

# Award Management and Funding Policy Guide



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# 1. Cancer Grand Challenges overview

Cancer Grand Challenges is a global research initiative that is building an elite, interdisciplinary community to tackle cancer's most complex problems.

Co-founded in 2020 by the two largest funders of cancer research in the world, Cancer Research UK and the National Cancer Institute in the US, it aims to accelerate high-impact research and translate discoveries for public and patient benefit through global team science.

#### 1.1. Cancer Grand Challenges funding model

Eligible teams must be international in composition, with investigators based at multiple research locations contributing to the programme.

Funding decisions for Cancer Grand Challenges awards are coordinated via a Joint Steering Committee (JSC) which is made up of NCI and CRUK leadership.

Each Host Institution (HI) belonging to a Cancer Grand Challenges team will receive funds directly from the Funders. Funding commitments will be issued annually, subject to successful Annual Review (see section 2.2 below), in the form of both a CRUK Grant Award Letter (GAL) and an NCI Notice of Award (NoA).

Generally, CRUK and NCI will each fund approximately 50% of the direct costs of research awarded to each HI over the full lifetime of the award. Any indirect costs awarded will also be included in the GAL and NoA in accordance with the funding principles outlined in section 3.1 below.

#### 1.1.1. Cancer Grand Challenges Award Management and Funding Policy Guide

This document is a guide to the management of all Cancer Grand Challenges awards co-funded by CRUK and NCI, and includes policies relevant to their funding. Teams must manage their CRUK and NCI funds according to the requirements set out in this guide. This guide should be read in conjunction with the following:

- The Cancer Grand Challenges Award Agreement (CGC Award Agreement) (see section 1.1.2);
- The CRUK Grant Award Letter (GAL) (see section 1.1.4);
- The NCI Notice of Award (NoA) (see section 1.1.5);
- The NCI Cancer Grand Challenges OT Policy Guide (see section 1.1.3);
- The Cancer Grand Challenges Commercialisation Policy.

CRUK and NCI may amend the content of this guide from time to time. It is the responsibility of the Team Lead to ensure that each HI is aware of changes to the guide so that HIs can maintain compliance (see



section 1.1.2 below). The Funders will make every effort to inform TLs and all Co-Investigators (Co-Is – see section 1.2.1 below) directly of any policy changes.

Unless otherwise defined in this Award Management and Funding Policy Guide, capitalised terms used in this Award Management and Funding Policy Guide will have the same meaning as they do in the CGC Award Agreement.

If you require assistance in understanding these documents, please contact your Cancer Grand Challenges operations officer (see section 1.2.3 below).

#### 1.1.2. Cancer Grand Challenges Award Agreement

All Host Institutions (HI – see section 1.2.2 below) will enter into a Cancer Grand Challenges Award Agreement (CGC Award Agreement) with CRUK and NCI.

The CGC Award Agreement, in combination with 1) this guide, 2) the NCI Cancer Grand Challenges <u>OT Policy</u> <u>Guide</u>, and 3) the Cancer Grand Challenges <u>Commercialisation Policy</u>, set out the contractual arrangements for managing Cancer Grand Challenges teams. His should note that the CGC Award Agreement specifically incorporates by reference the three documents enumerated in this paragraph.

The NCI NoAs and the CGC Award Agreement, referencing this guide, form the formal funding contract between NCI and each funded HI within a team.

The CRUK GALs and the CGC Award Agreement, referencing this guide, form the formal funding contract between CRUK and each funded HI.

#### 1.1.3. NCI Cancer Grand Challenges OT Policy Guide

NCI will issue CGC awards to HIs using the NIH Other Transaction (OT) Authority, granted under Section 402(n) of the Public Health Service Act. The terms and conditions that apply to the use of NCI OT funds appear in the NoA, the CGC Award Agreement and the NCI Cancer Grand Challenges OT Policy Guide.

#### 1.1.4. CRUK Grant Award Letter

For CRUK funding, the GAL is the legal document issued to notify an awardee that an award has been made, subject to its terms and conditions. After the CGC Award Agreement (see section 1.1.2 above) has been signed, an initial GAL will be issued to each participating HI, usually covering the first 12 months of the award. Subsequent GALs will then be issued annually, subject to successful Annual Review (see section 2.2.1 below).



CRUK will send the GAL via email to a named investigator at each HI, as well as the HI Administrator (see 1.2.2 below).

#### 1.1.5. NCI Notice of Award

For NCI funding, after the CGC Award Agreement has been signed, an initial NoA will be issued to each participating HI, usually covering the first 12 months of the award. NCI will notify the HI via email when an award has been issued. NCI will thereafter issue subsequent NoAs, usually on an annual basis, subject to successful Annual Review (see section 2.2.1 below). In general, if there is a change to the terms and conditions for an HI, NCI will issue a revised NoA. After informing CRUK, NCI reserves the right to act independently to modify the terms and conditions of award in the NoA or CGC Award Agreement as needed. If necessary, a change to the terms and conditions for each HI on a CGC Team may also require revisions to the CGC Award Agreement.

#### 1.1.6. Summary of CRUK Grant Award Letters and NCI Notices of Award

When a new set of GALs and NoAs have been issued, CRUK, in consultation with NCI, will provide the TL (see section 1.2.1 below) of each Cancer Grand Challenges team with a full summary of the funding issued by both CRUK and NCI to each participating HI in their team.



#### 1.2. Roles and responsibilities

Once a team has been recommended for Cancer Grand Challenges funding, a meeting will be set up to introduce team members to relevant contacts at CRUK and NCI.

Although there will be various people from both organisations involved in supporting Cancer Grand Challenges teams, CRUK will provide a main scientific contact (research portfolio manager or lead) and a main operational contact (operations officer) to act as the first points of contact for all general queries. See section 1.2.3 below for more information on these roles.

#### 1.2.1. Roles and responsibilities (funded teams)

Funded teams must comprise a TL; multiple Co-Is; patient advocate(s); and a full-time Programme Manager (PM). Teams must be international in nature, with no more than 70% of the activity (and funding) based in a single country.

Role	Description
Team Lead (TL)	The TL is the person responsible for the overall scientific and technical direction of the team. The TL, in coordination with the assigned staff at each HI, must ensure that team members manage their funding as set out in this guide, in the CGC Award Agreement, and in other documents incorporated by reference into the CGC Award Agreement. The TL is the primary contact for Cancer Grand Challenges staff at both CRUK and NCI and should maintain regular communication with their assigned contact(s) at CRUK and NCI. The TL must be based at a research institution which is appropriately accredited or registered in the country in which it is based.
	The TL must spend a significant proportion of their research time (25% minimum effort) on the Cancer Grand Challenges award.
Co-Investigator (Co-I)	Co-Is provide significant intellectual input into the research, and lead or contribute to individual work packages. Each Co-I is responsible for the scientific and technical direction of their work package.
	Co-Is may be based at commercial entities, but requests for funding for commercial entities will be considered only for small and medium-sized enterprises (SMEs), and following case-by-case review. Both commercial entities and research institutions named on Cancer Grand Challenges awards must be appropriately accredited or registered in the country in which they are based.
	Co-Is must contribute at least 10% of their research time to the Cancer Grand Challenges award.
	One Co-I at each HI will be the named awardee on the CRUK GAL (see section 1.1.4 above) and NCI NOA (see section 1.1.5 above). For NCI award administration purposes, this Co-I will generally be the Program



Director/Principal Investigator (PD/PI), i.e. the individual designated by the HI to have the appropriate level of authority and responsibility to direct the project or programme to be supported by the Other Transaction award. NCI will recognise multiple PD/PIs with prior approval. See section 1.2 of the NCI Cancer Grand Challenges OT Policy Guide for additional details.

#### Patient Advocate

Teams must look for opportunities to involve advocates for people affected by cancer (patients, survivors, caregivers) in their research. Teams must recruit a team of Patient Advocates with clearly defined roles and remits. Patient Advocates bring the perspectives of those affected by cancer to the work of a Cancer Grand Challenges team. They represent people affected by cancer as a group and therefore should not just provide their individual viewpoint or that of any advocacy organisation. Patient Advocates work with the TL and Co-ls as a member of the team to develop the Patient Advocate involvement and engagement strategy into a detailed plan that will be delivered during the lifetime of the award.

#### Programme Manager

Funded teams are required to recruit a full-time Programme Manager to coordinate the research team, with responsibilities which could include, but are not limited to:

- Assisting the TL and Co-Is in monitoring and ensuring team compliance with CRUK and NCI award requirements;
- · Making sure that milestones are being met;
- Facilitating team communication, as well as communicating frequently and directly with leadership across participating HIs;
- Interfacing frequently with the Funders;
- Ensuring timely publication of findings, availability of high-quality data and proper Intellectual Property (IP) management;
- Preparing for Annual Reviews (see section 2.2 below) and meetings;
- Coordinating with, as well as ensuring information is disseminated to and collected from, relevant contacts (e.g. research, finance, technology transfer) at HIs.

Programme Managers should have relevant prior experience, e.g. previous experience managing large interdisciplinary and multi-institutional research efforts.



#### 1.2.2. Roles and responsibilities (Host Institutions)

The Funders require a named contact at each HI as follows. The same individual may fill the roles of HI Administrator and Authorized Organization Representative.

Role	Description
CRUK Host Institution (HI) Administrator	<ul> <li>HI Administrators are individuals at an HI with the authority to complete the following tasks on behalf of the HI:</li> <li>Approve grant applications;</li> <li>Accept grants and other forms of research awards;</li> <li>View GALs at the HI;</li> <li>Submit financial reconciliation forms;</li> <li>View remittance information.</li> </ul>
NCI Authorized Organization Representative (AOR)	AORs are the designated representatives of the HI in matters related to the administration of its Cancer Grand Challenges award. AORs are named by the applicant and authorised to act for the applicant and to assume the obligations imposed by US federal laws, regulations, requirements, and conditions that apply to Other Transactions, including the Cancer Grand Challenges award.

#### 1.2.3. Roles and responsibilities (CRUK)

In addition to its role as a funding partner in Cancer Grand Challenges, CRUK acts as the Operational Manager for the initiative, collaborating closely with NCI. Therefore, most of an HI's day-to-day interactions with the Funders (other than those related to the specific administration of NCI funds) will be managed in the first instance by CRUK.

Role	Description		
Research portfolio manager or lead	The Cancer Grand Challenges research team at CRUK is responsible for providing scientific support and oversight of Cancer Grand Challenges teams on behalf of CRUK. Each team will be assigned a research portfolio manager or lead who will be the primary contact for teams for all updates and queries regarding the scientific direction of the team. This could include:		
	<ul> <li>Receiving updates on forthcoming publications and other Research Outputs;</li> <li>Receiving updates on changes to, or advances in, workstreams;</li> <li>Attending funded teams' scientific symposia (see section 2.5 below) and in-person Management Group meetings (see section 2.3 below);</li> <li>Minuting Annual Review interviews (see section 2.2 below) and providing written feedback;</li> </ul>		



	<ul> <li>Facilitating and coordinating inter-team collaborations and opportunities;</li> <li>Connecting teams to other CRUK functions, including the Cancer Research Horizons Search and Evaluation Team and Cancer Grand Challenges Communications and Philanthropy teams.</li> </ul>		
Operations officer	<ul> <li>The Cancer Grand Challenges operations team supports teams with any non-scientific matters. The operations officer will coordinate with appropriate colleagues within CRUK and NCI to: <ul> <li>Oversee the financial management of the awards, and answer queries specific to CRUK funding;</li> <li>Administer the CRUK component of Cancer Grand Challenges awards;</li> <li>Communicate with teams about, and support with, funding policies;</li> <li>Handle any contractual issues, i.e. questions related to the Cancer Grand Challenges Award Agreement (see section 1.1.1 above);</li> <li>Liaise with teams' Programme Managers (PMs – see section 1.2.1 above) to schedule funded teams' scientific symposia (see section 2.5 below) and in-person Management Group meetings (see section 2.3 below);</li> <li>Liaise with HIs.</li> </ul> </li> </ul>		
Cancer Research Horizons search and evaluation team	The Cancer Research Horizons search and evaluation team works to develop and commercialise discoveries from Cancer Grand Challenges teams. The team will work with funded teams to ensure the translation of Cancer Grand Challenges research for patient benefit, and to support with any matters related to Intellectual Property (IP) and commercialisation.		
Cancer Grand Challenges communications team	The Cancer Grand Challenges Communications Team works on behalf of both CRUK and NCI to support funded teams to ensure the Results of their research achieve public recognition. They also work to secure appropriate acknowledgement for the Cancer Grand Challenges initiative in press coverage and other communications. See section 3.3.5 below for more details.		
Cancer Grand Challenges Scientific Committee	<ul> <li>The Cancer Grand Challenges Scientific Committee reports to CRUK. Its role is to:</li> <li>Recommend to CRUK the challenges to be set;</li> <li>Recommend to CRUK teams to be funded;</li> <li>Contribute to the Annual Reviews of funded teams.</li> <li>The committee draws on the expertise of world-leading experts in and beyond the cancer field.</li> </ul>		
Cancer Grand Challenges Advocacy Panel	The Advocacy Panel is composed of individuals who have been affected by cancer. It advises and supports teams as they develop and execute their plans for patient advocate involvement and engagement.		



#### 1.2.4. Roles and responsibilities (NCI)

The following are the major functions and areas of responsibility of NCI staff.

Role	Description
Other Transactions Agreement Officer (OTAO)	<ul> <li>The OTAO, whose name appears on the NoA, is the individual responsible for the administrative aspects of NCI funding under the Cancer Grand Challenges award. This includes:</li> <li>Receiving and acting on requests for NCI approval for changes to the NoA, such as significant budget virements as set out in section</li> </ul>
	<ul> <li>2.1.5 below;</li> <li>Monitoring expenditure, including by reviewing milestones, progress reports (see section 2.2 below) and audit reports.</li> </ul>
	The OTAO is the only US federal employee who has signatory authority for Other Transactions awards and the only NCI individual who can authorise funding or changes to the terms and conditions of an award.
Other Transactions Agreement Specialist (OTAS)	The OTAS is a federal employee delegated responsibility by the OTAO and is assigned the day-to-day review and management of Other Transactions applications and awards.
Other Transactions Program Official (OTPO)	The OTPO, whose name appears on the NoA, is the federal employee responsible for the programmatic, technical and/or scientific management aspects of the Other Transactions award. The OTPO is responsible for providing scientific support and oversight of Cancer Grand Challenges teams on behalf of NCI. Each team will be assigned an OTPO who will be the NCI contact for all updates and queries regarding the scientific direction of the team. This could include:
	<ul> <li>Receiving updates on forthcoming publications and other Research Outputs;</li> <li>Receiving updates on changes to, or advances in, workstreams;</li> <li>Attending funded teams' scientific symposia (see section 2.5 below) and in-person Management Group meetings (see section 2.3 below);</li> <li>Facilitating inter-team collaboration opportunities.</li> </ul>
Program Coordinator	The Program Coordinator is a federal employee who works on the Cancer Grand Challenges initiative and assists the OTPO in their oversight of selected Cancer Grand Challenges teams. The Program Coordinator activities could include:
	<ul> <li>Attending funded teams' scientific symposia (see section 2.5 below) and in-person Management Group meetings (see section 2.3 below);</li> <li>Facilitating inter-team collaborations and opportunities.</li> </ul>



# 2. Award management guide

#### 2.1. Financial management of Cancer Grand Challenges Award

The HI must ensure proper financial management of the Cancer Grand Challenges award as set out in this section. CRUK and NCI will award funds in parallel through their established processes, endeavouring to ensure each participating HI is able to start the award on the same date.

#### 2.1.1. Payment process (CRUK)

CRUK pays grant funds quarterly in arrears in pounds sterling (GBP) to the account nominated by the HI. The HI must therefore nominate a bank account that can accept payments in GBP. The payments each represent an equal 25% of the budget allocation to that HI for that year. In the final year of Cancer Grand Challenges funding, CRUK will not pay the final quarterly payment until it has processed the final reconciliation submitted as per section 2.2.6.

The HI must account for all income and expenditure related to the Cancer Grand Challenges award through a separate cost centre or, if it does not use cost centres, it must keep the Cancer Grand Challenges award in a separate bank account used exclusively for these funds.

#### 2.1.2. Payment process (NCI)

HIs will be able to draw down funding from the Department of Health and Human Services Payment Management System. Payments may be made by one of several advance payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis, as specified in Part II, section 4 of the NCI Cancer Grand Challenges OT Policy Guide.

#### 2.1.3. Budgeting

Cancer Grand Challenges teams are required, prior to the release of any funding, to submit a budget for the full duration of the award. This overarching budget must include a budget request for each participant HI for each year of the award. Teams are expected to provide a sufficient level of granularity to justify these budgets, including individual salary costs, running expenses and equipment purchases. The budget must comply with the cost principles outlined in section 3.1 below, and the year one budget will form the basis of the initial CRUK GAL (see section 1.1.4 above) and NCI NoA (see section 1.1.5 above) issued to each HI.

Cancer Grand Challenges awards are in principle approved for support in their entirety at the outset of the award but are funded on an annual basis, subject to successful Annual Review.

The GAL and/or NoA may reference the anticipated total award period and/or anticipated levels of future support, but there is no guarantee of further support until a future GAL and NoA is issued.



#### 2.1.4. Discretionary fund

Teams must leave at least 10% of their overall budget unallocated as a 'discretionary fund' to support emerging lines of scientific investigation in outer years of the award, not anticipated at time of application. This should be included as a cost line in the finance schedule completed for the Team Lead's host institution, although the expenditure may end up being incurred by other participating institution(s). Use of the discretionary fund should be proposed as part of the team's annual review submissions over the lifetime of the award.

Annual reprofiling of budgets and allocation of the discretionary fund may not result in more than 70% of the Cancer Grand Challenges funding being distributed to institutions in one country.

#### 2.1.5. Budget transfers

Teams are generally expected to use their funds in line with the approved Research Proposal and budgets (see section 2.1.3 above) and/or changes approved through the Annual Review process (see section 2.2.3 below). However, in exceptional circumstances, teams may need to modify the use of funds between budget submissions and therefore CRUK and NCI will try to be as flexible as possible when teams make reasonable requests to repurpose their Cancer Grand Challenges funds.

For further information, TLs should contact their CRUK operations officer (see section 1.2.3 above). The following actions require written prior approval from CRUK and NCI:

- Changes that necessitate a substantial repurposing of funds (i.e. increasing expenditure against any budget line by GBP 25,000 or more, unless that change is less than 25% of the originally budgeted cost) or significant changes in the scope of the research (including use of human or animal subjects);
- Changes that would increase the proportion of the award used for indirect costs of research (see section 3.1 below; note such changes will not be considered by CRUK);
- Plans to recruit a subcontractor for work that requires an allocation of award funds.

Requests to make any of these changes should be made in the first instance to CRUK by the TL. CRUK will consult with NCI, and if CRUK and NCI approve the changes, NCI requires that a request be submitted from the Authorized Organizational Representative (see section 1.2.2 above) of any impacted HIs.

Other changes beyond those listed above, i.e. minor virements resulting in changes of less than GBP 25,000 (or changes of GBP 25,000 or more where this is less than 25% of the originally budgeted cost), do not require prior approval, as long as all costs comply with the cost principles outlined in section 3.1 below. If



in doubt, teams should contact their CRUK operations officer to discuss. The operations officer will coordinate with the appropriate NCI staff prior to providing a response.

#### 2.2. Reporting

Prior to the release of any subsequent CRUK GALs (see section 1.1.4 above) and/or NCI NoAs (see section 1.1.5 above), teams are required to participate in an Annual Review process which involves the submission of a written progress report and financial report (including a budget or budget updates for the next period of the award), and an interview with reviewers, including members of the Cancer Grand Challenges Scientific Committee (see section 1.2.3 above).

In addition to providing the Funders with a chance to understand a team's progress, the Annual Review is an important opportunity for external feedback and advice. Following the Annual Review, written feedback is provided in the form of key points raised by individual reviewers during the interview.

Teams will be notified of reporting requirements no less than three months before the deadline for the written submission. The outcome of the review (see section 2.2.4 below) will be communicated to teams as early as possible after the interview.

The written submission will include:

- Scientific progress report, according to section 2.2.1 below;
- Financial report, according to section 2.2.3 below;
- Patient advocate involvement and engagement report, for which instructions will be provided;
- Researchfish® outputs upload, according to section 2.2.2 below;
- Update on personnel, i.e. investigators, technicians, postdoctoral fellows, PhD students, etc.

In some circumstances, there may be different reporting deadlines for the various components of the written submission (e.g. the financial report may be requested after the scientific progress report and/or the interview).

It is the responsibility of the Programme Manager, accountable to the TL, to coordinate the drafting of the annual report, and all Co-ls should contribute.

Teams will be advised of the attendance requirements for their interview, which will always include the TL and Programme Manager, and generally involve up to seven Co-Is.

In addition, each HI is required to submit institution-level reports to NCI pursuant to the NCI Cancer Grand Challenges <u>OT Policy Guide</u> and NoA. See Part II, section 9 of the NCI Cancer Grand Challenges <u>OT Policy</u> Guide for more information.



#### 2.2.1. Scientific progress reports

The format of the scientific progress report is as follows. Teams will be advised of page counts for each section.

Section	Description
Part A: Research impact	Teams are asked to provide a brief overview of progress in their Cancer Grand Challenges programme to date. This should include up to 10 key research-related achievements from the past year and their impact. These can be included as bullet points.  Research impact and scientific progress will be used by the reviewers to assess the development of the programme and the research field. They may also be drawn upon in communication activity to support and promote the Cancer Grand Challenges initiative. The office will always work with teams to ensure accuracy when talking about research externally, but it should be made clear where information is sensitive/embargoed and should not be disclosed more widely.
Part B: Addressing the challenge	Teams are asked to provide an overview of how the work they are delivering will enable them to address the challenge as originally articulated by the Cancer Grand Challenges Scientific Committee. Teams should discuss how insights to date will be useful in the context of the challenge, and summarise ways in which the prospects of addressing the challenge have both increased and become more difficult. An update on risks to the programme, both those identified at the outset and previously unforeseen problems, should be included along with mitigation strategies.  Please include how the CGC model (interdisciplinary, global, team science) benefits the team's ability to address the challenge.
Part C: Scientific progress	This section should focus on work to date. For each work package, a summary is required of key research achievements/milestones met over the past year, demonstrating, where appropriate, the impact (or potential impact) of these achievements for the programme as a whole. Any key changes or any go/no-go decisions that were reached as part of the work package should be noted. This section should also describe any challenge encountered with specific work packages and how those challenges were (or will be) overcome. Teams may comment on any changes to the governance and leadership structure of the team. Please include the impact that an interdisciplinary team environment is having on your progress.  Please ensure all team leads and co-investigators are mentioned and it is clear which achievements/progress they have made by work package over the past year. Please see example below:  We made significant progress on (Investigator, Institution). This led to (Investigator, Institution) and this data is being analysed by (Investigator, Institution).  Any relevant data that helps support this narrative can be provided as an appendix document of up to five pages: it is also helpful for unpublished data to



	be included, to allow the reviewers to view it before the interview. This should be included in the submission as a separate file.
Part D: Future plans	<ul> <li>This section should focus on plans for the year ahead and, where applicable, beyond. The future scientific direction for each work package should be clearly described.</li> <li>Outline plans for how the research/activities will be progressed within the work package in the next year of funding. Information which should be provided includes: any key milestones; novel technologies/approaches that require further elaboration; a significant change of direction of work; vital collaborators and their roles etc.</li> <li>As in Part C, please ensure all team leads and co-investigators are mentioned and it is clear which plans they will work on next year by work package.</li> <li>Provide a top-level view of any work planned for subsequent years, including any key strategic decision points and go/no-go decisions for the programme in a table format.</li> <li>Teams should be clear about how all plans should relate to progressing against</li> </ul>
	the original challenge.
Part E: Challenges and feedback	Teams are welcome to provide feedback on the Cancer Grand Challenges initiative and on their experience to date as a funded team. Any challenges teams have faced in operating successfully across multiple institutions should be described.
Part F: Collaborations	<ul> <li>This section should be used by teams to provide a narrative description of any collaborations that have been established in the past year, as well as any currently under discussion. It is particularly helpful to discuss collaborations with other Cancer Grand Challenges teams.</li> <li>Please include information such as: <ul> <li>Number of active inter-team collaborations by year including technologies, data and sharing of best practices;</li> <li>Number of new collaborations established with non-CGC investigators (domestic and international) and/or industry in the challenge area;</li> <li>Number of publications resulting from collaborations outside of CGC in the challenge area.</li> </ul> </li> </ul>
	Teams should include any information related to challenges they have experienced setting up collaborations.
Part G: Publications	Teams are asked to provide a full list of publications resulting from Cancer Grand Challenges funding. This should include published, pending and submitted papers and be divided into separate sections for papers, book chapters, reviews, preprints and datasets.



#### 2.2.2. Output reporting

Teams are required to submit information on the Research Outputs, outcomes and impacts arising from their Cancer Grand Challenges funding via the <a href="Researchfish">Researchfish</a>® system.

A user guide for Researchfish® can be found <a href="here">here</a>. TLs should add PMs (see section 1.2.1 above) as delegates for the Cancer Grand Challenges award, as per pages 20-23 of the user guide. PMs can then add all relevant Research Outputs to the award as per pages 5-9. Once teams are happy that all relevant outputs have been collated, PMs should hit the 'Submit' button and then 'Download Award'. This will generate a document which should be included alongside other review documents.

All outputs attributable to Cancer Grand Challenges funding should be reported by the TL (or the PM as his/her delegate), even where he or she was not directly involved in the output (e.g. a paper arising from Cancer Grand Challenges funding on which the TL is not listed as an author).

Please ensure that the following outputs are included. The below is not an exhaustive list, and further examples can be found <a href="https://examples.com/here">here</a>.

- Publications;
- Number of invited talks to scientific conferences;
- Intellectual property (IP) and new patents arising from foreground IP;
- New available Cancer Grand Challenges tools and resources such as: databases, datasets, data repositories, animal models and model systems;
- Projects receiving follow-on funding from other sources (e.g. venture capital), and amount of funding
- Start-ups formed based on Cancer Grand Challenges research;
- New techniques, validations and interventions;
- Software tools and technologies arising from CGC research including information on whether it has been fully commercialised and/or broadly disseminated by other means;
- Cancer Research Horizons licensing agreements with commercial partners;
- Research awards and recognitions.

Output reporting via Researchfish® is required for the duration of the award and a minimum of three years after the award End Date.



#### 2.2.3. Financial reports

Teams have an annual opportunity to reprofile their budgets, identifying underspend and/or reallocating funding between investigators, HIs, work packages or specific costs.

Teams will be provided with a finance schedule containing their existing budget.

For each cost line, teams are asked to provide:

- The actual amount spent in all past years (in GBP for costs charged to the CRUK GAL and in USD for costs charged to the NCI NOA);
- A forecast for total spend in the current year (in GBP for costs charged to the CRUK GAL and in USD for costs charged to the NCI NOA);
- A budget for each future year (in GBP revised where necessary);
- A rationale for any revisions.

Institutions incurring costs in currencies other than those in which the awards were issued (GBP for the CRUK GAL; USD for the NCI NOA) may report using the exchange rate that was applied when they converted the GBP to local currency. Institutions may use their CGC funding to manage currency fluctuations and to absorb any downsides within their existing funding envelope. However, no further funding will be issued to account for financial exchange losses.

Teams do not need to specify which funder they expect to cover which future costs; or to include indirect costs in their finance schedules.

Use of the discretionary fund should be proposed as part of the team's annual review submissions over the lifetime of the award. Annual reprofiling of budgets and allocation of the discretionary fund may not result in more than 70% of the Cancer Grand Challenges funding being distributed to institutions in one country.

Each institution's budget should be broken down by year of award, under the following categories:

Category	Information required	
Personnel	<ul> <li>Name of staff member (or TBC if pending recruitment)</li> <li>Job title</li> <li>Basic salary</li> <li>% Full-Time Equivalent (FTE)</li> <li>Brief description of the role, and the work package(s) on which the individual will be working</li> </ul>	



Category	Information required
Lab consumables	<ul> <li>Description of consumables required for each staff member</li> <li>Justification for any request of more than £17,500 per full-time equivalent staff member</li> </ul>
Institutional (core) services	<ul> <li>Description of services required</li> <li>Short narrative justification with key calculations</li> </ul>
Clinical costs	Detailed description and justification
Animal costs	<ul> <li>Description and justification of costs, with key calculations including number of animals, cost per cage, husbandry, etc.</li> </ul>
Student fees	<ul> <li>Description of role and explanation of cost per student</li> </ul>
Equipment	<ul> <li>Description of purpose on the Cancer Grand Challenges award and justification for purchase</li> <li>A recent quote for any equipment purchase over £25,000</li> </ul>
Computing costs	<ul> <li>Justification for any costs of more than £2,000 per staff member</li> </ul>
Travel costs	<ul> <li>Justification for any costs of more than £2,500 per staff member per year</li> </ul>
Publication costs	<ul> <li>Justification for any costs of more than £10,000 per lab</li> </ul>
Patient advocacy costs	Description and justification of costs
Sub-awards	<ul> <li>Justification for requiring sub-award, detailed description of costs</li> </ul>
Other costs	As required



#### 2.2.4. Outcome of Annual Review

Following a successful Annual Review, CRUK and NCI will calculate the amount to be issued to each HI. This calculation involves:

Deducting any underspend forecast to be held by the end of the current year at each HI (an example
is provided for illustrative purposes in the following table);

A. Amount issued to HI to date	B. Amount forecast to be spent by HI by end of instalment	C. Forecast underspend by end of instalment (A-B)	next instalment	E. Amount to be issued for next instalment (D-C)
£1,000,000	£750,000	£250,000	£1,500,000	£1,250,000

- Agreeing the allocations to each HI which will be supported by CRUK and NCI respectively. Per section 1.1 above, this is typically a 50:50 split of the direct costs of research;
- Applying the agreed level of indirect costs to be supported by CRUK and NCI respectively, according
  to section 3.1 below. For clarity, in general, each funded HI will receive one GAL (see section 1.1.4
  above) and one NoA (see section 1.1.5 above) per year. Following approval of the team's budget for
  the forthcoming year, CRUK and NCI will provide the team and participating HI with details of which
  approved costs are to be provided by CRUK and NCI respectively.

This approach allows TLs to propose the use of funds in a dynamic manner, including through increased or decreased funding to individual team members, institutions or work packages annually, based on scientific progress and plans. This approach prevents HIs which are underspending for any reason from continuing to accrue excess funds.

In order to issue a NoA (see section 1.1.5 above), NCI will require that each HI submit a budget request directly to NCI. See Part II, section 9.3 of the NCI Cancer Grand Challenges OT Policy Guide for more information on this process.

If significant concerns are raised during the Annual Review process, CRUK and NCI will agree on a course of action, which could include:

- Revision of funding level;
- Additional reporting requirements;
- Suspension or termination (see section 2.4 below).



#### 2.2.5. Final scientific reporting

Within the 12 months prior to a team's End Date, CRUK and NCI will organise a final-year research retreat. This is intended to provide an opportunity to:

- Celebrate the progress and scientific output of the team;
- Reflect on the progress made to address the challenge the team was funded to address;
- Facilitate a final review of the team, to be conducted by Cancer Grand Challenges Scientific
   Committee members and external experts.

The final-year research retreat will include scientific sessions and a final review in which the team's work will be independently evaluated. The review will be conducted by an Expert Review Panel (ERP), comprising members of the CGC Scientific Committee as well as invited external reviewers.

In advance of the final-year research retreat, teams will be required to submit a Final Report. Teams will receive full guidance for the expected content and format of the report, but it will include a description of:

- The starting point of the challenge;
- An impact statement;
- · Key research achievements;
- A future view of the challenge area;
- Research outputs;
- Challenges and mitigations.

Following the final-year research retreat, CRUK and NCI will also work with teams to produce and publish publicly available reports and other content showcasing the achievements made over the lifetime of the Cancer Grand Challenges funding.

CRUK will set a budget for the final-year research retreat and work with the programme manager to agree a date and location at least 12 months in advance.



#### **2.2.6.** Final financial reporting (CRUK)

Each HI must submit a final reconciliation to CRUK at the end of the award, summarising actual spend across the lifetime of the award.

Once the reconciliation is submitted, CRUK may recover funds from an HI. Funds may be recovered because they were used for ineligible costs (see section 3.1 below) or due to underspend.

CRUK may reconcile funds by:

- Requesting reimbursement, which should be honoured promptly by the HI; or
- Offsetting against any other sums, including award payments, owed to the HI.

The final reconciliation, should be submitted in pounds sterling (GBP). Institutions incurring costs in other currencies may report using the exchange rate that was applied when they converted the GBP to local currency.

#### 2.2.7. Final financial reporting (NCI)

NCI requires that a financial expenditure report be submitted at the end of the funding period. Recipients are required to electronically submit the final Federal Financial Report (FFR) through the Payment Management System (PMS). The final FFR must cover the entire award period. HIs will be provided with instructions on how to submit the FFR.

For further information, please see Part II, section 9.3 of the NCI Cancer Grand Challenges OT Policy Guide.

#### 2.3. Management Groups

Awarded teams are expected to establish a Management Group to oversee the delivery of the team's goals. The role of the Management Group is to:

- Manage the Cancer Grand Challenges team proactively to drive and direct research, challenge current thinking and provide scientific input in an open and constructive manner;
- Review and approve reporting including signing off the annual financial statements described in section 2.2.3 above;
- Review progress against the team's plan and milestones, and take steps to keep the research on course for completion on time and within budget;
- Discuss and advise how to resolve scientific and technical difficulties that arise;
- Actively seek and identify opportunities for publishing Foreground and support the drafting and preparation of publications of Foreground in accordance with the policy outlined in section 3.3.1 below;



Assist the HIs in ensuring compliance with the terms and conditions of funding.

The Management Group will comprise the TL, the Programme Manager, several or all Co-Is as deemed appropriate, and one Patient Advocate where appropriate. See section 1.2.1 above for descriptions of these roles.

Teams can determine the frequency of Management Group meetings but meeting at least every two months is recommended. Once a year, one meeting of the Management Group should be embedded in the team's scientific symposium (see section 2.5 below) and representatives of CRUK and NCI invited to attend in an observational capacity.

#### 2.4. Responsibilities and monitoring

#### 2.4.1. Responsibilities of Host Institutions

Each HI funded via Cancer Grand Challenges will use their existing staff and systems to support the funded work. It is the responsibility of HIs to:

- Abide by all Cancer Grand Challenges policies provided in section 3 below;
- Comply with the terms of the CGC Award Agreement (see section 1.1.2 above);
- Comply with the terms of the NCI CGC NoA;
- Provide a safe, constructive working environment for all staff and have in place appropriate HR
  policies and procedures;
- Ensure adequate resources, premises and facilities are provided to support the award activities. This
  includes making any reasonable adjustments for staff who have a disability;
- Have in place financial management and control systems, which have the capacity to track income and expenditure;
- Procure goods and services in compliance with established policies and procedures;
- Maintain equipment safely and responsibly;
- Have in place appropriate policies and procedures for subcontracting and for notifying NCI and CRUK of any plans to do so;
- Manage and/or prevent conflicts of interest including by declaring any potential conflicts to the Funders;
- Ensure that the CGC award activities are carried out in accordance with all applicable legal, health
  and safety, ethical and regulatory requirements and obtain all licences and approvals necessary for
  the CGC award activities;
- Ensure that actions of the HI do not inadvertently risk CRUK breaching UK charity legislation/regulation;



- Ensure that the HI (and, where relevant, the research personnel and institutions) holds all appropriate
  insurance policies during the Cancer Grand Challenges award period and for a period of six years
  following the End Date of the Cancer Grand Challenges award and during any commercialisation of
  the Foreground;
- Share data across teams under the direction of the Management Group (see section 2.3 above) and
  as required by this document and the NCI Cancer Grand Challenges <u>OT Policy Guide</u> including
  through the timely execution of Material Transfer Agreements and/or Data Sharing Agreements as
  required;
- Ensure all Results are appropriately validated before publication;
- Notify the Management Group, CRUK and NCI immediately upon becoming aware of any circumstances likely to affect the HI's ability to comply with the CGC Award Agreement and NCI CGC NoA;
- Notify and consult with CRUK on the response to any request under the <u>UK Freedom of Information</u>
   Act relating to the Cancer Grand Challenges award.

#### 2.4.2. Audit

Both CRUK and NCI have the right to seek confirmation from an HI or its external auditors that the Cancer Grand Challenges award has been used in compliance with the terms and conditions of award. The HI must cooperate fully with any request by the Funders to inspect books, records and facilities related to the award and ensure that any subcontractors cooperate as well.

HIs are subject to review from CRUK and/or NCI for three years after submission of the final financial reports. During this three-year period, HIs must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by, or may reasonably be considered pertinent to, the terms of the CGC Award Agreement or the NoA. If any litigation, claim, financial management review or audit is started before the expiration of the three-year period, the records must be retained until all litigation, claims, financial management reviews or audits involving the records have been resolved or final action taken.

For further information on NCI audit requirements, please see Part II, section 9.6 of the NCI Cancer Grand Challenges OT Policy Guide.

#### 2.5. All-team scientific symposia

Each year, teams are expected to organise an in-person scientific symposium to bring together the TL, Co-Is, Patient Advocates and Programme Manager (see section 1.2.1 above), as well as trainees such as PhD



students and postdoctoral researchers. The symposium provides an opportunity for the team to share and discuss scientific updates, progress and future directions.

The Programme Manager should work with the CRUK operations officer (see section 1.2.3 above) to agree dates and a location for each symposium at least 12 months in advance. In doing so:

- All dates and venues must be discussed and approved by the CGC office team in advance of booking. Teams should consult the CRUK operations officer (see section 1.2.3 above) in the first instance, who will secure approvals from CRUK and NCI;
- Venues must be selected with a view to minimising overall costs charged to CGC awards –
  considering venue, accommodation, catering/subsistence and travel. Specifically, the venue should
  be located where there is a significant hub within the team (most often the base of the TL) and
  wherever possible, teams should aim to secure space free-of-cost from their host institutions;
- All meetings paid for through CGC funds must be cost-effective and must not put the Funders' reputations at risk;
- In order to be able to send representation from CRUK and NCI to attend all-team meetings, the CGC office team will try to spread meetings throughout the year of course taking into account what works best for individual teams. To make this possible, the CGC office team will appreciate help and flexibility from the Cancer Grand Challenges teams.

The scientific symposium will be attended by CRUK and NCI representatives in an observational capacity, and, in some cases, members of the Cancer Grand Challenges Scientific Committee (see section 1.2.3 above).

Teams should embed a meeting of the Management Group (see section 2.3 above) into the agenda of each Research Retreat. CRUK and NCI representatives will also attend this part of the meeting in an observational capacity.

Teams in the first year of their award are not required to organise a scientific symposium, but are welcome to do so. For teams in the final year of their award, a final-year research retreat (see section 2.2.5 above) will be organised by CRUK and NCI in place of the annual symposium.



#### 2.6. Making changes to Cancer Grand Challenges funding

HIs and awardees must notify CRUK and NCI if there is any change in their status, or the status of any research personnel that may affect their eligibility to hold the Cancer Grand Challenges award.

NCI and CRUK must approve the following:

- The transfer of any part of a Cancer Grand Challenges award to another HI;
- Changes to the PD/PI, TL or Co-Is;
- The addition of a new HI into the Cancer Grand Challenges team;
- The addition of new sub-contracts to a Cancer Grand Challenges award;
- A change in the scope or specific aims of the Cancer Grand Challenges Team, or to any clinical trial
  or animal research, described in the application or subsequent Annual Reviews.

Approval should be requested in writing to the research portfolio manager or lead (see section 1.2.3 above) who will coordinate with CRUK and NCI colleagues to consider such requests.



# 3. Funding requirements and policies

This section sets out the funding policies that apply to Cancer Grand Challenges teams. Where policies overlap, all requirements apply.

Please contact your Cancer Grand Challenges operations officer (see section 1.2.3 above) for support.

#### 3.1. Allowable costs

#### 3.1.1. Costs principles

Cancer Grand Challenges awards provide up to GBP 20m for the direct costs of research and all patient advocate involvement and engagement activities.

Each HI participating in a Cancer Grand Challenges award will be individually issued their proportion of the direct costs. In general, NCI and CRUK intend to support:

- ~50% of the direct costs will be issued in GBP by CRUK in the form of a GAL (see section 1.1.4 above).
- ~50% will be issued in USD by NCI in the form of a NoA (see section 1.1.5 above).

In addition to the direct costs of research, some HIs may be eligible to request indirect costs (sometimes called 'overheads').

For all funding issued to HIs based in the UK:

- CRUK will not fund indirect costs.
- NCI will issue indirect costs up to 8% of the direct costs awarded by NCI to that HI.

For all funding issued to HIs based in the US:

- CRUK will issue indirect costs up to 10% of the value of the direct costs of research funded by CRUK at that HI.
- NCI will generally follow the federal government indirect cost rate at that HI. Any HI that has never
  received a negotiated rate may propose a rate with a justification and NCI will determine the rate for
  the awards. NCI reserves the right to negotiate an F&A / indirect cost rate for OT awards to CGC
  teams.

NCI will not fund indirect costs in any jurisdictions other than the US or UK.



CRUK will consider funding indirect costs to HIs only in jurisdictions where indirect costs are typically funded through charitable or public research grant funding, up to 10% of the value of the direct costs of research funded by CRUK at that HI.

Direct costs of team members based at commercial (rather than academic) institutions may be supported but will be considered only for small and medium-sized enterprises (SMEs), and on a case-by-case basis.

The Cancer Grand Challenges award may only be used for CGC award activities and only for costs incurred during the award period.

#### 3.1.2. Costs that can be charged to CRUK

Please refer to the <u>CRUK Allowable Costs Guidance document</u>, which outlines what may be charged against the direct costs proportion of the CRUK Cancer Grand Challenges award, with CRUK approval.

#### 3.1.3. Costs that can be charged to NCI

Please refer to the NCI Cancer Grand Challenges <u>OT Policy Guide</u> and NoA for details of what may be charged to the NCI Cancer Grand Challenges awards, with NCI approval.

#### 3.2. Conducting research

#### 3.2.1. IRBs and IACUCs

HIs must have established Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs) if their CGC award involves animal studies or clinical studies involving human subjects, respectively.

#### 3.2.2. Animal studies

CRUK and NCI require team members/HIs to adhere to the highest animal welfare standards. As such, the Funders have policies that apply to funded animal research.

Only animal work specifically set out in the full application or otherwise approved may be conducted. Animal studies should only be carried out where there are no feasible alternatives, and must comply with the principles of reduction, refinement and replacement.

Additional information on the policies relating to animal research are available:

- On the CRUK web page <u>The Use of Animals in Research</u>;
- In section 16.18 of the NCI Cancer Grand Challenges OT Policy Guide.



#### 3.2.3. Clinical studies

CRUK and NCI are committed to ensuring clinical studies are designed, delivered and monitored to the highest standards.

Where clinical studies are approved in principle, team members/HIs will be required to provide more detailed information about the design of the study for approval, and to report on the progress of the study on an ongoing basis.

Team members/HIs will also be provided with guidance on how CRUK and NCI will fund clinical studies, including setting out any requirements for how team members/HIs should manage and report on these studies. CRUK and NCI require that Results from all clinical studies are published as soon as Results are validated, for use by the wider research community. See section 16.19 of the NCI Cancer Grand Challenges OT Policy Guide.

Any proposed clinical studies should be discussed with your research portfolio manager or lead and OTPO (see section 1.2.3 above) at the earliest opportunity.

#### 3.2.4. Use of generative artificial intelligence tools

When using Generative artificial intelligence ("Generative AI") tools, Cancer Grand Challenges Teams should consider the issues and risks associated with using such tools and are strongly encouraged to refer to CRUK's <u>Guidance for researchers on the use of generative AI</u>.

Furthermore, Cancer Grand Challenges teams are required to:

- Support the highest levels of research integrity as set out in section 3.2.5 below, including in relation to their use of Generative AI tools;
- Ensure Generative AI tools are used in accordance with relevant legal and ethical standards, including data privacy where those standards exist or as they develop;
- Use Generative AI tools responsibly to ensure the originality, validity, reliability and integrity of
  outputs created or modified by Generative AI tools. This includes ensuring reports to CRUK and NCI,
  as well as any published research, contain accurate information and do not contain false or
  misleading information;
- Correctly and explicitly attribute outputs from generative AI tools in reports to CRUK and NCI, as well
  as any published research, by listing the generative AI source, where practicable, naming the specific
  model(s) used and software, and specifying how content was generated (such as listing the prompt
  used);



 Adhere to HI policies on the use of Generative AI tools, particularly those concerning plagiarism and fabrication.

#### 3.2.5. Research misconduct

Cancer Grand Challenges research should be conducted according to the highest standards of research practice to ensure the integrity and reliability of the research and outputs.

HIs must have in place a research integrity officer; produce a short annual statement on research integrity; and have in place written procedures for the handling of allegations of research misconduct made against its staff and students.

Details of the requirements and policies to which HIs must adhere are available:

- On the CRUK web page Guidelines for research conduct;
- In Part II, section 16.17 of the NCI Cancer Grand Challenges OT Policy Guide.

Note that the reporting requirements set out in both policies apply to all funded team members regardless of jurisdiction, i.e. allegations of research misconduct at an institution in the UK, US or elsewhere must be reported to both CRUK and NCI.

#### 3.3. Research outputs

#### 3.3.1. Publications

All original, peer-reviewed research articles that are supported in whole, or in part, by Cancer Grand Challenges funding must be made immediately and freely available online by the official publication date; and published under a Creative Commons attribution licence (CC BY 4.0).

Publications should include a data access statement stating that the data is available for academic non-commercial research only. Commercial organisations wishing to access datasets should liaise with the Cancer Grand Challenges Team's assigned Portfolio Manager (see section 1.2.3 above) and an appropriate data access committee, who will consider any pre-existing legal encumbrances that apply to the data before release.

Where the paper is a collaborative output of the Cancer Grand Challenges team and has broad relevance to the programme, key authors should be listed as per traditional scientific custom, with joint first and last authorship where appropriate. In addition, the Cancer Grand Challenges team should also be listed as an author, e.g. on behalf of the XXXX team, with team members listed alphabetically.



All teams should acknowledge Cancer Grand Challenges funding in each publication using the following statement:

"This work was delivered as part of the [insert team name] team supported by the Cancer Grand Challenges partnership funded by Cancer Research UK ([insert award reference]) and the National Cancer Institute ([insert award reference]) [and any additional partners]."

Please refer to your team's specific brand guidelines for the correct acknowledgement statement to be included with publications.

CRUK and NCI expect teams to first and foremost review outputs intended for publication or public presentation at Management Group level. To support teams with the publication process, the following requirements apply.

During review of a publication, a copy should be sent in confidence to the Cancer Grand Challenges research portfolio manager or lead (see section 1.2.3 above) for comment. Comments could include matters such as:

- Issues with non-compliance with the open access requirements given above;
- A request that specific confidential information be removed;
- A request to delay submission for 90 days if there is an opportunity to explore the commercial potential of any Foreground;
- A request relating to a contractual obligation related to commercialising a discovery.

Once a publication has been accepted, the Cancer Grand Challenges Portfolio Manager should be notified as soon as possible, no later than 30 days prior to publication. See the press and publicity policy in section 3.3.6 below.

#### 3.3.2. Presentations

All public presentations of the outputs of Cancer Grand Challenges funding should clearly acknowledge the initiative and Funders.

#### 3.3.3. Data sharing

CRUK and NCI believe that data generated from research should be made broadly available for secondary use, in order to maximise the potential impact of the data for patients. Any primary data underlying work published as a result of Cancer Grand Challenges funding must be made broadly available within two months for use only in academic non-commercial research through an appropriate data repository (such as the Genomic Data Commons or dbGaP) while:



- Protecting confidential and proprietary data (and may include restrictions to access based on the commercial nature of research proposed to be conducting using such data);
- Safeguarding the privacy of participants through pseudo or anonymisation.

CRUK and NCI recognise that research does not always lead to a publication that would itself trigger the release of data. Therefore, data that do not form the basis of a publication produced during the award period should be shared by the end of the award period. Underlying primary data must:

- Be properly curated throughout its life cycle and released with the appropriate high-quality metadata
  in order to make stored data findable, accessible, interoperable and reusable (FAIR) in a manner
  appropriate to the discipline and/or the methodology that was used to produce the data;
- Be made available on suitable CC licenses (to be determined in consultation with their Cancer Grand Challenges research portfolio manager or lead and local technology transfer office) for academic non-commercial purposes and deposited in suitable public repositories that facilitate this access;
- Be published alongside a data access statement such as 'the underlying primary data is available
  for academic non-commercial research only' to make it clear to third parties accessing the data
  indirectly through these repositories what restrictions exist as per section 3.3.1.1 above.
- Be de-identified prior to deposit, consistent with applicable laws and policies, to ensure that the identities of research subjects cannot be readily ascertained with the data.

Before submitting underlying primary data, teams must assess the informed consent materials to determine whether the underlying primary data may be shared in compliance with this policy. Teams are strongly encouraged to seek the widest possible consent rights allowing primary and secondary research use of the data, and permitting research involving commercial entities where possible to maximise the impact of the data generated.

CRUK and NCI believe that data generators and sharers should receive full and appropriate recognition (e.g. by acknowledged collaboration and/or citation) by Funders, academic institutions and new users. To enable this, researchers are encouraged to use persistent identifiers such as Digital Object Identifiers (DOIs) and ORCID identifiers.

Cancer Grand Challenges teams are required to work with the research portfolio manager or lead (see section 1.2.3 above) and their respective Technology Transfer Offices to develop an appropriate commercial data sharing strategy prior to sharing any data with a commercial entity. Data which might have the potential to be exploited commercially or otherwise to deliver patient benefit should be discussed with your research portfolio manager or lead in the first instance. Please refer to section 3.3.4 below for more information.



#### 3.3.4. Commercialisation

It is important that Foreground capable of being translated to deliver benefits to patients and advance public health through commercialisation is not fragmented and remains capable of being commercialised in a coordinated fashion. To achieve this objective, teams are required to comply with the Cancer Grand Challenges Commercialisation Policy.

#### 3.3.5. Branding

Funded teams are required to adhere to the initiative's brand guidelines.

#### 3.3.6. Press and publicity

CRUK and NCI may use material from Cancer Grand Challenges research for publicity purposes. Funded team members are asked to respond positively to all reasonable requests to attend or speak at events and provide help with images and copy for any communication materials. Funded teams should cooperate with any reasonable publicity or research engagement.

Funded team members may be asked to act as ambassadors for the initiative in connection with fundraising activity for CRUK.

Where press or publicity is sought for research predominantly funded by Cancer Grand Challenges, CRUK reserves the right to lead on publicity, in consultation with NCI.

#### 3.4. Host Institution working practice and compliance policies

#### 3.4.1. Tobacco funding (CRUK)

CRUK will not provide financial support to those supported by tobacco industry funding. CRUK will also not provide financial support where those who are, or would be, supported by CRUK funds are working in such proximity to others supported by tobacco industry funding that there is any possibility or likelihood that facilities, equipment or other resources will be shared.

Please refer to CRUK's <u>Tobacco funding policy</u> for details.

#### 3.4.2. Dignity at work

The highest standards of dignity at work must be upheld, with bullying and harassment of any kind, in any context, unacceptable.

CRUK's policies outline the conditions that anyone involved in our research activities and their HIs must meet when applying for funding and for the duration of their funding. The policy also applies to all members of our Committees and Panels.



Please refer to CRUK's Dignity at Work in Research policy for details.

Please also refer to Part II, section 16.1 of the NCI Cancer Grand Challenges <u>OT Policy Guide</u> for NIH policies and requirements governing anti-harassment.

Note that the reporting requirements set out in this policy apply to all funded team members regardless of jurisdiction, i.e. allegations of bullying or harassment at an institution in the UK, US or elsewhere must be reported to CRUK and NCI.



# 4. Glossary

Term	Definition
Authorized Organization Representative	Member of a funded Host Institution's staff with authority to commit to terms and conditions of award and perform other responsibilities identified in section 1.2.2 above and in other sections of this Award Management and Funding Policy Guide
Award	Funding awarded to Host Institutions by CRUK and NCI for Cancer Grand Challenges research
Cancer Grand Challenges Advocacy Panel (CGCAP)	A panel of independent Patient Advocates who review the Patient Advocate Involvement and Engagement plans of shortlisted and funded Cancer Grand Challenges team (see section 1.2.3 above)
Cancer Grand Challenges Award Agreement (CGC Award Agreement)	Agreement into which all Host Institutions in a team will enter along with CRUK and NCI (see section 1.1.2 above)
Cancer Grand Challenges Scientific Committee (CGCSC)	A committee of internationally recognised experts who make recommendations to CRUK on teams who should be shortlisted and selected as Cancer Grand Challenges teams (see section 1.2.3 above)
Cancer Research Horizons (CRH)	Has the meaning set out in the CGC Award Agreement
Cancer Research (CRUK)	Founding partner and operational manager of Cancer Grand Challenges. A registered charity in England and Wales (1089464), in Scotland (SC041666) and in the Isle of Man (1103) and a company limited by guarantee registered in England and Wales (4325234) and the Isle of Man (5713F), whose registered address is 2 Redman Place, London, E20 1JQ
Co-Investigator (Co-I)	An investigator providing significant intellectual input into a Cancer Grand Challenges team's research, and leading/contributing to individual work packages. Co-Investigators may or may not be named on a CRUK Grant Award Letter and/or NCI Notice of Award. Co-Is must contribute at least 10% effort to the award (see section 1.2.1 above).
Commercialisation Policy	A document that establishes policies for commercialising Foreground arising from Cancer Grand Challenge Awards



Term	Definition
Direct costs of research	As <u>defined by NIH</u> , any cost that can be specifically identified with a particular project, programme, or activity or that can be directly assigned to such activities relatively easily and with a high degree of accuracy. Under the UK <u>Full Economic Costing model</u> , this is synonymous with 'Directly incurred costs'. See section 3.1.1 above,
End Date	Date on which final CRUK Grant Award Letter and NCI Notice of Award expire. All funded HIs within one team will typically share one end date. HIs may not charge costs to the Cancer Grand Challenges award after the end date.
Federal Financial Report (FFR)	Statement of expenditures associated with an NCI award, required from Host Institutions at junctures specified in the Notice of Award
Final Report	Scientific report required from each Cancer Grand Challenges team within the 12 months prior to the End Date of the award (see section 2.2.5 above)
Final-year research retreat	Meeting of the Cancer Grand Challenges funded team held within 12 months prior to the End Date at which the Final Report will be reviewed
Flexi-Grant	CRUK's application and award management system. All funded Host Institutions and awardees must be registered with Flexi-Grant.
Foreground	Has the meaning set out in the <u>Commercialisation</u> <u>Policy</u>
Funders	Cancer Research UK and the National Cancer Institute
Generative AI	Has the meaning set out in section 3.2.4 above
Grant Award Letter (GAL)	Formal commitment of CRUK funds detailing the grant offered to each HI (see section 1.1.4 above)
Host Institution (HI)	The university, research institution, company or other entity at which specific Cancer Grand Challenges research will be carried out, as a result of funding issued to that entity in a CRUK Grant Award Letter and/or NCI Notice of Award



Term	Definition
Host Institution (HI) Administrator	One or more individuals at an HI who are nominated to perform certain activities related to CRUK funding on its behalf (see section 1.2.2 above)
Indirect costs of research	Costs of research that cannot be specifically identified with a project, programme, or activity or that can be directly assigned to such activities relatively easily and with a high degree of accuracy. These include Facilities and Administration costs under definitions used by the National Institutes of Health, and all directly allocated, indirect and estates under the UK Full Economic Costing model. See section 3.1.1 above.
Instalment	Individual period of funding covered by a CRUK Grant Award Letter and/or NCI Notice of Award. Typically, an Instalment will be 12 months.
Intellectual Property (IP)	Has the meaning set out in the <u>Commercialisation</u> <u>Policy</u>
Investigator	Any Team Lead or Co-Investigator in a Cancer Grand Challenges team (see section 1.2.1 above)
IRB and/or IACUC protocol	Protocols submitted to a Host Institution's Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) to protect human and animal research subjects respectively
Joint Steering Committee (JSC)	The committee comprising CRUK and NCI leadership who have the authority to authorise funding decisions on behalf of CRUK and NCI, respectively
Management Group	Has the meaning set out in section 2.3 above
National Cancer Institute (NCI)	The US federal government's principal agency for cancer research and training. Part of the National Institutes of Health.  NCI receives its budget from the US Congress as part of the federal budget process through appropriations for the Department of Health and Human Services and National Institutes of Health.
National Institutes of Health (NIH)	One of eight health agencies of the US Public Health Service which, in turn, is part of the Department of Health and Human Services. NIH is made up of 27 institutes and centres, all but three of which receive their



Term	Definition
	funding directly from the US Congress, and administrate their own budgets. NIH leadership plays an active role in shaping the agency's research planning, activities, and outlook.
NCI Cancer Grand Challenges OT Policy Guide	A document containing terms and conditions that govern the use of OT award funds that an HI receives from NCI
Notice of Award (NoA)	Formal commitment of NCI funds detailing the award offered to each Host Institution (see section 1.1.5 above)
Other Transactions Agreement Officer (OTAO)	Member of NCI staff authorised to sign an OT agreement and to issue a Notice of Award (see section 1.2.4 above)
Other Transactions Agreement Specialist (OTAS)	Member of NCI staff who may be delegated limited responsibilities by the OTAO (see section 1.2.4 above)
Other Transactions Program Official (OTPO)	Member of NCI staff responsible for the programmatic, technical and/or scientific management aspects of the Other Transaction (see section 1.2.4 above)
Other Transaction awards	NCI uses Other Transaction Authority to issue funding to Cancer Grand Challenges HIs. Other Transactions are legally binding instruments that may be used to engage academia and industry for a broad range of research and prototyping activities. They are not standard procurement contracts, grants, or cooperative agreements.
Patient Advocate	Advocates for people affected by cancer (patients, survivors, caregivers). Funded consortia must recruit a minimum of one patient advocate with a clearly defined role and remit (see section 1.2.1 above). Patient advocates also compose the membership of the Cancer Grand Challenges Advocacy Panel (see section 1.2.3 above).
Patient advocate involvement and engagement	Involvement is when Patient Advocates use their experiences of cancer to help shape research. Engagement is where information and knowledge about research is shared by researchers or Patient Advocates with other Patient Advocates and the public who are not associated with their research programme.



Term	Definition
Payment Management System (PMS)	The centralised payment system operated by the Payment Management Service, Program Support Center. Most US Department of Health and Human Services' (and some other federal government agencies') OTA recipients receive payments through this system.
Programme Manager	A full-time member of staff in a Cancer Grand Challenges team who coordinates the research team (see section 1.2.1 above)
Reconciliation	Final summary of expenditure to be submitted by each Host Institution to CRUK and NCI (see 2.2.6 above)
Research Outputs	Any publication, product, activity, paper, dataset, award, entity or other achievement attributable to Cancer Grand Challenges funding (see sections 2.2.2 and 3.3 above)
Research portfolio manager or lead	Science specialist at CRUK responsible for providing scientific support and oversight of Cancer Grand Challenges teams (see section 1.2 above)
Research Proposal	Application for Cancer Grand Challenges support based on which a CGC team was recommended for funding
Researchfish	A platform on which funded scientists record the outputs of their work, and attribute them to relevant grants (see section 2.2.2 above)
Results	Has the meaning set out in the <u>Commercialisation</u> <u>Policy</u>
Small and medium-sized enterprises (SMEs)	Non-subsidiary, independent firms which employ fewer 250 employees
Team Lead (TL)	The researcher responsible for the overall scientific and technical direction of a Cancer Grand Challenges team (see section 1.2.1 above)
Underspend	Any money allocated to a Host Institution through a CRUK Grant Award Letter or NCI Notice of Award that has not been spent (or is not expected to be spent) by the end of the funding Instalment



Term	Definition
Virement	Transferral of Cancer Grand Challenges funding from one cost line, work package, Host Institution or funding Instalment to another (see section 2.1.5 above)



# 5. Version notes

Document version	3.0
Document date	May 2025
Document owner	CGC Operations Manager, CRUK
Next review date	May 2026

### 5.1. Summary of changes

Section	Changes
General	Formatting, revision of wording for clarity, fixed broken links
1. Cancer Grand Challenges overview	Updated to latest brand statement
1.1. Cancer Grand Challenges Award Management and Funding Policy Guide	Clarified that this document is for teams co-funded by CRUK and NCI Changed primary contact for assistance understanding document from portfolio manager to operations officer
1.2.1. Roles and responsibilities (funded teams)	Added % effort for TL and Co-I  Moved text about NCI Program Director/Principal Investigator (PD/PI) here.  Clarified that a team of Patient Advocates is required, rather than a minimum of one  Updated Programme Manager responsibilities
1.2.2. Roles and responsibilities (Host Institutions)	Moved text about NCI Program Director/Principal Investigator (PD/PI) from here to 1.2.1.
1.2.3. Roles and responsibilities (CRUK)	Changed title 'portfolio manager' to 'research portfolio manager or lead' Removed reference to Cancer Grand Challenges philanthropy team
2.1.1. Payment process (CRUK)	Removed requirement for final scientific report prior to final quarterly payment
2.1.3. Budgeting	Removed reference to funding instalments of more or less than 12 months



Section	Changes
2.1.4. Discretionary fund	New section
2.1.5. Budget transfers	Clarified that approval is required for increases of budget lines of GBP 25,000 or more (unless this is less than 25% of the originally budgeted cost)  Clarified that CRUK will not consider requests to increase the proportion of the award used for indirect costs of research
2.2. Reporting	Clarified that the PM, accountable to the TL, is responsible for meeting reporting requirements  Specified attendance requirements for Annual Review interviews
2.2.1. Scientific progress reports	Added content required
2.2.2. Output reporting	Added examples of outputs that should be reported
2.2.3. Financial reports	Added level of detail required and currencies for reporting  Moved text about currency fluctuations here  Clarified that use of discretionary funds should be proposed in annual financial reports
2.2.4. Outcome of Annual Review	Moved text about CRUK and NCI informing HIs about which costs are to be provided to which Funder here Removed requirement for annual NCI Federal Financial Report
2.2.5. Final scientific reporting	Added content required  Clarified that CRUK and NCI will organise the final-year research retreat
2.2.6. Final financial reporting (CRUK)	Moved text about currency fluctuations from here to 2.2.3.
2.2.7. Final financial reporting (NCI)	Added requirement for final NCI Federal Financial Report
2.3. Management Groups	Changed requirements for composition of Management Group Removed reference to suggested terms of reference



Section	Changes
	Added review of reporting to role of Management Group Removed requirement to provide CRUK and NCI with minutes of all Management Group meetings
2.4.1. Responsibilities of Host Institutions	Added provision that potential conflicts of interest be reported to the Funders  Added provision for timely processing of MTAs and DTAs  Removed text duplicative of Cancer Grand Challenges Award Agreement
2.4.2. Audit	Removed requirement for both paper and electronic information to be retained
2.5. All-team scientific symposia	Renamed from 'Research Retreats'  Specified how and when symposia will be organised
2.6. Making changes to Cancer Grand Challenges funding	Removed reference to relationships with the tobacco industry
3. Funding requirements and policies	Removed reference to local and national laws
3.1.2. Costs principles	Clarified NCI indirect rates  Moved text about CRUK and NCI informing HIs about which costs are to be provided to which Funder from here to 2.2.4.
3.2.3. Clinical studies	Removed reference to all appropriate laws Removed duplicative text
3.2.4. Use of generative artificial intelligence tools	Removed introductory text
3.3.1. Publications	Removed introductory text and fourth-level sub- headings Removed references to presentations Corrected Funders' right to request delay of submission for 90 days per the Award Agreement
3.3.2. Presentations	New section
3.3.3. Data sharing	Clarified timelines and specifications for data sharing



Section	Changes
	Re-ordered paragraphs  Added requirement that data not forming the basis of publication must be shared by the end of the award period
3.3.5. Branding	Removed introductory text
3.4.2. Dignity at work	Changed introductory text
4. Definitions	Removed some redundant definitions  Added definition of Other Transactions Program Official (OTPO)
5.1. Summary of changes	New section



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