APPLICATION FOR NORTH WEST CANCER RESEARCH PROJECT GRANT – APPENDIX A

1. USE OF ANIMALS North West Cancer Research is a member of the Association of Medical Research Charities (AMRC). We support the use of animal research where there is no alternative available and all research must follow the 3 Rs – replace, reduce and refine. For more information, please refer to the AMRC statement on the use of animals in research. The provision of insufficient experimental details and/or a lack of justification for animal usage and numbers on the basis of defined endpoints, expected 'response' outcomes and Power Calculations could trigger the rejection of the proposal without review.
a) Does your proposal involve the use of animals?
b) Does your proposal involve the use of animal tissue?
c) Does your proposal include procedures to be carried out on animals in the UK which require a Home Office licence under the Animals (Scientific Procedures) Act 1986?
d) Does the organisation in which the animal work is to be carried out hold a certificate of designation under the Animals (Scientific Procedures) Act 1986?
e) Does your proposal involve the use of animals or animal tissue outside the UK? If so, please provide more details relating to the procedures that are to be undertaken and the regulatory approvals for these that have been obtained (and from which organisation).
f) If your project does involve the use of animals, provide a description of the procedures that are to be used and define the severity of these procedures? Please indicate whether these procedures have been categorised as being 'Mild', 'Moderate' or 'Substantial'. Outline proposed actions and approaches for refining the techniques. Also provide details (either here or in the main body of the text) on the regularity of monitoring and whether monitoring requires anaesthesia (i.e. as would be required for *in vivo* imaging of tumours) (maximum 250 words)
g) Why is animal use necessary? Are there any other possible approaches? What other approaches have been considered and why are these not suitable? (maximum 250 words)

h) What species is to be used, and why is this species the most appropriate? (maximum 250 words).	
i) Does the proposed study involve the use of genetically-modified animals? If so, then what are the mutations and will these be harmful mutations?	
j) Is the appropriate Project Licence in place?	

2. SUMMARY OF ANIMAL COSTS

The table below should be duplicated for each different species.

Animal species to be used, and strain if relevant:	
Source of supply	
Purchase:	
Purchase price per animal	
Total number of animals to be purchased	
Total purchase cost:	
Maintenance:	
Total number of animals to be maintained	
Total number of weeks' maintenance required	
Cost per animal per week	
Total maintenance cost:	
Experimental procedures	
Types of procedure(s)	
Cost per procedure(s)	
Total procedures cost:	

Total purchase cost:	
Total maintenance cost:	
Total procedures cost:	
TOTAL	

3. JUSTIFICATION FOR SUPPORT REQUESTED (maximum 500 words). Please justify the use of animals (numbers and species). Justify animal usage and numbers on the basis of defined endpoints, expected 'response' outcomes and Power Calculations. Also describe any plans to reduce bias (eg. blinding, randomisation).

4. 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 for what ethical approval is needed and why.
b) Will personal data be used?
c) Will your project involve use of human biological samples?
d) Please state: i) By whom and when the ethics of the project has been reviewed, and specify any other regulatory approvals that have been obtained.
And/or ii) By whom and when the ethics of the project will be reviewed, and specify any other regulatory approvals that will be sought.
e) In the course of your project: i) Do you propose to use facilities within the National Health Service (NHS)?

ii) Does your research involve patients being cared for by the NHS?

iii)	If the answer is yes to (i) or (ii) 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 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 any interim analyses and/or subgroup analyses. Please provide a power calculation to support your sample size and statistical analysis. 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 clinical 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)