Guidance for MRC Confidence in Concept Scheme Round 8

MRC Confidence in Concept (CiC) Round 8 funding has been obtained by a consortium led by University of Sheffield (TUoS) with Sheffield Children's NHS Foundation Trust (SCH), Sheffield Hallam University (SHU) and Sheffield Teaching Hospitals NHS Foundation Trust (STH).

UPDATE V2.0 21 August 2020

- Key Points To Note viii sponsorship added
- 2.4 sponsorship added

Key Points To Note

i. To help with application development it is required that all applications must also involve appropriate business/commercial/innovation/research manager support from the lead applicant’s host institution. See Contacts.

ii. Due to the volume of applications anticipated, the appropriate business/commercial/innovation/research manager your institution must be contacted by 1 October 2020 with the title and a brief statement on the proposed concept to be taken forward. This is to ensure that applications fit the remit of the scheme, are registered and there is sufficient time to compile the application ahead of the submission date.

iii. A series of online workshops by the University of Sheffield Royal Society Entrepreneur in Residence, Dr Michael Murray, is being run to help applicants better understand device/drug development/industry engagement/IP and commercialisation.

iv. An online information session is planned (anticipated in early Sept 2020). Further details will be circulated and shared via the Sheffield CiC scheme web-page (https://www.sheffield.ac.uk/rs/mrc/cic).

v. Updates to the scheme, including a Frequently Asked Questions, will be published via https://www.sheffield.ac.uk/rs/mrc/cic

vi. Collaborative projects involving one or more CiC Consortium partners are strongly encouraged.

vii. Where projects involve Sheffield Children’s Hospital and Sheffield Teaching Hospitals, these institutions make a 10% contribution (financial or in-kind) to the work that they are carrying out. The two universities have contributed at source; SHU is contributing £30k and TUoS £80k.

viii. Where work with patients is planned it is essential that ethics and sponsorship is considered and initial plans are in place to address these topics (please use ‘the project plan’).

1. What is the purpose of the MRC CiC Scheme?

1.1 MRC CiC is part of the MRC’s Translational Research Strategy and is a component of the MRC/Innovate UK Biomedical Catalyst. The scheme is designed to “accelerate the transition from discovery research in any healthcare area within MRC remit into translational development projects by supporting preliminary work or feasibility studies to establish the viability of an approach”. Details of the MRC’s remit can be found in Appendix 1. If you have questions about
whether your project is within MRC remit, please get in touch with your business / commercial / innovation / research manager.

1.2 The Sheffield CiC Consortium is Sheffield Children’s Hospital NHS Foundation Trust (SCH), Sheffield Hallam University (SHU), Sheffield Teaching Hospitals NHS Foundation Trust (STH) and the University of Sheffield (TUoS).

The Sheffield CiC Consortium uses its MRC CiC award flexibly to support a diverse portfolio of preliminary-stage translational projects. We will aim to support projects across this broad remit. Importantly, the CiC projects selected for support should, by their completion, provide sufficient preliminary data to establish the viability or ‘confidence in concept’ of an approach before more substantive funding is sought for example from the MRC Developmental Pathway Funding Scheme (DPFS) or others such as, but not limited to, NIHR i4i, Wellcome Innovator, or Innovate UK funded initiatives.

1.3 The questions asked in the CiC form are representative of the information requested in more substantive translational funding schemes. Brief, bullet point answers to questions are acceptable. Business / commercial / innovation / research managers at your institution will advise and assist you with questions relating to market, exploitation IP and commercialisation. Due to the number of applications anticipated, these colleagues must be contacted by 1 October 2020. The date business / commercial / innovation / research managers are contacted is captured on the application form.

1.4 The financial support available through CiC is intended to ensure that fundamental science is translated into new therapies, biomarkers, diagnostics and medical devices in line with the MRC’s strategy. The scheme aims to accelerate the transition from discovery science to the early stages of intervention development by supporting preliminary translational work.

1.5 The MRC anticipates that projects submitted to the CiC scheme will have emerged from strong fundamental research. The awards are to address a gap in the funding between discovery research and translational research to develop a product/therapy/diagnostic/device for healthcare benefits. The aim of a CiC award is to generate the data package necessary for a project to be competitive for more substantive follow on funding. Hypothesis driven discovery research is NOT eligible for this funding stream.

1.6 While it is acknowledged that early stage ‘confidence in concept’ work is risky, please note that future awards of MRC CiC monies to the Sheffield consortium rely on the success of previously funded MRC CiC projects. As evidenced, for example, by securing further grants (translational and Innovate UK etc), patent applications, setup of spin-out companies, licencing of know-how and results.

2. Project Development & Eligibility

2.1 Academics, clinical academics and clinicians from TUoS, SCH, SHU and STH are eligible to lead an application for this funding. Collaborative applications are strongly encouraged Projects that do span across institutions must clearly describe the role and workstreams being led by the various collaborating applicants. Where applications are collaborative, a business / commercial / innovation / research manager should also be involved from the collaborating institution(s).

2.2 Project applications should request what is needed to conduct the project. Applications are expected to be £50-75k of directly incurred research costs but, where exceptional costs are anticipated and can be justified, applicants may request up to £100k.

2.3 Projects that received MRC CiC funding in Rounds 1-7 are not eligible for Round 8 funding to continue the work. However, there are some exceptional situations where it may be appropriate
for a previously funded CiC project to re-approach the scheme for support. These are:

- the previously CiC funded project generated results that indicated that there may be merit in taking a **different** approach and this alternative strategy may warrant an application to CiC Round 8
- the previously CiC funded project received consultant advice or reviewer input following an application to a substantive translational grant scheme, and such feedback identified an unanticipated piece of work needed in order to re-apply to that scheme.

**Please seek advice from your institution business / commercial / innovation / research manager before preparing your application.**

2.4 Projects may be up to 12 months in duration. Please carefully consider all pre-work required when planning your start and end dates i.e. recruitment processes, ethics approvals, governance review, sponsorship.

2.5 Projects must be completed by 31 March 2022.

2.6 Given the potentially tight timelines for completing Round 8, appropriate time for receiving ethics and governance approvals and the recruitment of any new staff must be factored into the planning. Reviewers will be looking for confidence that, if successful, the project start quickly and complete by the end date above.

2.7 Please ensure that projects are registered with your business / commercial / innovation / research manager with your host institution by 1 October 2020. A registry of anticipated applications will be maintained by the TUoS along with the title, brief description and date of contact.

2.8 Individual project agreements will be put in place once funding is awarded. The template has been agreed by the Sheffield partners and is available on request to r.m.dwyer@sheffield.ac.uk. Included within the agreement are terms relating to confidentiality and intellectual property (IP). With respect to IP generated by the project, each Party shall own the Arising IP generated by its employees, students and/or agents in the performance of the project and shall ensure that it secures ownership of such Arising IP from its employees, students and agents. Each Party shall co-operate, where required, in relation to the preparation and prosecution of patent applications and any other applications relating to Arising IP.

**MRC have requested that institutions select projects that provide evidence of good translational pathways and do not represent extended discovery projects. While applications will contain an element of risk, they should also demonstrate a viable translational direction and that the unmet medical need and solution proposed will have been discussed with key opinion leaders, practicing clinicians and/or patients.**

Applicants who have not been able to discuss their idea with clinicians, please contact Dr Dipak Patel / Mr Daniel Lawrence (STH) or Dr Gillian Gatenby / Dr Keith Pugh (SCH) who will help identify appropriate clinical staff. Contacts below.

As the MRC CiC is to provide confidence in concept funding of translational ideas, the application form asks many questions required in substantive translational funding schemes including technology readiness levels ([https://ncai.nhlbi.nih.gov/ncai/resources/techreadylevels](https://ncai.nhlbi.nih.gov/ncai/resources/techreadylevels)), IP, prior art, freedom to operate and commercialisation route to market.

The scheme will aim to support and accelerate the earliest stages of research translation across the MRC remit. Example projects may include but are not limited to:

- developments of new therapies (cell-, protein- or small molecule-based)
● improvements in existing therapies
● drug re-profiling
● development of imaging methodologies, assistive technologies, diagnostics or medical devices, including software
● biomarker or in vitro diagnostics

Applicants are required to categorise their project on the CiC application form.

2.9 Successful applications will clearly and succinctly address each aspect of the various application questions and demonstrate through the information provided.

● A clear description of the historic project context. Proposed CiC project details.
● A clear clinical challenge/problem/unmet medical need that underpins the proposed concept for development, how this has emerged from fundamental research and is supported by discussions with key opinion leaders, clinicians and/or patients.
● How the concept to be developed is aligned to the MRC strategy.
● A description of the concept proposed and how this relates to your identified clinical challenge/problem/unmet medical need, its current development stage (Technology Readiness Level, TRL) and the anticipated beneficiaries/customers.
● The expertise and limitations of the project team. The areas where the team has the necessary translational research skills and knowledge and areas where additional input is needed, including how this additional input will be accessed.
● Information on engaged industry partners or why none have been engaged at this stage.
● A good, clear project plan (and Gantt) with specific, measurable, achievable, realistic and timely (SMART) milestones and objectives.

Cross-institutional projects will need to demonstrate where there is collaborative working e.g. where co-applicants are leading discreet work-streams within the project.

● Clear project outputs and how the information and data obtained will help with taking the project forward to the next stage of development funding.

Risk associated with the CiC project

● Clear appreciation of the risks and uncertainties that may affect the anticipated output and how these could be mitigated.

Follow-on plans post CiC funding

● A clear and feasible follow-on package of work quoting specific relevant target funding schemes and anticipated submission dates
● That thought has gone into how your concept will get to market and/or enable patient benefit
● That credible external partners including industry, if not engaged at this stage, are on the radar

Intellectual Property

● An appreciation of what, if any, IP has been disclosed), the IP the proposal will generate that may be registrable or, if there is no proprietary IP, a realistic route to market.
● that there is likely to be freedom to operate and that the proposed IP is novel

Market and Competition

● Knowledge of the accessible market - i.e. the proportion of the market that your innovation has the potential to access or achieve, not simply the total market size for any intervention in the relevant area.
● Awareness of any competing products already in development or on the market as well how your concept will be distinguished from these

Costs

● Costs should be well defined and justified, paying attention to cost eligibility guidelines
Partner contributions should be accurately calculated and articulated. If this is not done adequately, there can be a significant delay in releasing funds should an application be successful.

Upcoming funding opportunities (with example deadlines) that may represent possible means to progress the work supported by an MRC CiC award include, but are not limited to:

- **MRC DPFS outline deadlines** – November 2021 (anticipated), March 2022, July 2022 (anticipated).
- **BBSRC Follow-on fund**: October 2021 (anticipated)
- **Wellcome Innovator Awards**: no deadline
- **NIHR Research for Patient Benefit** – November 2021 (anticipated), March 2022 (anticipated), July 2022 (anticipated)
- **NIHR Invention for Innovation (i4i) and i4i connect** – Nov 2021 (anticipated), Apr 2022 (anticipated)
- Charitable funding – anticipated schemes should be specified in the application.

Please check the individual funder’s eligibility criteria to ensure that your project is suitable.

2.10 It is appreciated that word limits are tight on the various questions in the CiC application form. **Applicants however must remain within the specified word count for each section. Any text exceeding the limit will be removed before review.** Additional information using a minimum of font size 11 can be supplied in an optional, 2page “Information Annex” located at the end of the application form.

2.11 Eligible costs include:
- directly incurred research costs associated with the project.
- staff conducting the research, but not senior staff (including the lead applicant or co-applicants) in a supervisory capacity. Standard practice is for research assistants’ time to be costed into applications.
- senior staff should not be costed unless they are undertaking research activity that cannot be performed by anyone else. Timesheets recording such work will be required.
- technical and clinical project-related consumables and equipment (IT equipment such as computers and tablets will only be funded in very exceptional circumstances)
- subcontracted consultancy or other development services
- market assessment
- travel to collaborators/contractors and subsistence

2.12 Ineligible costs include:
- indirect, estates and overhead costs (this funding scheme aims to pump prime activity for larger grant applications, hence directly incurred costs are the only eligible costs)
- senior staff (directly allocated) salary costs where the activities can be undertaken by others
- entire translational projects
- staff between posts/funding (i.e. as “bridging” funds) or PhD studentships
- continuation of normal research grants
- costs of HR processes and recruitment
- stationary/paper
- costs relating to protection of IP
- research administrator, coordinator or manager time unless specifically undertaken roles outside their normal functions and specific to the scientific activities of the proposal
- capital equipment purchases that equal or exceed £10k
- impact costs (i.e. publication and open access costs, conference attendance for dissemination purposes, dissemination costs for websites or newsletters except when used to provide direct feedback to study participants)
● salary costs will not be paid as personal salary (as with consultancy).

2.13 Institutional Contributions
Where a CiC project is led by, or includes work conducted in collaboration with SCH and/or STH, these institutions will make a 10% institutional contribution (financial or in kind) to their eligible research costs. In-kind contributions such as, but not limited to, clinical research time, direct research delivery, the cost of market assessment or access to specialised equipment.

2.14 A CiC project led by, or including work conducted in collaboration with, any of the Sheffield CiC Consortium members the application must:
● be registered with each relevant research office
● contain costs provided by each relevant research office
● be signed by a representative from each relevant research office.

2.15 TUoS, as institutional holder for the overall award of MRC CiC Round 8 monies, must adhere at all times to its Financial Directives for the expenditure of funding and all projects involving TUoS must be costed and approved using the Costing and Awards Tool.

2.16 Applications with industrial collaborators are eligible for the scheme. Standard MRC guidelines and IP arrangements for industrial collaboration will apply. For further information please see http://www.mrc.ac.uk/innovation/mrc-industry-collaboration-agreement-mica/ and contact your business / commercial / innovation / research manager for guidance.

3. Monitoring and Training

3.1 Prospective applicants (and/or members of their team where applicants are unable to join sessions) are strongly encouraged to participate in training being provided by Dr Michael Murray, Royal Society Entrepreneur in Residence. Information regarding these workshops will be circulated and will be listed on the TUoS CiC web-page (https://www.sheffield.ac.uk/rs/mrc/cic).

3.2 TUoS is required to monitor how the scheme funds are used and to follow project progress, providing MRC with a progress report every six months (including completion of the annual ResearchFish return), plus a final accounting and brief report on the outcomes of funded projects at the end of the programme.

3.3 By accepting the award, the applicant(s) and, if appropriate, their Sheffield consortium partner host organisation(s) agree to provide a sufficiently detailed (with timesheets where appropriate) Interim Report, dependent on length of project, (one is expected, at the half-way stage); a Final Report upon completion; and the post-award follow-up Reports that will provide information to be captured via ResearchFish. A presentation to the external review panel members may be required regarding progress with either the interim and/ or final report.

3.4 By accepting the award, the applicant(s) agree to engage with their local professional support staff and/or to work with TUoS Research Services to monitor the progress of the project to allow the reporting of outcomes back to the funder. This will include assisting with the development of funder and/or case study reports as appropriate.

3.5 By accepting the award, the applicants agree to engage with training provided by their local professional support staff and/or the TUoS Research Services and business / commercial / innovation / research manager.

3.6 TUoS reserve the right to recover funds where there is evidence that a project is failing to adhere to the agreed application. Similarly, funds may be recovered where these have not been spent in accordance with the application, unless a change has been agreed in writing.
3.7 This funding may only be used to support eligible project activities.

4. Application Process

4.1 Application for MRC CiC funding is a single stage process open to SCH, SHU, STH and TUoS for projects with a MRC healthcare remit. Applications can only be made via the MRC CiC application form.

4.2 Step by Step Guide to Application Process

- Register your project with the research office of each partner institution (SCH, SHU, STH, TUoS), who will in turn provide information to the central TUoS registry.
- **All Primary Investigators must provide the title, a brief summary of their project and discuss their project with the business / commercial / innovation / research managers by 1 Oct 2020 to receive advice and guidance.**
- Meet with the appropriate professional services staff for your institution to discuss the application. See the Contact section.
- Email a signed PDF and an unsigned Word version of the application form to RSRResearchGrowth@sheffield.ac.uk by 4pm Thursday 3 December 2020.
- Applications will be assessed for application completeness, adherence to the word limit and fit to the CiC scheme by internal experts.
- Those deemed in scope will be reviewed by a panel of external experts bound by non-disclosure agreements and discussed at the panel meeting alongside senior academic and clinical leaders from each of the four partner institutions. Conflicts of interest will be eliminated prior to full applications being shared externally.
- Funding decisions are expected by end Feb 2021 and will be communicated by TUoS Research Services.

4.3 Applications should address the points detailed/raised in each section of the application form.

4.4 Application Submission

Email a signed PDF and an unsigned Word version of the application form to RSRResearchGrowth@sheffield.ac.uk.

5. Contacts

5.1 Scheme Organisation

| Research Services, TUoS          | Rachel Dwyer             | r.m.dwyer@sheffield.ac.uk |

5.2 Sheffield Children’s NHS Foundation Trust

| Directorate of Research & Innovation | Gillian Gatenby       | Gillian.Gatenby@nhs.net  |
|                                      | Keith Pugh             | keith.pugh1@nhs.net     |

5.3 Sheffield Hallam University

| Research & Innovation Services     | Sarah Molton          | S.Molton@shu.ac.uk     |
|                                    | Georgia Hatzigiannidou | G.Hatzigiannidou@shu.ac.uk |

5.4 Sheffield Teaching Hospitals NHS Foundation Trust

| Clinical Research & Innovation Office | Dipak Patel | dipak.patel12@nhs.net |
|                                      | Dan Lawrence  | Daniel.Lawrence12@nhs.net |

5.5 The University of Sheffield business / commercial / innovation / research managers

| Faculty of Medicine, Dentistry & Health | Sue Smith         | sue.smith@sheffield.ac.uk |

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| Faculty of Engineering | Stephen Pyke  
|                       | Hannah Askew  
| Faculty of Science   | Richard Senior (life sciences)  
|                       | Joe Gaunt (physical sciences)  

For TUoS enquiries outside the faculties listed above, please contact the TUoS business/commercialisation manager allocated on submission of your Initial Commercial Enquiry (ICE) form.
Appendix 1: Information relating to MRC remit

MRC supports research across the entire spectrum of medical sciences
https://mrc.ukri.org/

The MRC’s mission is to support research and skilled researchers to improve human health, advance the dissemination of knowledge and technology for the benefit of society and the economy and engage with the public to promote medical research.

MRC supports research relevant to human health and disease – from fundamental discovery science in non-clinical, clinical, and population settings, through to development and initial testing of new treatments or preventive measures – and focuses on the areas of fundamental science most important for health. MRC develops routes into industrial and public sector translation of human health research.

The scope of MRC-funded research is not limited to the development of new therapeutic drugs. These account for just 32 per cent of medical products reported. New surgical techniques, behavioural and physical therapies and approaches for disease prevention are all developed as a result of MRC research. Likewise technological advances for disease monitoring and diagnostics, ways to guide treatment decisions and predict patient outcomes, are also impacting positively on health care.

MRC will fund innovation in medical technologies where it is driven by the biomedical and clinical sciences rather than engineering and physical sciences, for example, the application of standard imaging methodologies in the study of disease states.

Where there is overlap with the other research councils, the MRC CiC will NOT fund

- important underpinning questions in biology or normal human physiology, which can advance knowledge and innovation across many sectors, or
- seeks to develop new tools, technologies and approaches that have broad application across bioscience research, e.g. data rich and systems biology, or
- informs / is informed by research into animal or plant health
- engineering-led project work to solve technical problems

https://mrc.ukri.org/funding/science-areas/translation/
Figure 1 MRC’s Research Funding Schemes across the translational pipeline

EDCTP • European and Developing Countries Clinical Trials Partnership (Infections)
GACD • Global Alliance for Chronic Diseases
JGHT • Joint Global Health Trials Scheme (with WT, DH and DFID)
HSRI • Health Systems research Initiative (with WT, DH, DFID and ESRC)
PHIND • Public Health Intervention Development Scheme
DPFS • Developmental Pathway Funding Scheme