

## Audit Risk Assessment

|                          |  |
|--------------------------|--|
| <b>Research Title</b>    |  |
| <b>Lead Investigator</b> |  |
| <b>Start Date</b>        |  |
| <b>Length of Study</b>   |  |

|    | <b>Indicator</b>         | <b>Score 0-3</b> | <b>Justification</b> |
|----|--------------------------|------------------|----------------------|
| 1  | Study Type               |                  |                      |
| 2  | Sample Size              |                  |                      |
| 3  | Study Population         |                  |                      |
| 4  | No. of Sites             |                  |                      |
| 5  | No. of Study Arms        |                  |                      |
| 6  | Demands on Participants  |                  |                      |
| 7  | Equipment                |                  |                      |
| 8  | Endpoints and Objectives |                  |                      |
| 9  | Facility Requirements    |                  |                      |
| 10 | Off Site Requirements    |                  |                      |
| 11 | Training Requirements    |                  |                      |
| 12 | Research Team Experience |                  |                      |

This form is a controlled document.

Please refer to the GCU website to ensure you have the most current version



|                    |  |  |
|--------------------|--|--|
| <b>TOTAL SCORE</b> |  |  |
|--------------------|--|--|

| Name | Signature | Designation | Date |
|------|-----------|-------------|------|
|      |           |             |      |
|      |           |             |      |

This form is a controlled document.

Please refer to the GCU website to ensure you have the most current version

**Audit Risk Assessment Examples for Indicators of Risk**

|    | <b>Example</b>   | <b>Score</b> |
|----|--|--------------|
| 1  | Study administering questionnaires/interviews for quantitative or mixed; Study involving qualitative methods only; Study limited to working with human tissue samples and/or analysis of data; Study limited to working with data; Research tissue bank; Research database | 0            |
|    | Basic science study involving procedures with human participants   | 1            |
|    | Clinical trials of investigational medicinal products; Clinical investigations or other studies of medical devices; Clinical trial of a drug/device combination; Other clinical trials or clinical investigations  | 2            |
| 2  | Below 50   | 0            |
|    | 50 – 200   | 1            |
|    | 200 -500   | 2            |
|    | 500 + ( <i>N.B risk score for sample size dependent on study type</i> )  | 3            |
| 3  | Standard demographic   | 0            |
|    | Nonstandard demographic  | 1            |
|    | Vulnerable group   | 2            |
| 4  | Sites out with Scotland  | 1            |
|    | 5+ sites across Scotland   | 1            |
| 5  | Up to and including 3 arms   | 1            |
|    | 4 or more arms   | 2            |
| 6  | Frequent visits - more than 1/month, long visits, unusual travel required, source data provided by patients  | 1            |
| 7  | Equipment requiring regular maintenance and testing  | 1            |
|    | Study specific equipment, off-site equipment, experimental equipment   | 2            |
| 8  | Safety data as secondary or lesser objectives/endpoints  | 1            |
| 9  | Additional clinic provision, childcare facilities, storage of equipment, samples storage/ testing.   | 1            |
| 10 | Offsite investigations, 3 <sup>rd</sup> party data sources   | 1            |
|    | More than 2 sites required for a visit, source data processed by multiple off-site agencies  | 2            |
| 11 | Additional training for non-standard/study specific non-medical processes (e.g. investigations, non-invasive procedures)   | 1            |
| 12 | PI/CI for first time. Small support team with little research experience. No Project Management/coordination. Multi sites with varying experience  | 1            |

- Low risk < 12 (midpoint of all medium scores of 24) 1 audit minimum
- Medium risk >=12 but <= 24 (maximum of all medium score) 1 audit minimum, potential for others after discussion between auditor and PI.
- High Risk >24 study will require multiple audits (e.g. annually, at particular endpoints, specific research project stages such as during recruitment/end of recruitment/ mid-way thorough visits). To be discussed and in agreement with PI.

This form is a controlled document.

Please refer to the GCU website to ensure you have the most current version