**RMU Protocol Review Checklist for Interventional Research**

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|  | **Rawalpindi Medical University Rawalpindi**  **Department of research and Development** |

**Instructions for Protocol Review**

1. Before submission to the Ethical Review Board (ERB), the study protocol should be reviewed by a subject specialist.
2. This checklist is for the interventional research protocols
3. This review checklist should be submitted **along with the protocol** to the ERB.
4. **Do not delete** any item from the checklist. If an item is not applicable to the study, please mark it clearly as **"Not Applicable (N/A)"**.
5. If a reviewer does **not have expertise** in a particular area (e.g., statistical analysis), they may **leave those items blank**.
6. **Unanswered items** should be forwarded to a **second reviewer** with expertise in the skipped areas.
7. Investigators are required to provide **written responses** to the reviewer’s concerns. If deemed appropriate, protocol modifications should be made accordingly.
8. The reviewer should be a **Senior Registrar or above** in designation.
9. The reviewer should **not have any conflict of interest** related to the study.

**Version number**

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| --- | --- | --- |
| Version number | Date | Summary of revisions |
| 01 | 11/06/2025 | Original draft |
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| **Items** | **Assessment** | | | **Page number** | **Comments** |
| Yes | No | Not applicable |
| **Title** |  |  |  |  | |
| Is the title comprehensive and reflective of PICO model? |  |  |  |  |  |
| Is the study design written in the title? |  |  |  |  |  |
| **Introduction** |  |  |  |  | |
| Is the introduction adequate and well structured? |  |  |  |  |  |
| Is the research problem clearly described? |  |  |  |  |  |
| Is the scientific rationale for the study well justified? |  |  |  |  |  |
| **Study interventions** |  |  |  |  | |
| Are the study interventions/ drug(s) /device(s) being used in the study FDA, DRAP approved for the dose, regimen, duration and population specified in the protocol? |  |  |  |  |  |
| Are the references for the study interventions provided in the protocol and the current guidelines followed? |  |  |  |  |  |
| Are the adverse events associated with study interventions enlisted in the protocol adequately? |  |  |  |  |  |
| Are any potential adverse events missed or omitted in the protocol? |  |  |  |  |  |
| Is the risk/benefit assessment appropriate and do the expected benefits outweigh the potential risks? |  |  |  |  |  |
| Is the risk level classification by investigators appropriate as per regulatory definitions? |  |  |  |  |  |
| Are the investigators adequately trained for the study interventions? |  |  |  |  |  |
| Do the study site has appropriate infrastructure including equipment to carry out study interventions? |  |  |  |  |  |
| **If placebo or standard care is used:** |  |  |  |  | |
| Is the use of placebo justified and ethically appropriate? |  |  |  |  |  |
| Are participants adequately informed about placebo use in the consent materials? |  |  |  |  |  |
| **Sample size** |  |  |  |  | |
| Is the sample size adequate for the condition under study and meeting the study objectives? |  |  |  |  |  |
| Are sample size parameters: confidence level, power & effect size clearly stated? |  |  |  |  |  |
| Is the effect size used for the sample size estimation is realistic, justified and supported with evidence from literature? |  |  |  |  |  |
| Are expected drop-out accounted for sample size calculation? |  |  |  |  |  |
| **Study population** |  |  |  | | |
| Is the target population clearly defined and appropriate for the health condition under study? |  |  |  |  |  |
| Are potential risks mitigated for defining target population? (for example, exclusion of immunosuppressed patients) ? |  |  |  |  |  |
| Does the study include any vulnerable population (children, pregnant women, prisoners, etc.)? |  |  |  |  |  |
| If yes, are additional protections including consent procedures outlined in the protocol and are they adequate? |  |  |  |  |  |
| **Study settings** |  |  |  |  | |
| Is the study site(s) clearly described? |  |  |  |  |  |
| Is the selected site(s) having suitable infrastructure in place for clinical trials? |  |  |  |  |  |
| Is the study site(s) DRAP approved for clinical trials? |  |  |  |  |  |
| **Study drug(s)/ device(s) procurement storage accountability** |  |  | | | |
| Are appropriate procedures outlined in the protocol for procurement of study drug(s) /device(s) |  |  |  |  |  |
| Are study drug/device storage, handling and dispensing procedures clearly outlined and are these compliant with GCP standards? |  |  |  |  |  |
| **Group allocation masking and blinding procedures** |  |  |  |  | |
| Are randomization procedures clearly described and are they appropriate? |  |  |  |  |  |
| Is the randomization technique correctly stated and is it justified? |  |  |  |  |  |
| Are sequence generation and implementation techniques valid and well explained? |  |  |  |  |  |
| If web source/digital platform is used, do the investigators have full access to that program for the trial duration? |  |  |  |  |  |
| Is there an independent trained team for randomization? |  |  |  |  |  |
| Is the randomization process free from the influence of investigators? |  |  |  |  |  |
| If the study is blinded, are appropriate code breaking procedures described for emergency unblinding? |  |  |  |  |  |
| **Study endpoints** |  |  |  | | |
| Are primary end point(s) clearly stated and are they scientifically justified? |  |  |  |  |  |
| Are all primary and secondary endpoints listed appropriately and is the selection rational? |  |  |  |  |  |
| Are any important outcomes omitted or missed by the investigators? |  |  |  |  |  |
| Are scales and measurement procedures for data capture on study end points correctly described? |  |  |  |  |  |
| Is follow up schedules adequate to measure all study endpoints? |  |  |  |  |  |
| Is the overall study duration justified for expected outcomes? |  |  |  |  |  |
| Is the participants’ timeline adequate, with clearly defined visits and interval schedules? |  |  |  |  |  |
| **Data collection** |  |  |  |  | |
| Are the data collection methods appropriate and clearly described? |  |  |  |  |  |
| Is the method of data capture (CRF or EDC system) identified? |  |  |  |  |  |
| If using EDC system, do investigators have full access? |  |  |  |  |  |
| Is the training of research staff in data handling procedures documented? |  |  |  |  |  |
| Are data storage, security and safety procedures adequately described? |  |  |  |  |  |
| Are the source documents identified? |  |  |  |  |  |
| Are data sharing and access procedures described in the protocol? |  |  |  |  |  |
| **Study harms** |  |  |  |  | |
| Does the protocol include standard definitions of:   * Adverse events * Serious adverse events * Unanticipated problems |  |  |  |  |  |
| Is the process for monitoring, documenting and reporting adverse events described in the protocol and is it appropriate? |  |  |  |  |  |
| Are the timelines reporting pathway for adverse events clearly defined? (to sponsor regulatory authority etc.) |  |  |  |  |  |
| **Statistical analysis** |  |  |  |  | |
| is the study hypotheses (null and alternate) stated correctly? |  |  |  |  |  |
| Is the statistical analysis plan appropriate for the study design and objectives? |  |  |  |  |  |
| Are the planned statistical tests appropriate for the study design and objectives? |  |  |  |  |  |
| Is the confidence interval and p-value clearly stated? |  |  |  |  |  |
| Are the methods for handling missing data (imputation, sensitivity analysis) described? |  |  |  |  |  |
| Is any interim analysis planned and is it appropriately justified? (for safety and/or efficacy) |  |  |  |  |  |
| Is a plan described for subgroup analysis (if relevant)? |  |  |  |  |  |
| Is the software or statistical package to be used (e.g. SPSS, R STATA) mentioned? |  |  |  |  |  |
| **Ethical issues** |  |  |  |  | |
| Is the statement that participation is voluntary included? |  |  |  |  |  |
| Is the statement that participants can withdraw from the study at any time without penalty or loss of benefits included? |  |  |  |  |  |
| Are the informed consent procedures described, ensuring these are free of coercion or undue influence? |  |  |  |  |  |
| Are the participants provided with complete information about the study, including its purpose, procedures, risks, benefits and alternatives? |  |  |  |  |  |
| Are procedures in place to assess participants’ comprehension of the study before consent? |  |  |  |  |  |
| Is the language of the consent document simple, clear and in a language understandable to the participants? |  |  |  |  |  |
| If the study involves vulnerable populations (minors, prisoners, pregnant women etc.) are additional safeguards in place and are they documented? |  |  |  |  |  |
| If the study involves collection, storage and future use of biological samples additional consent procedures outlined? |  |  |  |  |  |
| Is the procedure for data confidentiality and participation privacy adequality described? |  |  |  |  |  |
| Are compensation details (for participation or in case of injury) provided in the consent document? |  |  |  |  |  |
| Is the contact information for the principal investigator and ethics committee included in the consent document? |  |  |  |  |  |
| Additional queries: the reviewer can state additional queries. The investigators should answer the query which include defending the investigators view point or making necessary amendments in the protocol. If there are additional queries then create more space in this checklist. The investigators should cite references where applicable from their protocol in support of their arguments | | | | | |
| Query 1 | | | | | |
| Investigators response | | | | | |

Reviewer 2

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer 1

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_