There are many knowledge generating activities that are outside the scope of the HSE RGMS framework and do not require approval by a Research Ethics Committee.

These includes: clinical audits, standard service evaluations and quality improvement projects, statutory public health work, advanced health analytics routinely carried out by the HSE and its funded organisations for the purpose of discharging their legal obligations and for the planning and delivery of health and social health care services.

**However, in certain instances, ethical oversight outside the remit of the REC maybe required for such activities**. This oversight can be provided by a variety of mechanisms in accordance with the local governance requirement of each service. When ethical oversight is deemed necessary but no other arrangement for ethical governance exist at local level, the relevant REC may agree to review the projects. In these case, it is recommended that the REC membership includes members with expertise in such types of activities. The tool below[[1]](#footnote-1) can be used to assess such a risk- answering Yes to any of the questions below would indicate that ethical oversight is required.

|  |  |  |  |
| --- | --- | --- | --- |
| **Will the proposed activity** | **Yes** | **No** | **N/A** |
| Infringe on any patient’s rights or risk breaching any patient’s confidentiality or privacy? |  |  |  |
| Test a hypothesis as distinct to measuring against a recognised benchmark? |  |  |  |
| Involve the use of any untested intervention - clinical or system? |  |  |  |
| Pose any risk for or burden on a patient beyond those of his or her routine care? |  |  |  |
| Involve any clinically significant departure from usual clinical care? |  |  |  |
| Gather any information about any patient other than information that is ordinarily collected as part of providing routine care for the patient? |  |  |  |
| Collect data directly from any patient or carer, and if so, could the activity subject a patient or carer to more than a minimal burden or risk if it requests sensitive information or is time consuming? |  |  |  |
| Collect or disclose any data that could be used to identify any patient or any practitioner? |  |  |  |
| Have someone carrying out the activity who does not normally have access to patient’s records? People who normally have access to patients’ records when a duty of confidentiality is included in their job descriptions providing direct patient care and staff employed to support clinical audit or QI activities include clinical staff. |  |  |  |
| Involve a potential conflict of obligation to individual patients or to all patients such as if the activity involves a trade-off between cost and quality? |  |  |  |
| Allocate any interventions differently among groups of patients or staff, for example, in implementing a change in practice? |  |  |  |

1. Clinical Audit A Practical Guide 2023, HSE National Centre for Clinical Audit, National Quality and Patient Safety Directorate. Dublin: Health Service Executive [↑](#footnote-ref-1)