

CRACK IT

Business Growth Scheme Guide for Participants

Contents

1. Overview	3
Table 1: Business Growth Scheme overview	4
2. Eligibility criteria and scheme remit.....	5
2.1 Scheme remit.....	5
Table 2: Modified Technology Readiness Levels (mTRL) and their definitions	7
3. How to apply.....	7
3.1 CRACK IT Advisory Panel presentation	7
3.2 General guidance.....	8
3.3 Attachments	9
4. BGS application form	9
4.1 Completing the application form	9
Table 3: Summary of attachments.....	13
4.2 Animal use and experimental design.....	13
5. Assessment procedure	18
Table 4: CRACK IT Advisory Panel scoring criteria	18
6. Award process.....	18
6.1 Important information	19
7. Post award information	19
7.1 Intellectual property.....	19
7.2 Project management.....	20
7.3 Reporting.....	20
Table 5: Researchfish reporting requirements	21

1. Overview

The NC3Rs has introduced a Business Growth Scheme (BGS), where CRACK IT Challenge contractors can apply for additional support, of up to £50k (inclusive of VAT / Reverse Charges) for 12 months, to maximise their business strategy for near-market ready products and services.

The BGS has been designed to support the business and commercial opportunities that arise from technology developed during the Challenge. These funds will not be awarded to support further R&D work that was not completed in the Challenge period.

This document provides a comprehensive guide to participants applying to the BGS. The BGS provides funding in line with the Subsidy Control Act 2022. Further information about the Subsidy requirements can be found within the [Subsidy Control Act 2022](#). EU State aid rules now only apply in limited circumstances; please see [the Windsor Framework](#) to check if these rules apply to your organisation.

Table 1: Business Growth Scheme overview

<p>Scheme</p>	<p>The Business Growth Scheme (BGS) has been designed to support the business and commercial opportunities that arise from technology developed from CRACK IT Challenges.</p> <p>CRACK IT Challenge contractors can apply for additional support of up to £50k (inclusive of VAT / Reverse Charges) for 12 months. Awarded funds will not support R&D non-completed during the Challenge period.</p>
<p>Eligibility</p>	<ul style="list-style-type: none"> ▪ Open to any CRACK IT Single Phase or Phase 2 contractor (includes sub-contractors). ▪ Applicants must be UK- or EU-based and from an established commercial entity. ▪ Only one application to the BGS, per Challenge, will be accepted. ▪ The BGS provides funding in line with the Subsidy Control Act 2022. Further information about the Subsidy requirements can be found within the Subsidy Control Act 2022. EU State aid rules now only apply in limited circumstances; please see the Windsor Framework to check if these rules apply to your organisation.
<p>Application and review process</p>	<p>Applications to the BGS:</p> <ul style="list-style-type: none"> ▪ Will only be accepted following the end of Challenge presentation to the CRACK IT Advisory Panel (CAP). ▪ Will be within one year of completion of the Challenge contract. ▪ Must be made using the application form provided. ▪ Will be reviewed by the CAP within six weeks of the NC3Rs receiving the application.
<p>Agreements and awards</p>	<p>Prior to award, the successful applicant's organisation signs an agreement with the NC3Rs. Up to two awards will be made each financial year.</p> <p>The lead applicants are informed by email of the decision of the CAP approximately one week after the Panel meeting.</p>
<p>Post-award</p>	<p>The lead contractor will be responsible for ensuring key deliverables of the BGS plan are met within agreed timeframes.</p> <p>All BGS awardees are required to submit a final report and a final expenditure statement (FES) within three months of the completion/termination date.</p>

2. Eligibility criteria and scheme remit

- The BGS is open to any CRACK IT Single Phase or Phase 2 contractor, including sub-contractors that were part of the original winning consortium who have approval to apply from their CRACK IT Challenge Project Management Team.¹
- All CRACK IT Challenge contractors are invited to present their Challenge outcome to the CRACK IT Advisory Panel (CAP) within the period of six months before and one year after their contract with NC3Rs expires. Applications for the BGS will only be accepted following the end of Challenge presentation to the CAP. See [Section 3](#) for more information on how to apply.
- The CAP will provide feedback on the proposed use of the BGS and recommend whether an application should be invited.
- An application form will be provided by the CRACK IT team who will advise on deadlines for submission and decision dates.
- Applicants must be UK- or EU-based and from an established commercial entity at the time of application.
- Only one application to the BGS, per Challenge, will be accepted.
- This document provides a comprehensive guide to participants applying to the BGS. The BGS provides funding in line with the Subsidy Control Act 2022. Further information about the Subsidy requirements can be found within the [Subsidy Control Act 2022](#). EU State aid rules now only apply in limited circumstances; please see [the Windsor Framework](#) to check if these rules apply to your organisation.
- All awards made under the BGS constitute de minimis aid. Applicants are required to complete a Minimal Financial Assistance / De Minimis declaration form as part of the application process.

2.1 Scheme remit

BGS applications are expected to address the commercialisation of a technology/product that, through the CRACK IT Challenge competition, has already completed the majority of R&D work required to produce a market-ready product. Using the modified technology readiness levels (mTRL) defined by Phadke &

¹ A Project Management Team consisting of representatives from the contractors, sub-contractors, Sponsors and NC3Rs is established for each funded CRACK IT Challenge. The Project Management Team is responsible for ensuring key deliverables are met within agreed timeframes during the CRACK IT Challenge.

Vyakarnam² as guidance, a mTRL level of 3-6 is expected to be the minimum starting point for applying to the scheme. The aim of the scheme is to support activities towards mTRL 7-9 ([Table 2](#)).

The remit of the BGS includes:

- Validating the core technology to increase customer confidence (mTRL7).
- Building a portfolio of clients and prospective clients (mTRL7 and 8).
- Establishing confidence (scientifically and commercially) to operate in the market (mTRL7 and 8).
- Delivering a product scaled to a level appropriate for commercial activities and attracting investment capital, where appropriate (mTRL 9).

Activities **within scope** may include but are not limited to:

- **Validation for customer confidence:** specific testing of a small set of potential customer/sector defined compounds to build customer confidence. (mTRL7, 8).
- **Consultancy:** for example, advice on business/commercialisation strategy, business development, pitching for investment and market analysis (mTRL 8,9).
- **Marketing:** communications to attract potential investors and customers including website design, travel, academic publications, conference and exhibition fees (mTRL 8,9).
- **Demonstrators:** for example, production and installation of demonstrators at one or more sites to generate new client interest and provide access for trial use. Costing of equipment to be used primarily for this purpose is also within scope (mTRL 7,8).
- **Manufacture:** for activities including design for manufacturability, manufacture, miniaturisation, manufacturing efficiencies and investigating and implementing a supply chain for product generation. Costing of equipment to be used primarily for this purpose is also within scope (mTRL 8,9).

Activities **not** in scope for the BGS include:

- Research and development as a core activity.
- Validation and/or other activities that were included in the original CRACK IT Challenge project plan.
- Merchandising and advertising activities and materials.
- Export activities.

² Taken from Phadke & Vyakarnam, *Camels, Tigers and Unicorns: Rethinking Science and Technology-enabled Innovation*, World Scientific Publications, 2017.

Table 2: Modified Technology Readiness Levels (mTRL) and their definitions

mTRL 0	<p>Research in progress</p> <p>Fundamental research activity before any potentially useful and validated science or technology has been established</p>
mTRL 1	<p>Validated research: start concept definition</p> <p>At the point at which the conceptual application of the technology has been defined in outline terms</p>
mTRL 2	<p>Initial concept defined</p> <p>The conceptual application has now been converted to a definition of the product or service which can potentially be offered using the technology</p>
mTRL 3	<p>Working prototype or demonstrator</p> <p>A working prototype or demonstrator has been built</p>
mTRL 4	<p>Product or service testing and concept refinement</p> <p>The new product, service or technology has been refined/modified following feedback from the initial customer</p>
mTRL 5	<p>Proven product or service</p> <p>The product or service is ready at a functional level, without the collateral around the product including the method of deployment and the proposed business model</p>
mTRL 6	<p>Deployment with early customers in real commercial environment</p> <p>The product or service is now ready for use with early Customers, and so includes all the associated collateral, including a service infrastructure where relevant.</p>
mTRL 7	<p>Product or service ready for testing in real user environment</p> <p>Early customer feedback has been used to define the modified product or service functionality, its required performance and critically, the chosen business model.</p>
mTRL 8	<p>Techno-commercial refinement of product or service</p> <p>The refined product or service is now ready for deployment with mainstream customers.</p>
mTRL 9	<p>Ready for commercial deployment with real customers</p> <p>The final product or service is now ready for commercial launch, including go-to-market collateral and proven business model. The challenge now is growing the mainstream customer base.</p>

3. How to apply

3.1 CRACK IT Advisory Panel presentation

Applications for the BGS will only be accepted following the end of Challenge presentation to the CAP. All Challenge contractors are invited to present the outcomes from their project to the CAP with six months before and one year after their contract with the NC3Rs expires. Contractors wishing to be considered for the BGS will have the opportunity to pitch to the CAP either at the same time as their end of Challenge presentation or at a separate occasion within one year of their contract expiring.

A template slide deck will be provided by the NC3Rs to guide contractors on the content for the presentation(s), however it is not a requirement to use the NC3Rs' branding. Following the BGS pitch, the Panel will provide feedback on the proposed use of the BGS funds and recommend whether an application should be invited. The following points should be including when compiling a presentation to the CAP:

- A short executive summary.
- An overview of the product/platform/solution (i.e. what you will be offering to end-users).
- The current mTRL level of the technology and the intended mTRL level at the end of the project.
- The composition of the project team and organisation that will be providing the product/platform/solution.
- A current understanding of the market and what research may be needed to fully understand it.
- An overview of the business model.
- The use of BGS funds and key milestones in the project.
- The future aims following successful completion of the BGS project.

Applicants are expected to have discussed their proposal with their own organisation or any other body whose co-operation will be required in the conduct of the project, including sub-contractors and their Project Management Team, before submitting an application.

By submitting an application, applicants are confirming that the information provided in the application is complete and true, that they are actively engaged in the project and will be responsible for its overall management, and that they agree to administer the award if made.

3.2 General guidance

Applications for the BGS must be made using the application form provided. Guidance on completion of the application form can be found in [Section 4](#). Completed applications must be sent by email to crackitenquiries@nc3rs.org.uk. All applications are treated in confidence.

- Application forms and attachments must be submitted as **PDF files**.
- Failure to complete mandatory fields on the application form and to submit all required attachments may result in the return of the application without review.
- The application form should be completed using a font size no smaller than 10pt (Arial) and text limits must not be exceeded.
- The use of acronyms should be kept to a minimum.

3.3 Attachments

Supporting information can be provided in the form of attachments as indicated within this guidance and the application form. Attachments must:

- Be submitted as separate PDF files and not added or pasted within the application form.
- Be named appropriately and indicate the application form section number to which they refer (e.g. 'Section 6 – Additional pictures/diagrams').
- Be completed using a font size no smaller than 10pt (Arial).

Only provide attachments as specified in the application form and in this guidance. Any additional materials or documentation submitted will not be considered and may result in your application being rejected or returned.

Questions about the application process should be addressed directly to your NC3Rs Representative or via email crackitenquiries@nc3rs.org.uk.

4. BGS application form

This section contains guidance on how to complete the BGS application form. Sub-sections are numbered as they appear in the application form.

4.1 Completing the application form

1. Application

- **Project title:** Please provide your own title for the project. This should be both clearly descriptive and concise. It should contain keywords relevant to the project.
- **Project duration:** Applicants can request up to the maximum duration of 12 months, as specified in the BGS brief.
- **Proposed start date:** Please specify the date upon which BGS activities will commence. This must be within eight (8) weeks of confirmation of the award.
- **Total project cost:** Applicants can request up to the maximum total cost, (inclusive of VAT / Reverse Charges) of £50k. Requests for more than this sum will be rejected.

For applications from organisations based outside of the United Kingdom, please note that a Reverse Charge of VAT will be applied to your award. This will be charged at 20% and will need to be taken into consideration when costing your application, as the maximum amount that will be paid out, inclusive of VAT and Reverse Charges, will not exceed the total amount of £50k.

2. Details of Lead Applicant Organisation

Please include the name of the company applying to the BGS, registered address, company and VAT registration numbers and other details as requested on the application form. Applicants must be a registered commercial entity and based within the UK, European Union, European Economic Area and European Free Trade Association.

3. Details of Lead Contact in Organisation

Please include the name of the lead contact in the company applying to the BGS, position in the company and contact details.

4. Original CRACK IT Challenge awarded

- **CRACK IT Challenge number and title:** Please provide the number and title of the CRACK IT Challenge.
- **CRACK IT Challenge funding received:** Please detail the amount of funding received for the CRACK IT Challenge award from the NC3Rs.
- **CRACK IT Challenge start date:** Date on which the CRACK IT Challenge commenced.
- **CRACK IT Challenge completion date:** Date on which the CRACK IT Challenge completed or if still in progress, the date on which the CRACK IT Challenge is due to complete.

Provide details of the CRACK IT Challenge lead applicant organisation and lead contact, if different from that stated in Section 2 and 3.

5. Commercial opportunity

- **Market opportunity:** Please describe the unmet need, size of the market opportunity and potential customers for the technology/product. The maximum word limit for this section is 300 words.
- **Competition:** Please describe competing technologies/products and the competitive advantage of your approach. The maximum word limit for this section is 200 words.
- **Intellectual property:** Please provide details of any existing patents or other forms of intellectual property (i.e. know how, trademark) that have arisen from the original CRACK IT Challenge. In addition, please indicate any anticipated IP, which may arise in the process of commercialising the technology/product and how this would be handled (i.e. the proposed arrangements for ownership). Please provide details of any freedom to operate searches conducted to date (or plans for the future) and any restrictions this may impose on the dissemination and exploitation of the technology/product. The maximum word limit for this section is 200 words.

Associated attachment (optional): Summary of patent filings – template provided as Annex 1.

- **Business model:** Please describe the business model and route to commercialisation of the technology/product. Please include the barriers and key risks to commercialisation and how you plan to address them. Please also describe any interactions with potential customers and/or investors, together with any feedback received. The maximum word limit for this section is 300 words.

Associated attachment (optional): Letters of support/intent from potential customers.

6. Use of BGS funds

Please explain in detail the proposed use of BGS funds including milestones, timelines and costs. Describe how BGS funding will de-risk your commercialisation strategy and how this aligns with the goals of the BGS scheme as set out in the BGS guidelines document and mTRLs. Please outline your future plans (milestones, timelines, costs and longer-term financing plans) following successful completion of your BGS proposal. Activities included as part of the original Challenge project which were not completed are not eligible for BGS funding. The maximum word limit for this section is 600 words.

Associated attachment (optional): Additional milestones / Gantt chart (maximum two sides of A4).

Please note: If a proposal includes animal work, the 'Justification of animal use / experimental design' form must be completed and included as part of the application. Further guidance can be found in [Section 4.2](#).

7. Team and expertise

Please provide a detailed description of the current team (skills, expertise and track record). Identify any gaps in your team/experience where additional support is anticipated in the future. Relevant commercial and management expertise must also be included. The maximum word limit for this section is 600 words.

Associated attachment (compulsory): The CVs of up to five (5) principal team members may be combined and included as a separate attachment (maximum one (1) side of A4 per team member).

8. Application Finances

BGS contracts are non-Full Economic Costing (FEC) and as such, applicants can apply for **100% directly incurred costs**. Please provide a summary of the overall costs for the whole project, inclusive of VAT / Reverse Charges, as appropriate.³

For applications from organisations based outside of the United Kingdom, please note that a Reverse Charge of VAT will be applied to your award. This will be charged at 20% and will need to be taken into consideration when costing your application, as the maximum amount that will be paid out, inclusive of VAT and Reverse Charges, will not exceed the total amount of £50k.

Direct costs (these are costs that are specific to the project, including):

- Labour costs for all those contributing to the project broken down by individual.
- Material costs (including consumables specific to the project).
- Equipment costs.
- Animal costs*.
- Travel and subsistence costs.
- Other costs specifically attributed to the project.

*Where applications involve the use of animals, applicants are expected to provide justification for this – see [Section 4.2](#) for further information.

Itemisation of costs and methods of calculation may be requested to support the application at a later date.

In addition, please provide justification for the resources required to undertake the proposed project.

- **Additional funding from external sources:** Please provide details of additional funding from external sources that will support this project.
- **Subsidy control:** please note BGS provides funding in line with the Subsidy Control Act 2022. Further information about the Subsidy requirements can be found within the [Subsidy Control Act 2022](#). EU State aid rules now only apply in limited circumstances; please see [the Windsor Framework](#) to check if these rules apply to your organisation.

9. Declaration

The BGS applicant is expected to have discussed and sought approval of the application with their own organisation and with any other body whose co-operation will be required to deliver the project, including the CRACK IT Challenge Project Management Team. The applicant will need to obtain consent from an authorised officer or appropriate signatory who will sign the agreement if successful. The agreement is a

³ It is the responsibility of the lead applicant to determine whether VAT/RC should be paid; if VAT/RC should be paid, the total amount, including VAT/RC, will not exceed the total amount of £50k.

legally binding document and subject to the outcome of this competition. By submitting the application, you are confirming that the information given, in this application, is complete and that you are actively engaged in this project and responsible for its overall management and agree to administer the award if made. You are also confirming that you have read and understood the relevant explanatory materials including this Guide for Participants.

Table 3: Summary of attachments

Application form section	Attachment name	Page limit (sides of A4)
Section 5.3	Summary of patents	Template provided in application form
Section 5.4	Letters of support	One per letter
Section 6	Additional milestones / Gantt chart	Two pages
Section 7	CVs (up to five)	One per team member

4.2 Animal use and experimental design

Where a proposal includes animal work, the '**Justification of animal use / experimental design**' form must be completed and included as part of the application. This form is included in the application form as Annex 2. Guidance on completing this form can be found within this section.

Applicants are expected to have developed their application in accordance with the cross funder guidance for the use of animals in research [Responsibility in the Use of Animals in Bioscience Research](#) and, in the case of use of non-human primates, the [NC3Rs Guidelines: Primate Accommodation, Care and Use](#). Compliance with the principles within these documents is a condition of receiving funds from the NC3Rs.

It is expected that both sexes will be included in animal experiments but if a single-sex study is proposed, applicants must justify why using both sexes is not appropriate or possible. There is no requirement to 'balance' or use equal numbers of both sexes. More information on the use of both sexes in experimental design can be found on the [NC3Rs website](#) and the [Experimental Design Assistant](#).

Experiments using animals funded by the NC3Rs must also comply with the Animals (Scientific Procedures) Act 1986, amended 2012 (ASPA) and any further embodiments, in:

- Using the simplest possible, or least sentient, species of animal appropriate.
- Ensuring that pain and distress are avoided wherever possible.

- Employing an appropriate design and using the minimum number of animals consistent with ensuring that scientific objectives will be met.

Advice on opportunities and techniques for implementing these 3Rs principles can be found on the [NC3Rs website](#).

Researchers using animals are strongly advised to read this guidance carefully before preparing an application to ensure all the relevant information required is included in their application. In particular, applicants should ensure their application clearly sets out and justifies the following:

- Research objectives and how the knowledge generated will advance the field.
- The need to use animals and the lack of realistic alternatives.
- Choice of species of animals to be used.
- Type of animal(s) for example, strain, pathogen free, genetically modified or mutant.
- Planned experimental design and its justification.
- Number of animals and frequency of measurements/interventions to be used.
- Primary outcomes to be assessed.
- Planned statistical analyses.

4.2.1 Experimental design, avoidance of bias and statistical considerations

There are a wide range of designs and approaches to animal experimentation that are appropriate depending on the objectives of the application. In all cases, the NC3Rs expects that researchers provide well justified information in their applications concerning the experimental design and its suitability to answering the research questions posed. Applicants should therefore provide adequate justification for their choice of design and numbers of animals and interventions. It is important that adequate information is also given concerning methodological issues including (but not restricted to):

- The avoidance of bias (for example blinding of observers assessing outcomes to the group allocation in a randomised design).
- How randomisation will be carried out (if used) or why it is not appropriate if it will not be used.
- A clear definition of the experimental unit in the analysis and the implications thereof (that is there is a difference between N samples from one animal, as distinct from one sample from each of N animals/or combining samples from multiple animals).
- A principled justification of the adequacy of the number of animals to be included so as to be able to minimise the likelihood of spurious results due to the play of chance alone.
- Where animals are used in multiple types of experimental approach within a single application (e.g. for tissue supply, pilot experiments or more defined pre-clinical studies), exemplars for these types of experiment should be provided.
- The number of different time points at which measurements will be made on each animal.

- A description of the statistical analysis methods that will be used, explaining how they relate to the experimental design and showing that they are appropriate for the types of data that will be collected.
- An indication of the number of independent replications of each experiment to be performed with the objective of minimising the likelihood of spurious non-replicable results.

The [NC3Rs Experimental Design Assistant](#) (EDA) captures methodological details about the experimental plan in the form of a diagram and provides tailored guidance and feedback on the design. It can then generate a PDF report which provides a transparent description of the experimental design in a standardised format.

4.2.2 Guidance on completing the ‘Justification of animal use / experimental design’ form

Information must be provided for all applications involving animals (including where the only procedure is Schedule 1 killing), regardless of whether the animal costs are requested as part of the application.

- Please provide details of any procedures categorised as moderate or severe, including how the procedure is undertaken, adverse effects experienced by the animals, and measures taken to minimise any pain, suffering, distress or lasting harm (address this point in response to **question five** on the form).
- If use of **non-human primates, cats, dogs, pigs** or **equines** will be involved in addressing the Challenge, applicants must also complete the [Standard questions on the use of non-human primates, dogs, cats, equines and pigs form](#). All applications which involve the use of these higher species are reviewed by the NC3Rs Office to ensure the usage is fully justified and that the welfare and husbandry standards are optimal.
- Sound scientific reasons for the use of animals and an explanation of why there are no realistic alternatives must be given, along with an explanation of how the choice of species complies with ASPA. (Address this point in response to **question eight** on the form).
- The **experimental design** should be outlined, including a justification of the total numbers of animals to be used and, where appropriate, the frequency of measurements/interventions required on each animal. Planned procedures to minimise experimental bias (for example, randomisation protocols, blinding) should be outlined or an explanation included as to why such procedures are not appropriate. Each experiment does not need to be described in detail, but sufficient information must be included so that reviewers are readily able to understand the experimental plan. (Address this point in response to **question ten** on the form).

- Researchers must provide a properly constructed justification of how the numbers of animals to be used were determined. In general, it would be expected that professional statistical advice is sought in compiling this answer.
- In many instances this answer will include statistical power calculations⁴ based on justifiable and explicit assumptions about the anticipated size of the experimental effects. If statistical power calculations are not given, applicants should provide a principled explanation of the choice of numbers. In general, explanations based solely in terms of 'usual practice' will not be considered adequate. An overview of the planned statistical analyses and their relation to the choice of sample size should be included.
- Where experiments involve genetically altered animals, examples of the breeding strategies should be included to support the total number of animals requested. Please provide information on resources requested for breeding, maintaining and using the chosen number of animals; the scientific and statistical justification of how the chosen number of animals was arrived at.

4.2.3 Additional information

- The costs of both the animals themselves and their maintenance may be requested and should be listed in the 'Application Finances' section of the application form under Directly Incurred costs.
- Applicants contemplating the use of animals purchased from commercial suppliers should, wherever possible, use UK suppliers, to minimise the risk of suffering during transport. For cats, dogs and primates, Home Office-approved suppliers must be used. Applicants planning research using rhesus macaques should obtain animals from the Centre for Macaques.

4.2.4 Ethical and welfare standards and review

Applicants must ensure that best practice in relation to animal husbandry and welfare is followed. Where the work proposed is not covered by an existing Project Licence under ASPA, applicants should put their applications to the local Animal Welfare and Ethical Review Body (AWERB) for review prior to submission and ensure that ethical or welfare issues raised are addressed.

If applicants are proposing to undertake any animal experiments as part of collaborative programmes outside the UK, these experiments must be conducted in a way that conforms to the legal, ethical and normal practices in that country, as well as conforming to the standards (including animal welfare) required in the UK. Where the standards are different, the more rigorous will apply. See [Responsibility in the Use of Animals in Bioscience Research](#), p14.

⁴ Power calculations can be used to calculate the minimum sample size required so that one can be reasonably likely to detect an effect of a given size, or to calculate the minimum effect size that is likely to be detected in a study using a given sample size.

4.2.5 Home Office licences

It is the responsibility of all applicants to ensure that the appropriate Home Office licences are obtained. This will include the requirement that the research applications are approved by the local AWERB. Home Office licences (or amendments to existing licences) do not have to be obtained before the application is submitted to the NC3Rs, but if a contract is awarded, contractors (successful applicants) must have the necessary licences in place before any animal experimentation begins.

4.2.6 Mouse strains

The NC3Rs encourages the archiving and sharing of genetically altered mouse strains as a means of both reducing and refining animal use.⁵ The MRC supports a central repository of mouse strains, the Mouse Frozen Embryo and Sperm Archive (FESA) at MRC Harwell. FESA aims to ensure that valuable mouse strains are safeguarded, that the need to maintain colonies of live mice for long periods of time is reduced, and that the significant investment in engineering strains is capitalised upon fully.

Where there may be a need for the repeated creation of pre-existing genetically modified mouse strains, this must be fully justified. Applicants planning to produce genetically modified mouse strain(s) should investigate whether suitable strains are available via FESA or elsewhere before requesting resources for creating new strains. Applicants planning on creating new genetically altered mouse strains as part of their work should actively consider archiving and sharing these strains via FESA. When archiving and sharing of genetically modified mice is not possible, please clearly state in your application the reasons for this.

Contact FESA: fesa@har.mrc.ac.uk

4.2.7 Use of animals outside of the UK

If a project involves the use of animals outside of the UK, a dated and signed letter of support from all applicants stating the below must be included as a separate PDF attachment to the application:

- They will adhere to all relevant national and local regulatory systems in the UK and overseas.
- They will follow the guidelines laid out in the Responsibility in the Use of Animals in Bioscience Research and ensure that work is carried out to UK standards.
- Before initiation of the proposed research work, appropriate approvals from Institutional and/or central animal ethics committees will be obtained for experimental protocols to be adopted in their projects. Successful proposals may be expected to provide copies of these permissions before funding is released.

⁵ See "[Sharing and archiving of genetically altered mice: Opportunities for reduction and refinement](#)".

- Details on where the animal research will take place (UK or overseas) and through which funder the resources are being sought.

If the research involves the use of rodents outside of the UK, please also complete the ‘**Additional questions on the use of rodents overseas**’ form which is included in the application form as Annex 3.

Additional guidance on conducting and reporting animal research can be found on the [NC3Rs’ Peer review and advice service hub](#).

5. Assessment procedure

Once received, applications to the BGS will be reviewed by the [CRACK IT Advisory Panel](#) within six weeks of the NC3Rs receiving the application. Awards will be made to successful applicants, subject to them signing a non-negotiable agreement with the NC3Rs. Up to two awards can be made each financial year.

The lead applicants are informed by email of the decision of the CRACK IT Advisory Panel approximately one week after the Panel meeting.

The CRACK IT Advisory Panel’s decision is final and is not open to appeal.

Table 4: CRACK IT Advisory Panel scoring criteria

Assessment criteria
1. Potential for BGS funding to progress technology to mTRLs 7-9 (as defined in Table 2)
2. Scale of the market opportunity
3. Value for money and justification for use of funds in achieving deliverables
4. Expertise and track record of the team
5. Eligibility of funding within the de minimis aid criteria
6. Ability to secure independent funding

Membership of the Advisory Panel is published on the NC3Rs Innovation Platform. All panel members sign a confidentiality agreement upon appointment and are expected to abide by the principles set out in the [Code of Practice for members of Council and MRC boards](#).

Members also complete a Declaration of Interest form which is also published on the [NC3Rs Innovation Platform](#).

6. Award process

The NC3Rs leads the awards’ announcements via the [NC3Rs Innovation Platform](#). Award holders may be required to participate in media-related activities regarding the announcements.

BGS awards are made to the lead applicant's organisation which then administers the award and subsequent process requirements including returning signed documentation.

For successful applications, involving more than one organisation, the lead applicant (contractor) must agree to manage the award from the NC3Rs on behalf of the others (the sub-contractors). Sub-contractors negotiate their agreements with the contractor directly.

Applicants must be able to demonstrate that, should they be successful in their application, they have a team in place ready to start working on the project on receipt of the agreement.

Contracts are expected to be finalised and signed **within two weeks** of receipt.

BGS awards are made to the successful applicants subject to them signing a non-negotiable agreement with the NC3Rs. BGS work should commence promptly and within eight weeks of the confirmation of the award from the NC3Rs. Failure to comply will result in the award being terminated.

To ensure rapid commencement of the work, all funding will be provided upfront.

6.1 Important information

The terms and conditions for BGS awards are set out in the agreement between the NC3Rs and the successful applicant (BGS Contractor Agreement).

Agreements:

7. Agreements between the NC3Rs and the successful applicants take the form of standard contract research agreements from the NC3Rs.
8. These agreements are intended to protect and benefit both the NC3Rs and the Challenge winners to ensure the effective delivery of the research.
9. BGS agreements are standard and the NC3Rs will not make changes to them.

7. Post award information

7.1 Intellectual property

Intellectual property (IP) developed within the project is the property of the contractor (successful BGS applicant) and its sub-contractors, as described in the agreement between the NC3Rs and the contractor. One recipient of NC3Rs funding should be nominated as the IP manager for the project. The NC3Rs does not provide a model agreement but suggests as a default that IP arising from the project should be jointly owned by the contractor and its sub-contractors in equal shares. Failing this, they should agree among themselves on the ownership of IP, for example, by adapting one of the [Lambert Agreements](#). Further details on IP can be found in the agreement between the NC3Rs and the contractor.

Although the NC3Rs is not a joint owner of any IP arising from a project, it is a condition of funding from the NC3Rs that work furthering the 3Rs must be made available to the rest of the bioscience sector. The protection of IP through filing of patents should therefore be pursued without unreasonable delay, and access by third parties to 3Rs benefits must be provided through publication and dissemination, or by appropriate licences, royalty-free or royalty-bearing on fair and reasonable terms. The exact arrangements are detailed in the agreement between the NC3Rs and the contractor.

7.2 Project management

The lead contractor will be responsible for ensuring key deliverables of the BGS plan are met within agreed timeframes and will liaise with the NC3Rs to provide an update on progress at quarterly intervals unless otherwise agreed.

7.3 Reporting

All BGS awardees are required to submit a **final report** and a **final expenditure statement (FES)** within three months of the completion/termination date. The final report should describe the work undertaken, the achievements and outcomes of the project and details of how the project advanced the 3Rs. The report template, FES and additional guidance will be sent to all awardees four weeks before the completion date.

Failure to provide the requested report and FES, within the specified timeframe, may result in funding being rescinded. It is the responsibility of the contractor to manage the funds awarded responsibly and any additional costs incurred above the total amount awarded will not be reimbursed.

7.3.1 Researchfish and publications

Award holders are expected to disseminate their results by publishing in appropriate scientific journals and at relevant conferences. The [Research Council UK policy](#) on open access should be adopted. Award holders are required to report research outputs and outcomes on a regular basis using [Researchfish](#). There is a mandatory annual collection period for the submission of data.

The NC3Rs support for the project should be acknowledged on all publications and presentations where such support has been significant. The NC3Rs should be informed of any publications or other promotional material or events arising from the award.

It is the responsibility of the contractors to keep the NC3Rs informed in a timely manner of outputs from the BGS-funded project.

Studies using animals should be reported in accordance with the [ARRIVE guidelines](#) taking into account the specific editorial policies of the journal concerned.

Further information on [Researchfish](#) reporting requirements can be found in [Table 5](#).

Table 5: Researchfish reporting requirements

<p>Who</p>	<p>Compliance with Researchfish reporting is a requirement for every CRACK IT Contractor.</p> <p>The lead contractor/ BGS awardee is ultimately responsible for ensuring his/her Researchfish record is up to date.</p>
<p>When</p>	<p>Contractors can, and should, submit information to Researchfish all year round and after the contract has ended:</p> <ul style="list-style-type: none"> 10. Phase 1: for at least one year 11. Phase 2: for at least five years 12. Single Phase: for at least three years 13. BGS*: for at least five years <p>In line with the Research Councils, the NC3Rs also has an annual collection period.</p> <p>There is also a requirement to update Researchfish when your contract is coming to an end.</p>
<p>What</p>	<p>Details of all outputs, outcomes and impacts, when available, arising from the contract.</p> <p>Particularly, complete the sections on Publications and Replacement, Reduction and Refinement.</p>
<p>Why</p>	<p>Researchfish is one method by which we monitor progress on contracts. Contractors who do not report into Researchfish when requested to do so, or use the system inappropriately, may become ineligible to apply for additional awards from the NC3Rs (and potentially the Research Councils).</p> <p>Researchfish is not a publicly accessible data repository. However, data held in Researchfish may be used by the NC3Rs to populate our website and for production of publications such as our Annual Report.</p>

*For BGS reporting purposes: where a BGS award is made, the reporting requirements noted above will supersede those detailed for Single and Phase 2 awards.