Health and Disability Ethics Committees

Summary of HDEC scope of review

<table>
<tr><th colspan="6">HDEC Levels of Review- Risk Features</th></tr>
<tr><th></th><th>Observation Study Specific</th><th colspan="2">Observational and Intervention</th><th colspan="2">Intervention study specific</th></tr>
<tr><th></th><th></th><th>Involves use or disclosure of health information</th><th>Involves use/ storage/ preservation of human tissue</th><th colspan="2"></th></tr>
<tr><td rowspan="3">Out of Scope</td><td rowspan="3">Research wholly for attainment of a qualification- Masters or below</td><td>Using/accessing identifiable data without consent for audit or related activities</td><td rowspan="3">Tissue is disclosed in a non-identifiable form AND has existing informed consent for use (i.e. anonymous tissue from a biobank that has samples that are stored with consent for future research is given to a researcher)</td><td rowspan="3">Intervention studies always require review

Most require full review</td><td rowspan="3">Except low-risk device- Class I</td></tr>
<tr><td>Health information is disclosed to researchers in a de-identified form (NHI numbers are identifiers)</td></tr>
<tr><td>Consent for secondary use of health information (i.e. using it for research) has already been obtained</td></tr>
<tr><td rowspan="2">Expedited Review</td><td rowspan="2"></td><td>Using/accessing identifiable information without consent for research</td><td rowspan="2">Consent for future unspecified research (FUR)</td><td colspan="2">Using a medical device that is class IIa</td></tr>
<tr><td>Using/accessing identifiable health information to screen for potential participants for health research</td><td colspan="2">Any Intervention that does not contain any features in the full review section below</td></tr>
<tr><td rowspan="4">Full Review</td><td>Establishing a tissue bank</td><td rowspan="3">Use of large datasets, linking sensitive information or small potentially identifiable dataset</td><td rowspan="3">Use/storage/preservation without consent</td><td>New Medicine*</td><td>Vulnerable human participants</td></tr>
<tr><td>Vulnerable human participants</td><td>Use of a medical device that is Class IIb or III or an active implantable device or new surgical intervention</td><td>Approved medicine used for a different treatment or delivered in a new way*</td></tr>
<tr><td>If any participants are not consenting</td><td>Use of AI</td><td>Use of Guthrie cards</td><td>Withholding standard of care</td><td>If any participants are not consenting (or not able to)</td></tr>
</table>

**These studies will also require submission to SCOTT and/or GTAC in addition to HDEC. Please check and confirm with these committees.*

This is a high-level summary of the scope of HDEC's review and their pathways as outlined in the Standard Operating Procedures for Health and Disability Ethics Committees. Some research may not fit neatly under these headings. In these cases, please contact the Secretariat if it is still unclear where your study sits.

Studies out of scope may need Institutional Ethics Committee (IEC) consideration – the contact details for these committees are available here.

If no IEC is available, alternate Committees are available but may charge a fee and should be enquired independently.