## Useful links for researchers

Below are links to useful guidelines and information developed by the NCRI CTUs, Research Groups and Partners, which we ask you to consider when designing your research study, as appropriate.

# Broadening the eligibility criteria of study participants in clinical trials

- Lowering the age limit of clinical trials to 16, 13 or 12 years old <u>Fostering Age</u> <u>Inclusive Research (FAIR) trials for Adolescents and Young Adults.</u>
- <u>Guidance from the NIHR for researchers on Equality, Diversity and Inclusion for study participants</u>.
- <u>INCLUDE Ethnicity Framework</u> aims to help researchers think carefully about which ethnic groups to include in their trials for its results to be widely applicable and what challenges there may be to make them possible.
- You can find more information about broadening the eligibility criteria on the <u>ASCO website</u>

# Guidelines from NCRI Clinical Trials Unit (CTUs)

- Data access guidelines for Investigator Initiated Research (IIRs) within the NIHR
  CRN Cancer portfolio
- Principles for Collaboration with Pharmaceutical Company Partners

## NIHR Clinical Research Network (CRN) portfolio adoption process

• Applying for NIHR CRN study support

## NCRI Living With & Beyond Cancer (LWBC) Group

- NCRI's Living With and Beyond Cancer's (LWBC) Methodology Workstream has developed a process by which all new research proposals have access to a <u>Methodology AdVIsory Service (MAVIS)</u> to receive methodological review/input prior to submission to a funding body.
- The NCRI partnered with the James Link Alliance (JLA) on a Priority Setting Partnership to determine the <u>top 10 priorities for research that will help people live</u> <u>better with and beyond cancer</u> (26 key questions were identified and these were distilled to the top 10 questions).
- The LWBC Group recommend using the below guidelines depending on the type of study:

Guidelines (please click on the links below for further information)		
Randomised trials	<u>CONSORT</u>	<u>Extensions</u>
Observational studies	<u>STROBE</u>	<u>Extensions</u>
<u>Systematic reviews</u>	PRISMA	<u>Extensions</u>
<u>Study protocols</u>	<u>SPIRIT</u>	PRISMA-P
Patient-Reported Outcomes (PROs)	SPIRIT PRO	CONSORT PRO
Diagnostic/prognostic studies	<u>STARD</u>	TRIPOD
<u>Case reports</u>	<u>CARE</u>	<u>Extensions</u>

Clinical practice guidelines	AGREE	RIGHT
<u>Qualitative research</u>	<u>SRQR</u>	COREQ
Quality improvement studies	<u>SQUIRE</u>	

### Patient involvement in research

- <u>How to write a good lay summary</u>
- The <u>NCRI Consumer Forum</u>, an expert group of patients and carers and others affected by cancer, host a <u>Dragon's Den Workshop</u> during the year, where researchers can received feedback on their studies.
- Please see <u>UK Standards for Public Involvement</u> developed by NIHR INVOLVE and Health and Care Research Wales for researchers which provides clear, concise benchmarks for effective public involvement.

### Radiotherapy

- Radiotherapy Quality Assurance Service Support Costs Guidance
- <u>The Radiotherapy Protocol checklist</u>
- Radiotherapy clinical trials roles and responsibilities RTTQA and CTUs

### **SPIRIT** initiative

The <u>SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials)</u> <u>Statement</u> provides evidence based recommendations for the minimum content of clinical trials protocols to address the variability in the quality and content. Links to guidance on Patient Reported Outcomes and pathology in Clinical Trials are provided below:

- International Consensus Guidance on the Inclusion of Patient-Reported Outcomes
  (PROs) in clinical trials protocols: <u>SPIRIT PRO: Extension</u>
- International Consensus Guidance on the inclusion of pathology in clinical trials: <u>SPIRIT-Path Guidance</u>

#### Contact us

The NCRI Research Groups are made up of clinicians, scientists and consumers (patient, carers and others affected by cancer) amongst many others. If you are interested in receiving support for your study, please contact us on <u>proposal.guidance@ncri.org.uk</u> and we will put you in touch with our researchers to see if they could help with your study. Please note, our members work with us in a voluntary capacity and their ability to provide advice and support will depend on time they have available.