**Determining the level of risk posed by your study and**

**whether your application may receive full or delegated review**

Full review at a Research Ethics Board (REB) meeting is the default review process for all human participant research.

The delegated review process, conducted by two reviewers from the board, may be used when the research is determined to be at or below the threshold of ‘minimal risk.’

‘Minimal risk’ is defined as the probability and magnitude of possible harms implied by participation in the research that participants can reasonably expect to be no greater than those encountered by the subject in those aspects of their everyday life that relate to the research, or during the performance of routine physical or psychological examinations or tests.

To evaluate the risk for your proposed research, consider the following.

**Group vulnerability**

Any pre-existing vulnerabilities associated with proposed participant groups, including the following:

* pre-existing physiological or health conditions
* cognitive or emotional factors
* socioeconomic or legal status

**Research risk**

The probability and magnitude of harm participants may experience as a result of the proposed methods to be used and types of data to be collected, including the following:

* physiological or health issues such as clinical diagnoses or side effects
* cognitive or emotional factors such as stress or anxiety during data collection
* socio-economic or legal ramifications such as stigma, loss of employment, deportation, or criminal investigation (e.g., in the event of duty to report intent to cause serious harm, subpoena, or breach of confidentiality)

The assessments of group vulnerability and research risk (i.e., low, medium, high) can then be used through the Risk Matrix to determine REB process.

**Risk Matrix for human participant research**

|  |  |  |  |
| --- | --- | --- | --- |
| **Group Vulnerability** | **Research Risk** | | |
| **Low** | **Medium** | **High** |
| **Low** | Delegated | Delegated | Full |
| **Medium** | Delegated | Full | Full |
| **High** | Full | Full | Full |

**Using the Risk Matrix can help guide you in determining where you feel the risk level of your study fall, however, the REB makes the final determination whether a protocol is reviewed through delegated or full board process.** Other factors that the REB considers in assigning a protocol to full board may include the following:

* involvement of tests or interventions
* research complexity
* research involving specific communities or groups
* large participant populations or data subjects