



ETHICS REVIEW CHECKLIST

Use of this Checklist is designed to assist in identifying when a proposed QI activity entails ethical 'risks'.

Section 1: ISSUES THAT MAY REQUIRE CONSENT TRUE/FALSE

1. The project involves direct contact with practitioners, patients, carers, Council or hearing members, or members of the public.
2. The project poses additional risks or burdens to a practitioner or member of the public beyond the risks or burdens that would otherwise arise in the normal course of Council business
3. The data to be collected is of a sensitive nature or application.
4. The purpose of the activity is not 'directly related' to the primary purpose for which it was collected
5. The data will be used or available in such a way that may identify individuals.

*If the response to any of the above statements is "true", you should contact your nominated HREC delegate (or designated institutional body) to discuss. **Informed consent** is usually required. If approval is required, you will need to provide a project outline, including a description of how you intend to gain consent, as well a participant information statement.*

Section 2: PRIVACY and CONFIDENTIALITY TRUE/FALSE

1. There is no process for de-identification of data.
2. Access to personal information will extend beyond those who are members of the Council or HPCA staff, or to others who normally do not have access to the practitioner's record, or to other data sets.
3. The project involves rare conditions or a small community.
4. Data will be selected or identified by:
 - Aboriginal or Torres Strait Islander status; or
 - Ethnic, religious or minority group.
5. Data will be collected beyond that which is normally collected in routine regulatory activities.

*If the response to any of the above statements is "true", you will need to provide more information and you **may need full Ethics Committee approval**. Please provide a brief explanation and a description of the consent process with your application, and contact your nominated HREC or QI delegate to discuss.*

Section 3: OTHER IMPLICATIONS TRUE/FALSE

1. The project uses 'new' interventions, protocols or equipment.
2. The project will involve allocation of practitioners or patients or complainants to groups to enable comparisons.
3. The project will involve genetic tests/testing.
4. The project may potentially infringe the rights, privacy or professional reputation of practitioners, students, carers or institutions.
5. The project involves use of placebo.

*If the response to any of the above statements is "true", you will need to provide more information and it **is highly likely you will need full Ethics Committee approval** for your project. Contact your HREC representative.*

1. The project is likely to generate data that may lead to publication.

If responses to all of the above statements in the checklist are 'false', then no ethical risks have been identified with this project and no ethics review is required.