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**POLICY: RESEARCH PARTICIPATION**

Recognizing that it is in the best interest of residents and staff to participate in ethical research related to the care and support of nursing home clients, Rocmaura actively seeks collaboration with research partners. Proposals for any such research shall be reviewed by a Research Review Committee (RRC), which shall be comprised of at least one member from the Ethics Committee, the Physician or a representative of the physician, the Executive Director, the Program Co-ordinator, and the Director of Nursing. Each proposal shall be evaluated according to its ethical acceptability. Attention will be given to facilitating timely review of all proposals. The following criteria shall be applied (based on Horizon Health Network Research Review Criteria).

**Research Review Committee Terms of Reference**

**Membership:**

 A member of the Ethics Committee (Chair)

 The House Physician (or representative)

 Director of Nursing

 Executive Director

 Program Co-ordinator

**Process:**

1. Proposals will be submitted to the Executive Director.
2. Five copies are required.
3. A meeting will be called in a timely fashion when a proposal is submitted.
4. The proposal will be circulated in advance to all those sitting on the RRC.
5. Criteria for evaluation will be included in that package.
6. Each member will preview the proposal using the criteria and will bring their respective findings to the meeting for discussion.
7. There will be a decision made to sanction or not to sanction the proposal made by the committee based on its ethical appropriateness.
8. The committee may give unconditional approval, conditional approval with recommendations, request for revisions, which requires the proposal come back to the committee, or it can deny approval.
9. The researcher will be notified by letter of the findings of the committee.
10. Expedited review may be given when a proposal has already been approved by the research review committee of Horizon Health Network.

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**Research Review Committee**

***RESEARCH APPLICATION ASSESSMENT CHECKLIST***

***(As per Horizon Health Network’s Research Department)***

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| --- | --- |
| Project#: | RRC Date: |
| Principle Investigator: |  |
| Title/Keywords: |  |
| Approval Category | APPROVED CONDITIONALLY  Minor corrections required- Yes No Protocol clarification required- Yes No Revised consent form required- Yes No |
| Signature of Chairperson (or designate): Date: |
| **Principle:**Scientific quality and ethical considerations for all research activities are of paramount importance. The Research Review Committee (RRC) will be guided by the principles outlined in the Declaration of Helsinki (revised, 1996), by the guidelines accepted by the Therapeutic Products Directorate of Health Canada (1997) and provided in the International Conference on Harmonisation - Good Clinical Practices (ICH - GCP) Guidelines, and most importantly by the Tri-council Guidelines for research involving humans (code of Ethical /Conduct for Research Involving Humans, June, 1998). In addition, consideration will be given to guidelines provided by the federal drug administration (as described in the Federal Register) and similar organizations in the US (eg. NIH, OPRR). The primary role of the RRC is to safeguard the rights, safety, and well being of research participants. This is achieved through reviewing each research application for ethical, scientific, and medical merit and ongoing monitoring of studies.  |
| **Process:**Each submission will be evaluated under five headings: 1) Personnel and facilities2). Is the research protocol scientifically valid 3). Does the research have sufficient overall value, 4) is the subject treated with respect and dignity 5) and does the consent form correspond to the current standard and an acceptable format.The checklist provided below has been developed to guide the RRC in assessing the scientific and ethical merit of submissions. (Note: it has been designed primarily for evaluating clinical trials, however, the same principles are generally applicable to other studies). This does not restrict the Committee from inquiring into additional elements or from requiring additional information. |
| **Result:** | Following review, submissions will be placed into one of the three categories.  |
| Approval:   |  No major concerns exists with either the protocol or the consent form. The investigator has RRC permission to proceed with the study. |
| Conditional Approval  | Questions exist about the protocol, certain documentation has not been provided, or revisions (major or minor) to the consent form are required. This approval does not indicate permission to proceed with the study has been given. Revisions must be submitted to a representative of the Committee or the whole Committee before approval can be given. |
| Not Approved | Major methodological or ethical questions exist. The requested changes must be made and the application resubmitted and a re-review conducted by the RRC. |

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| **Rocmaura Research Review Committee** **Research Application Assessment Checklist** Page 2 |
| ***Personnel and Facilities?*** |  | Yes | No | NA |
| Personnel - Principal Investigator (PI) | Appropriately qualified/suitably experienced? |  |  |  |
| Personnel - Support | Adequate and appropriate support available? |  |  |  |
| Facilities | Appropriate and adequate facilities available? |  |  |  |
| ***Is the Research Protocol Scientifically Valid*?** | Yes | No | NA |
| Baseline for Comparison | Appropriate baseline (eg. Placebo used?)? |  |  |  |
| Necessary for the Research | Appropriate value to be gained from the project? |  |  |  |
| Method used | Basic methodological approach appropriate?  |  |  |  |
| Use of human subjects | Appropriate and necessary? |  |  |  |
| Category of human subjects | Appropriate? |  |  |  |
| Inclusion/exclusion criteria | Appropriate (no exclusion/no exploitation) |  |  |  |
| Research subjects | Different pool of subjects from similar studies? |  |  |  |
| Handling of gathered data | Appropriate confidentiality and analysis? |  |  |  |
| ***Does the Research have sufficient Overall Value?*** | Yes | No | NA |
| Benefits to the participant | Evidence of potential benefit to the participant? |  |  |  |
| Benefits to society | Evidence to potential benefit to society? |  |  |  |
| Acquisition of new knowledge | Evidence of acquisition of new knowledge? |  |  |  |
| ***Are Research Subjects Treated With Respect and Dignity*?** | Yes | No | NA |
| From a subject-centered perspective , determine subjects are treated with respect and dignity. |
| Study group | Appropriate selection (not unfair/biased)? |  |  |  |
| Risks and benefits | Appropriate risks and benefits? |  |  |  |
| ***Does The Consent Form Correspond to the Current Standard*?** | Yes | No | NA |
| Comprehension | Level of education adequate? |  |  |  |
| Content | Correct grammar and good fluency? |  |  |  |
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**Rocmaura Research Review Committee**

 **Research Application Assessment Checklist** Page 3

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| --- | --- | --- | --- | --- |
| ***Specific Content:*** |  | Yes | No | NA |
| Introduction | Study title, sponsor (if applicable)and local PI |  |  |  |
| Voluntary participation | Statement that participation is voluntary |  |  |  |
| Withdrawal | Statement that withdrawal permitted at any time, and will not adversely affect care. |  |  |  |
| Basic protocol observed | Purpose and rationale of study stated; number of participants, and study sites noted. |  |  |  |
| Study method | Methods outlined, including time commitment /any inconveniences to the participants. |  |  |  |
| Potential risks | Potential risks adequately described? |  |  |  |
| Alternatives | Alternative treatment options stated? |  |  |  |
| Confidentiality | Adequate statement/description of confidentiality and access by sponsor/regulatory authorities? |  |  |  |
| Additional information | Contacts for study: study information; emergency contact; third party contact? |  |  |  |
| Participant’s statement | Appropriate statement (s) and signature lines? |  |  |  |
| Investigator’s statement | Appropriate statement and signature lines? |  |  |  |
| The standard for informed consent is meant to be a realistic one. It is important that consent be obtained in a form that is meaningful to the participant. In some circumstances a written consent may not fulfill that criteria. In such cases, a judgement must be made as to whether the overall approach provides the participant with the information they need to make a meaningful choice. |
| Comments: |