
    c. Separate ethical approval would be required for research or projects involving data linkage and the third party conducting the linkage must have a data governance and data security plan in place.
    d. If a research or other project requires individual data for linkage, the individual data will not be provided directly. A data linkage plan will be developed with each new applicant with the overarching requirement that the privacy of individual sites and participants is maintained.

More information can be found at: https://fragilityfracture.co.nz/datarequest/

Appendix A: A Step-by-Step Guide to Requesting Data Access

Step 1: Review approved projects and requests under consideration

You are encouraged to contact the registry manager FFRManager@osteoporosis.org.nz to discuss your proposal.

Step 2: Submit an abstract outlining your proposal

Once completed email this to FFRManager@osteoporosis.org.nz

Step 3: Complete data access application and required amendments

If you receive support to complete a full application for data access, the registry manager will send you the most recent data access application form to complete.
Based on feedback from the ANZFFR Data Custodian, complete any requested amendments to the ANZFFR data access request form and resubmit.

Step 4: ANZFFR Data Management Committee Recommendation

ANZFFR Data Management Committee reviews data application and HREC approval and makes recommendation to the ANZFFR Steering Committee.
Once the application has been accepted by the Data Custodian, it will be submitted to the ANZFFR Data Management Committee for its review at its next scheduled meeting. Data Management Committee recommendations will be tabled at the next Steering Committee Meeting.

Step 5: Ethics approval

Submit and receive ethics approval from relevant HREC and governance body.
All research projects must undertake appropriate applications for ethics and governance approval and provide copies of approved documents and approval letter(s) prior to ANZFFR data being released.

Step 6: ANZFFR Steering Committee Recommendation

The ANZFFR Steering Committee will make recommendations to the Data Custodian (Australia / New Zealand) and contact the applicant with the outcome of the review.
Usually, aggregated data requests take 4 weeks to complete after Data Custodian sign-off, but ANZFFR will keep you updated with definitive timeline from this stage.

Step 7: Data extraction

The data extract will be provided to the applicant after returning signed confidentiality undertaking.
Data variables will be extracted into a csv or excel file. The file will be encrypted and the file protected with a password. The file will be sent to the applicant using a secure data transfer mechanism. The password to access the file will be delivered separately by telephone, person to person. The applicant will then use the password to open the file and then unencrypt the data in the file.

Step 8: Prior to publication

The applicant will provide the ANZFFR Steering Committee a copy of any manuscripts submitted to peer-reviewed journals, and the reference once published.
Abstracts submitted to conferences should also be provided.