**APPLICATION FOR NORTH WEST CANCER RESEARCH/TENOVUS CANCER CARE PhD GRANT – APPENDIX A**

|  |
| --- |
| 1. **RESEARCH INVOLVING HUMAN PARTICIPANTS, BIOLOGICAL SAMPLES AND PERSONAL DATA RELATING TO LIVING OR DEAD PERSONS** |
| a. Does your project involve human participants? If yes, please describe what ethical approval is required and why. |
|  |
| b. Will personal data be used? |
|  |
| c. Will your project involve the use of human biological samples? |
|  |
| d. Please state:  Who has or will review and grant ethical approval of the project. Additionally, please specify whether any additional regulatory approvals require or have been obtained. |
|  |
| e. In the course of your project:  Do you propose to use facilities within the National Health Service (NHS)? |
|  |

|  |
| --- |
| f. Does your research involve patients being cared for by the NHS? |
|  |
| g. If the answer is yes to e or f above, please indicate which organisation has agreed to be the sponsor for the project under the Research Governance Framework for Health and Social Care, published by the Department of Health in England or the corresponding departments in Northern Ireland, Scotland or Wales. **Please note that the NWCR cannot act as sponsor.** |
|  |

|  |
| --- |
| 5. **STUDY DESIGN FOR HUMAN SUBJECTS RESEARCH AND/OR RESEARCH USING HUMAN SAMPLES or DATA** |
| a. If recruiting new study subjects, what are the proposed participating centres and the roles of the clinical trial team members? Provide details of any activity to be undertaken by a third party and comment on the plans to ensure the presence of a formal contract. (maximum 200 words) |
|  |
| b. Please describe the study design and methodology including any planned interventions (experimental and control). (maximum 300 words) |
|  |
| c. Describe the inclusion/exclusion criteria or definitions of study groups, as appropriate. What are the proposed methods for avoiding bias? If applicable, what are the proposed arrangements for allocating participants to the trial groups? (maximum 200 words) |
|  |
| d. What are the primary and secondary outcome measures (clinical trial), or phenotypes (sample or data analysis), and how will these be assessed? If applicable, describe the proposed frequency and duration of follow up and any anticipated problems with non-compliance and/or loss to follow up. (maximum 200 words) |
|  |

|  |
| --- |
| e. Detail and justify the sample size and proposed statistical analysis including a power calculation, interim analyse and/or subgroup analyse plan. If recruiting new study subjects, outline and justify the strategy for recruitment. (maximum 200 words) |
|  |
| f. How have patients, patient advocacy groups or communities been involved in developing the aspects of this proposal? (maximum 300 words) |
|  |
| g. Describe anticipated regulatory and governance approvals, and the proposed arrangements for trial management. What is the proposed membership of the Trial Steering Committee and the Data Monitoring and Ethics Committees? (maximum 200 words) |
|  |