NCRI Proposal Guidance Proforma.

Please kindly refrain from sending the entire proposal/protocol and keep to a page limit of 5 pages. There is an option to upload the study flow chart separately.

|  |  |
| --- | --- |
| Proposal Guidance meeting and date: (e.g. Brain, November 2022) | |
| Researcher details | |
| Lead Researcher’s name |  |
| Other researchers’ names |  |
| Study overview | |
| Study name |  |
| Background and hypothesis | * [Patient population – who affected, how many] * [Typical management] * [Current therapy options] * [Problems, uncertainties with current options – e.g. survival, toxicities, difficulty in predicting who will benefit] |
| Aim of study / scientific question | * [What is the scientific question?] * [Please describe the primary aim(s) of the proposed study] * [Main question this trial will address] * [How this builds on the existing evidence base] |
| Proposed source(s) of funding | * [Please specify funder and funding call] * [Or, if the proposal has already been submitted for funding, please specify where and relevant dates] |
| Estimate of funding required | * [Have you performed cost estimates of your proposed study?] |
| Patient and public involvement | |
| Lay summary up to 300 words (Required) | * [Define in lay terms why the trial is needed, the basic design of the trial, how the treatment differs from current clinical practice, and how the trial results will be used / of benefit to patients] * [Check out the document ‘[How to write a good lay summary](https://www.ncri.org.uk/wp-content/uploads/CTRad-How-to-write-a-good-lay-summary.pdf)’] |
| Outline of patient and public involvement | * [Has patient input to the proposal/trial design been sought?] * [Is there a plan to get patient input for the patient information sheet etc if funded?] |
| Patients | |
| Estimated number of patients | * [please justify the sample size required] |
| Main  inclusion criteria |  |
| Main  exclusion criteria |  |
| Intervention | |
| Trial Phase | Pre-clinical ☐  Phase I ☐  Phase II ☐  Phase III ☐  [If applicable] |
| Study Design | * [Randomised/non-randomised; single centre/multicentre, Phase 1, 2, 3, feasibility, observational etc.] * [Include flow chart of study design where available - you can upload this at the end of the page] |
| Treatment or Intervention |  |
| Comparator |  |
| Outcomes | |
| Outcome measures / endpoints | * Primary endpoint * Secondary endpoints |
| Basic statistical concepts |  |
| Translational research | |
| Have you had translational / biomarker input? If so, from whom? |  |
| Outline of any translational/biomarker/imaging components |  |
| Sample collection? |  |
| Future translational hypothesis to be tested? |  |

|  |  |
| --- | --- |
| General information about your proposal status | |
| If the proposal has not been submitted for funding, would you say the proposal is almost ready for funding, can be submitted within 6-12 months, or at a very preliminary stage? | Almost ready for submission  Can be submitted within 6 months  Can be submitted within 1 year  At a very preliminary stage |
| Have you had statistical input? |  |
| Which CTUs or RDS are you working with? |  |
| Have you had pathology input? | [Check out the [SPIRIT-Path guidance](https://www.ncri.org.uk/spirit-path-extension/)] |
| Are there any genomics aspects to this research question? | [Consider submitting to the [NHS Genomics Medicine Service Research Collaborative](https://www.england.nhs.uk/genomics/genomic-research/nhs-genomic-medicine-service-research-collaborative/submissions-to-the-nhs-gms-research-collaborative/)] |
| For Radiotherapy studies: have you discussed your proposed study with the [Radiotherapy Trials Quality Assurance Group](http://www.rttrialsqa.org.uk/rttqa/)? |  |
| Have you had input from relevant NCRI Group(s)?  If so, please specify who/which group(s): |  |
| Future leaders – Have you identified a trainee interested in clinical trials to be involved in your study? |  |

|  |  |
| --- | --- |
| **Benefits from this Proposal Guidance meeting** | |
| Are there any specific areas you need help with? | [Please list up to three areas] |
| Please indicate what specialism(s) you require (e.g. palliative medicine, pathology, surgery etc): | [Please list up to three specialisms] |