Clinical Research Unit Suggested Criteria for Scientific Review

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| General Scientific Review considerations:   * Assessment of overall scientific merit -- quality, originality, and importance of the scientific hypothesis * The scientific and statistical validity of the study design * Judgment that the study is in alignment with the scientific priorities of the respective department/division |
| Review Criteria   1. Has an appropriate literature search been performed? 2. Are there adequate preliminary data in the literature to justify research? 3. Are the study objectives and hypotheses appropriated and clearly stated? 4. Are there other studies being conducted to address the proposed primary aims? |
| Study Design   1. Is the study design appropriate to achieve the objectives? 2. Is the study design clearly presented? (e.g., longitudinal or cross-sectional, cohort or case control, randomized controlled trial, etc.) 3. Are the inclusion and exclusion criteria complete and appropriate? 4. Are the endpoints (outcomes) identified and appropriated? 5. Are all study measures listed and all measurement tools included? 6. Is an appropriate sample size justification provided, including power calculations (when appropriate)? 7. Is the analytic plan adequate, addressing the study hypotheses and all proposed statistical tests and approaches to data analysis? |