University College London Hospitals NHS
NHS Foundation Trust

COMPANION STUDY POLICY
FOR
NIHR PROGRAMME GRANT RP-PG-1209-10013
BRIGHTLIGHT

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Contents

Glossary of terms

2012 TYA Cancer Cohort:
Generic name of the participants in BRIGHTLIGHT

2012 TYA Carers:
Carers who have participated in wave 1 of the survey, who were nominated by young people as being their main carers

BRIGHTLIGHT:
Name of the NIHR programme grant ref RP-PG-1209-10013

BRIGHTLIGHT Survey:
Name of the outcome measure used in BRIGHTLIGHT

Introduction

1.1 BRIGHTLIGHT is a 5-year National Institute for Health Research (NIHR) funded programme grant spanning four workstreams[1]. The primary aim of BRIGHTLIGHT is to evaluate cancer services for young people aged 13 – 24 years diagnosed with cancer. This companion study policy applies to all proposed studies that involve the 2012 TYA Cancer Cohort in research not included in the BRIGHTLIGHT protocol, requiring consent to be obtained through the BRIGHTLIGHT Office[2]. Companion studies accessing carers will also require assistance from the BRIGHTLIGHT Office to gain consent and therefore studies including 2012 TYA Carers are also included in this policy.

1.2 The primary purpose of the Companion Study Policy is to facilitate high quality, related research with the 2012 TYA Cancer Cohort without over burdening cohort participants. The Companion Study Policy **does not** relate to the use of previously collected data. Applicants wishing to use data collected through the BRIGHTLIGHT Survey need to refer to the Data Sharing Policy (protocol in development).

Information about BRIGHTLIGHT

2.1 BRIGHTLIGHT aims to recruit 2012 young people diagnosed with cancer after July 2012. Young people are recruited from over 100 acute NHS Trusts in England (Appendix 1 for a list of recruiting Trusts and Principal Investigators) within 4 months of diagnosis. Data are collected through a bespoke questionnaire, the BRIGHTLIGHT Survey, which has been designed with young people to describe their experience of cancer care and life as a young person (see www.brightlightstudy.com for more details about the survey). The first survey is completed 5 months after diagnosis by interviewers employed by Ipsos MORI, then either on-line or through telephone interview at 12, 18, 24 and 36 months after diagnosis. A full copy of the protocol is available to download from the website http://www.brightlightstudy.com/healthcare-professionals/study-documents.aspx

[1] Workstream 1 comprises a Delphi survey to define professional competencies; a case study of multiple cancer units to explore the culture of care; and a study to validate a bespoke metric categorising three levels of care. Workstream 2 and 3 are based on data collected in a cohort study of 2,012 young people diagnosed with cancer between July 2012 and December 2014 (www.brightlightstudy.com). Workstream 4 comprises a working party to develop service changes and pilot interventions based on data collected through Workstreams 1, 2 and 3.

[2] Young people can participate in whatever research is available through their NHS organisations; this policy applies only to any work requiring direct approach from the BRIGHTLIGHT Office team.

Management of BRIGHTLIGHT

3.1 BRIGHTLIGHT is collaboration between professionals working in the NHS, academia, National Cancer Research Institute (NCRI) and North West Knowledge Intelligence Team (NW KIT, formerly known as the North West Cancer Intelligence Service, NWCIS). See Appendix 2 for details of the Executive Team. The BRIGHTLIGHT Office is based in the Cancer Clinical Trials Unit at University College London Hospitals NHS Foundation Trust. Contact details of the team are detailed on page 1 of this policy.

3.2 The Steering Committee is the independent body overseeing the conduct of BRIGHTLIGHT (Appendix 3). Their role includes monitoring the scientific and ethical conduct of BRIGHTLIGHT, reviewing the quality of dissemination and ensuring evidence is either implemented in practice or goes toward policy development. All studies approved as a companion study will be monitored and discussed by the Steering Committee and therefore regular reports will need to be submitted.

Method of accessing the Cohort

4.1 The following mechanism is suggested as the way in which the Cohort is accessed and consent is obtained. This mechanism has been previously approved by London-Bloomsbury Research Ethics Committee (study reference 11/LO/1718) for an earlier study. This can be cited directly as written:

4.2 *Participants will be identified by the BRIGHTLIGHT Office team [based on study criteria]. Only young people who have consented to be contacted about another study will be selected. Participants will be contacted by a member of the BRIGHTLIGHT Office team to ask if they are interested in taking part in a study looking at [summary of what the study looks at]. Those who express interest will be sent study information and will be asked to contact the research team if they wish to take part. The information pack will include a stamped address envelope, email addresses and telephone number for the research team. Young people will be contacted a week after the information pack has been sent by the BRIGHTLIGHT Office team to ensure they have received it. Consent forms will be returned to the BRIGHTLIGHT Office, follow-up letters will be sent on two occasions to young people who have not returned a consent form. Consent forms will be sent to the research team on a weekly basis.*

4.3 Alternative suggestions for recruitment and gaining consent will be considered but applicants are asked to carefully consider burden not just for the Cohort but also for the BRIGHTLIGHT Office team who will be your bridge to the Cohort.

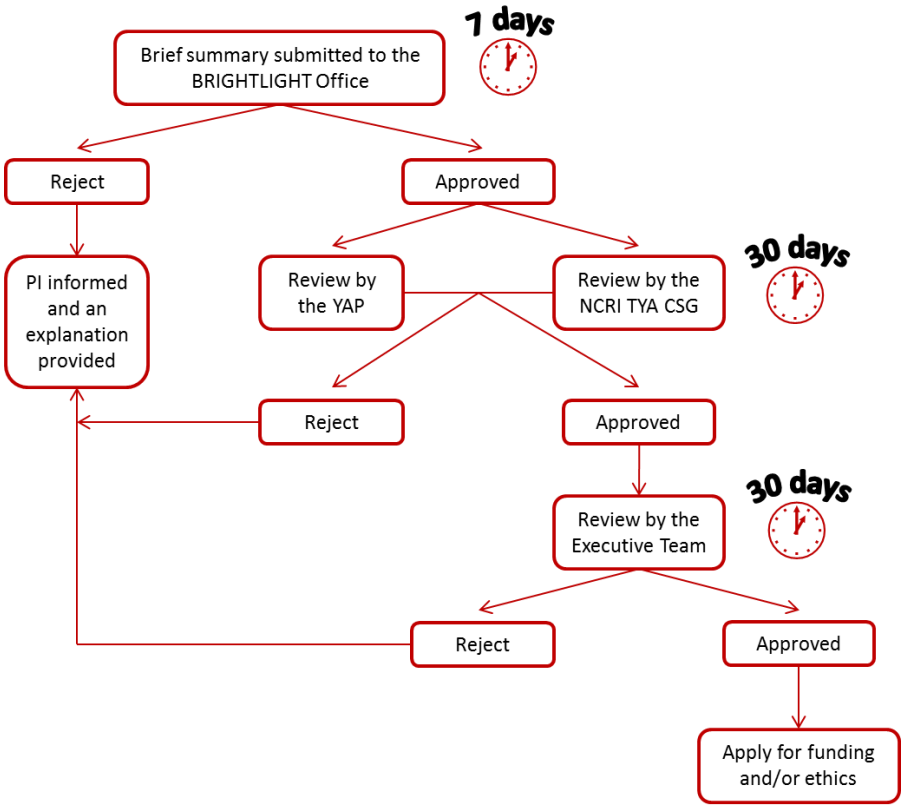
Cost of accessing the Cohort

5.1 For the standard method outlined in section 4.2, there will be an administration fee of **£30 per participant**. This is to cover the cost of identifying suitable young people, time required to contact them about the study and time required to gain consent. Consideration of circumstances under which this fee can be waived must be discussed with the Chief Investigator or Senior Research Manager prior to submitting a proposal.

Submitting a proposal

6.1 The process for gaining approval for a companion study is summarised in Figure 1.

Figure 1: Flow chart of the review process and timelines for gaining approval for a companion study involving the 2012 TYA Cancer Cohort



Step 1: review by the BRIGHTLIGHT Study Office

A brief summary of the proposed study needs to be sent to the BRIGHTLIGHT Office (Appendix 4; Brightlight@uclh.nhs.uk). The brief summary will be reviewed at the monthly team meeting[3] and will be assessed on the following criteria:

- Conflict with other companion studies;
- Conforms to ethical guidelines;
- Number of young people required;
- Mechanism of gaining consent (if different from section 4.2);
- Potential benefit to patients;
- Whether the applicant is from a recruiting Trust (applications from teams that are recruiting to BRIGHTLIGHT will be prioritised);
- Source of funding (priority will be given to studies being submitted for funding).

This will be reviewed at the monthly team meeting on the first Thursday of the month (except August where there is no meeting). The Principal Investigator will be informed of the outcome within 7 days of this meeting. If it has not been approved, a detailed explanation will be provided.

Step 2: review by the NCRI TYA CSG

The brief summary needs to be submitted to the NCRI Teenage and Young adult Clinical Studies Group (TYA CSG). The application will be reviewed in accordance to the protocols of the NCRI CSG. This review will provide independent peer review of the scientific quality of the study.

Step 3: review by the Young Advisory Panel (YAP)

This step runs concurrently with step 2. Although the CSG has a Core Consumer Group comprising of two young people, who review all proposals, the YAP works with BRIGHTLIGHT and the Cohort in all aspects of study management. They are therefore able to gauge what studies are and are not acceptable to the Cohort.

Step 4: review by the BRIGHTLIGHT Executive Team

After reports from each aspect of the review process, a minimum of 5 members of the Executive Team will make the final decision. Researchers are then able to make an application for funding and make necessary regulatory applications (all proposals will require independent NHS Research Ethics Committee (REC) approval). All documentation through the review will be available to applicants applying for funding to submit in support of the application.

[3] If there is no team meeting scheduled, the summary will be reviewed by a minimum of two members of the BRIGHTLIGHT Office (to include at least the Chief Investigator and Senior Research Manager).

Conduct of companion studies

7.1 As data is still being collected on the Cohort as part of BRIGHTLIGHT, young people identified to participate in companion studies will be those who have either taken part or are expected to take part in another wave of data collection within the next 2 months. This is to ensure participation in other studies does not impact on retention into BRIGHTLIGHT.

7.2 All principal investigators conducting studies approved as companion studies to BRIGHTLIGHT must guarantee that all contact and data collection with cohort members is within a time period agreed with the BRIGHTLIGHT Office (usually within 3 months of gaining consent but will vary depending on the inclusion/exclusion criteria of the study).

Companion study monitoring

8.1 All studies approved through the Companion Study Policy will need to submit the REC annual report to the BRIGHTLIGHT Steering Committee. The Chair of the Steering Committee may request the Principal Investigator provide more details or attend the next Steering Committee meeting.

8.2 When the study is complete a copy of the REC end of study declaration form needs to be submitted to the BRIGHTLIGHT Office along with the final report.

8.3 All publications, abstracts and conference presentations need to be submitted to the BRIGHTLIGHT Office so they can submit them to the NIHR.

Standard disclaimers

9.1 Participants in the 2012 TYA Cancer Cohort were recruited into an NIHR funded project and therefore all outputs from BRIGHTLIGHT companion studies must include the following acknowledgement and disclaimers should be used:

9.2 ‘This paper/abstract/presentation/poster***** involves the cohort of young people recruited into NIHR study reference RP-PG-1209-10013. The views expressed are those of the author(s) and not necessarily those of BRIGHTLIGHT, the NHS, the NIHR or the Department of Health.’ (*delete as appropriate)

9.3 ‘Young people were recruited with the assistance of the BRIGHTLIGHT Office team.’

Appendix 1: Trusts recruiting to BRIGHTLIGHT

Acute Trust	PI name
Aintree University Hospitals NHS Foundation Trust	Dr Jeffery Smith
Airedale NHS Trust	Dr Ann Cuthbert
Alder Hey Children's NHS Foundation Trust	Dr Barry Pizer
Barking, Havering and Redbridge Hospitals NHS Trust	Dr Claire Hemmaway
Barnet and Chase Farm Hospitals NHS Trust	Anita Amadi
Barnsley Hospital NHS Foundation Trust	Keith Elliot
Barts Health NHS Trust	Professor Jamie Cavenagh
Birmingham Children's Hospital NHS Trust	Dr David Hobin
Blackpool, Fylde and Wyre Hospitals NHS Trust	Leanne Smith
Bolton NHS Foundation Trust	Shirley Cocks
Bradford Teaching Hospitals NHS Foundation Trust	Victoria Drew
Brighton and Sussex University Hospitals NHS Trust	Dr Catherine Wynne
Buckinghamshire Hospitals NHS Trust	Dr Nick Bates
Calderdale and Huddersfield NHS Foundation Trust	Dr Jo Dent
Cambridge University Hospitals NHS Foundation Trust	Dr Helen Hatcher
Central Manchester and Manchester Children's University Hospitals NHs Trust	Elizabeth Pask
Chelsea and Westminster Hospital NHS Trust	Professor Mark Bower
Chesterfield Royal Hospital NHS Foundation Trust	Dr Justin Cooke
Christie Hospital NHS Trust	Rachel Campsey
City Hospitals Sunderland NHS Foundation Trust	Dr Scott Marshall
Clatterbridge Centre for Oncology NHS Foundation Trust	Dr Nasim Ali
Colchester Hospital University NHS Trust	Lorna Dewar
Croydon Health Services NHS Trust	Dr Nnenna Osuji
Dartford & Gravesham	Mr Seshadri Sriprsad
Derby Hospitals NHS Foundation Trust	Dr David Allotey
Dorset County Hospital NHS Foundation Trust	Dr Phil Wylie
East and North Hertfordshire NHS Trust	Heather Philips
East Lancashire Hospitals NHS Trust	Susan Ashworth

Acute Trust	PI name
East Sussex Hospitals NHS Trust	Dr Satyajit Sahu
George Eliot Hospital NHS Trust	Dr Mekkali Narayanan
Gloucestershire Hospitals NHS Foundation Trust	Dr Asha Johny
Great Western Hospitals NHS Foundation Trust	Sr Nicola Cowling
Guy's and St Thomas' NHS Foundation Trust	Dr Robert Carr
Hampshire Hospitals NHS Foundation Trust	Dr Alison Milne
Harrogate and District NHS Foundation Trust	Dr Claire J Hall
Heart of England NHS Foundation Trust	Dr Shankara Paneesha
Hull and East Yorkshire Hospitals NHS Trust	Dr James Bailey
Imperial Healthcare NHS Trust	Dr Izbel Yusuf
Ipswich Hospital NHS Foundation Trust	Chris Garlick
Isle of Wight Healthcare NHS Trust	Alison Brown
James Paget University Hospitals NHS Foundation Trust	Dr Richard Stock
Lancashire Teaching Hospitals NHS Foundation Trust	Carolyn Hatch
Leeds Teaching Hospitals NHS Trust	Dr Dan Stark
Liverpool Women's Hospital NHs Foundation Trust	Dr Bridget DeCruze
Medway NHS Foundation Trust	Dr Vivienne Andrews
Mid Essex Hospital Services NHS Trust	Dawn Beaumont-Jewell
Mid Staffordshire General Hospitals NHS Trust	Dr Paul Revell
Mid Yorkshire Hospitals NHS Trust	Dr David Wright
Milton Keynes Hospital NHS Foundation Trust	Sara Greig
Norfolk and Norwich University Hospital NHS Trust	Dr Jennifer Wimperis
North Bristol NHS Trust	Suriya Kirkpatrick
North Cumbria University Hospitals NHS Trust	Dr Jonathan Nicoll
North Tees and Hartlepool NHS Trust	Dr Philip Mounter
Northampton General Hospital NHS Trust	Dr Angela Bowen
Nottingham University Hospitals NHS Trust	Dr Ivo Hennig
Oxford Radcliffe Hospital NHS Trust	Karen Sherborne
Pennine Acute Hospitals NHS Trust	Richard Jones

Acute Trust	PI name
Plymouth Hospitals NHS Trust	Clare Turner
Poole Hospital NHS Trust	Dr Fergus Jack
Portsmouth Hospitals NHS Trust	Dr Ann O'Callaghan
Royal Berkshire Hospital NHS Foundation Trust	Dr Helen O'Donnell
Royal Cornwall Hospitals NHS Trust	Sue Derbyshire
Royal Devon and Exeter NHS Foundation Trust	Dr Corinne Hayes
Royal Free Hampstead NHS Trust	Angela McCadden
Royal Liverpool and Broadgreen University Hospitals NHS Trust	Dr Nagesh Kalakonda
Royal National Orthopaedic Hospital	Julie Woodford
Royal Surrey County Hospital NHS Trust	Claire Palles Clark
Royal United Hospital Bath NHS Trust	Chris Cox
Salford Royal NHS Foundation Trust	Helen Farrell
Salisbury NHS Foundation Trust	Dr Jonathan Cullis
Sandwell and West Birmingham Hospitals NHS Trust	Dr Nigel Trudgill
Sheffield Children's NHS Foundation Trust	Dr Daniel Yeomanson
Sheffield Teaching Hospitals NHS Foundation Trust	Ruth Logan
Shrewsbury and Telford Hospital NHS Trust	Helen Moore
South Devon Healthcare NHS Trust	Dr Deborah Turner
South London Healthcare NHS Trust	Dr Ildiko Schuller
South Tees Hospitals NHS Trust	Dr Dianne Plews
South Warwickshire General Hospitals NHS Trust	Dr Peter Rose
Southampton University Hospitals NHS Trust	Louise Hooker
Southend University Hospital NHS Foundation Trust	Juliah Jonasi
St George's Healthcare NHS Trust	Dr Jens Samol
St Helens and Knowsley Hospitals NHS Trust	Dr Maged Gharib
Surrey & Sussex Healthcare NHS Trust	Dr Kamal Khoobarry
Taunton and Somerset NHS Trust	Dr Belinda Austen
The Dudley Group of Hospitals NHS Foundation Trust	Angela Watts
The Newcastle-upon-Tyne Hospitals NHS Foundation Trust	Dr Emma Lethbridge

Acute Trust	PI name
The Princess Alexandra Hospital NHS Trust	Joanne Kellaway
The Royal Marsden NHS Foundation Trust	Louise Soanes
The Royal Orthopaedic Hospital NHS Trust	Claudette Jones
The Royal Wolverhampton Hospitals NHS Trust	Dr Supratik Basu
University College London Hospitals NHS Foundation Trust	Professor Jeremy Whelan
University Hospital Birmingham NHS Foundation Trust	Dr Vijay Agarwal
University Hospital Bristol NHS Foundation Trust	Dr Alison Cameron
University Hospitals Coventry and Warwickshire NHS Trust	Dr Beth Harrison
University Hospitals of Leicester NHS Trust	Dr Fiona Miall
University Hospitals of Morecambe Bay NHS Trust	Gail Wiley
University Hospitals of South Manchester NHS Foundation Trust	Lesley Howard
Walsall Hospitals NHS Trust	Lynda Wagstaff
Walton Centre for Neurology and Neurosurgery NHS Trust	Mr Michael Jenkinson
West Hertfordshire Hospitals NHS Trust	Fiona Smith
Western Sussex NHS Trust	Sarah Janes Dr Jonathan Rabbs
Weston Area Health NHS Trust	Dr Serena Hillman
Wirral Hospital NHS Trust	Dr Ranjit Dasgupta
Worcestershire Acute Hospitals NHS Trust	Jayne Tyler Dr Shamilla Sothi
Wye Valley NHS Trust	Rachel Lowe
Yeovil District Hospital NHS Foundation Trust	Dr Christopher Zaborowski
York Hospitals NHS Trust	Dr Lee Bond

Appendix 2: Executive Research Team

University College London Hospitals NHS Foundation Trust:

- Professor Jeremy Whelan (Chief Investigator, Workstream 2 lead)
- Dr Rachel Taylor (Senior Research Manager)
- Susie Pearce

TYA Commissioning lead

- Claire Foreman

University College London:

- Dr Julie Barber
- Professor Steve Morris (Workstream 3 lead)
- Professor Rosalind Raine

University of Leeds:

- Dr Richard Feltbower

St James' University Hospital

- Dr Dan Stark

Cancer Research UK

- Dr Lorna Fern (PPI lead)

London South Bank University & Great Ormond Street Hospital for children

- Professor Faith Gibson (Workstream 1 lead)

Southampton University Hospital NHS Foundation Trust

- Louise Hooker

North West Cancer Intelligence Service

- Dr Tony Moran

NCRI Clinical Studies Group TYA Core Consumer Group:

- Hannah Millington

Appendix 3: Steering Committee members

Chair:
Dr William Van't Hoff
LRN Director, Somers Clinical Research Facility, Great Ormond Street Hospital for Children NHS Foundation Trust

Members:
Lisa Calderwood
Senior Survey Manager, Institute of Education

Dr Zoe Coombe
NIHR Cancer Research Network Manager, Greater Manchester and Cheshire Cancer Research Network

Laura Clarke
Teenage Cancer Trust

Dr Meriel Jenney
Paediatric Oncologist, Children's Hospital for Wales, Cardiff

Jocelyn Walters
NIHR Cancer Research Network Manager, Central South Coast Cancer Research Network

Appendix 4: companion study application

Principal investigator
Name
Designation
Affiliation
Email
Telephone

Project duration
Start date:
End date:

Study aim:

Summary of study design and outcome measures (maximum 150 words)

Details of the sample
Number
Inclusion criteria
Exclusion criteria

Is the standard consent being used?
Yes
No – please provide details of recruitment and consent process

Is funding being sought?
Yes – please state where
No

Are you paying the administration fee?
Yes
No – please state who the waver agreement was discussed with

BRIGHTLIGHT Study Office use only

1.	Conflict with other companion studies	Yes	No
2.	Obvious ethical issues	Yes	No
3.	Number of participants acceptable	Yes	No
4.	Administration fee approved	Yes	No
5.	Mechanism of gaining consent acceptable	Yes	No
6.	Potential benefit to patients	Yes	No
7.	From a recruiting Trust	Yes	No

Approved
Yes
No (details below)

Signed
Date