2023

Healthy Longevity Catalyst Awards (HLCA)

PUBLIC DOCUMENT AND APPLICATION GUIDE

February 2023

Organised by:

Ministry of Health Singapore (MOH)

Supported by:

National Research Foundation (NRF)

In Collaboration with:

The United States National Academy of Medicine (NAM) and

the global collaborators of the Healthy Longevity Global Grand

Challenge

IMPORTANT NOTICES

1.1   For the avoidance of doubt, this Public Document and Application Guide for the Healthy Longevity Catalyst Awards (HLCA) shall be subject to the important notices for applicants as set out in the NMRC Research Grant Terms and Conditions and its Annex: Additional Terms and Conditions for Projects Funded under the National Innovation Challenge on Active and Confident Ageing (NIC on Ageing).
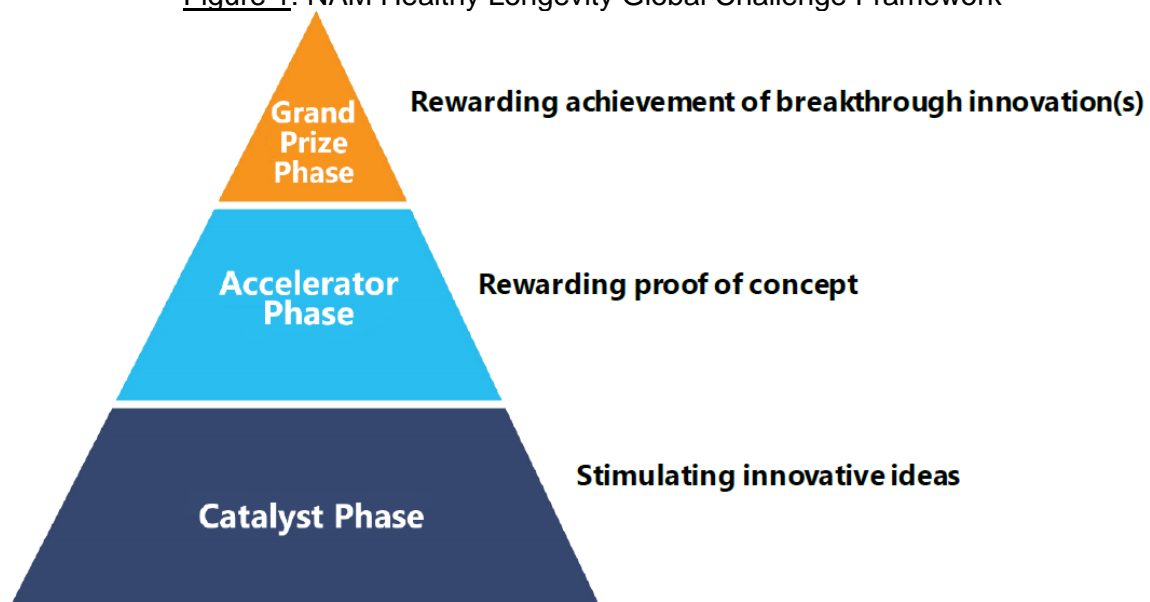
INTRODUCTION – HEALTHY LONGEVITY GLOBAL GRAND CHALLENGE

Healthy Longevity Global Grand Challenge

2.1   The Healthy Longevity Global Grand Challenge, launched by the United States National Academy of Medicine (NAM), is a worldwide movement to improve physical, mental, and social well-being for people as they age. The initiative has two components: (i) the Global Roadmap for Healthy Longevity, an evidence-based report authored by an international commission on the challenges and opportunities presented by global ageing; and (ii) the Healthy Longevity Global Competition, a series of awards and prizes to catalyze breakthrough innovations to extend the human healthspan. This document focuses on the second component.

2.2   The Global Competition is a multi-year, multi-million dollar international competition seeking bold and transformative innovations to extend human health and function later in life. The Global Competition employs a progressive model of awards and prizes, as seen in Figure 1:

Figure 1: NAM Healthy Longevity Global Challenge Framework

Catalyst Phase (originally 2020-2022; **now extending to 2025)**
- Catalyst Awards to support bold, innovative ideas to extend the human healthspan.
- Ideas may originate from any field(s) and focus on any stage of life provided they promote health as people age.
- As at the end of 2022, the NAM and its global collaborators have issued 429 **Catalyst Awards** worth over **$21 million USD.**

- An annual Global Innovator Summit provides awardees with an opportunity to showcase their work and connect with fellow innovators, researchers, policymakers, and potential investors around the world.

Accelerator Phase (2021-2025+)
- Accelerator Awards will reward Catalyst Awardees and Finalists who have made significant progress on advancing their ideas, and preferably achieved proof of concept.
- Accelerator Awards may be worth **$185,000 to $1 million USD, or more**, and may include monetary and in-kind supports. Award specifics vary by sponsor.
- Accelerator sponsors currently include Johnson and Johnson Innovation, Eisai, and the European Investment Bank (in partnership with kENUP Foundation). Additional sponsors may be added along the way.
- The Accelerator Phase is administered by the NAM.

Grand Prize Phase (Beyond 2025)
- One or more grand prizes of up to **$5 million USD** each will be awarded for achievement of a breakthrough innovation(s) that extends the human healthspan.
- The Grand Prize Phase will be open to anyone and administered by the NAM.

Healthy Longevity Catalyst Awards

2.4   As part of the Healthy Longevity Global Grand Challenge, the Healthy Longevity Catalyst Awards (HLCA) will reward bold, new, potentially transformative ideas to improve the physical, mental, or social well-being for people as they age, and in a measurable and equitable way. In particular, we seek ideas that will extend the human health span through innovations in disease prevention, biology, mobility and function, social connectedness, productive longevity and more. Ideas could focus on early-, mid-, or late-life, as long as it ultimately promotes health as people age.

TOPIC AREAS

3.1   **While the Catalyst Awards is open to all applications relating to the broad topic of healthy longevity, applications that are focused on Cognition will be prioritised for funding.** Examples include projects related, but not limited to, topics on cognitive decline and impairment, encouraging or optimizing senior learning, etc. Applicants are also encouraged to consider proposals with multi-disciplinary themes. For instance, twinning of Cognition as the main topic/focus area with other disciplines or subjects like technology and social sciences.

GUIDELINES AND CONSIDERATIONS

4.1   Project Teams must be willing to collaborate with the Grantor or Grantor's Affiliates to ensure that proposed solutions are flexible, extensible and based on open data standards used by organisations in Singapore. This is to facilitate future enhancements, information exchange and backend integration of services and functionality, to both existing and future systems.

ELIGIBILITY

General Eligibility

5.1   HLCA is open to teams representing public and/or private sector institutions or organisations across all disciplines. Individuals are not eligible to apply. While there is no restriction on the nationality of members in the project team, the entity represented must be legally registered in Singapore. Consortiums with Singapore-registered entities are also eligible to apply.

5.2   Please note that the HLCA is targeted at supporting new and exploratory seed projects, rather than extensions of existing projects (unless the current proposal is to translate findings from an earlier project that has already achieved proof of concept). Where there are new and transformative ideas resulting from project offshoots and applicants would like to submit a proposal for HLCA, applicants are required to declare in the HLCA application (a) whether the proposal is part of a larger project and its funding source(s); and (b) explain if there are any overlaps between the current proposal and their existing funded project(s). Please refer to Section 'Other Attachments' template, Section (II) Other Support for detailed instructions.

GUIDELINES AND CONSIDERATIONS

Project Team Composition

5.3   Applicants for the Healthy Longevity Catalyst Awards may form a Project Team comprising members from multi-disciplinary (e.g. pairing medical and technology, engineering) backgrounds.

5.4   Applicants are expected to form their own Project Teams to participate in the Healthy Longevity Catalyst Awards. The Grantor reserves the right to disqualify or reject any Project Team at any time in the event of the withdrawal of any member and his/her affiliate institution from the Project Team.

Lead Principal Investigator

5.5   Each Project Team must appoint a Lead Principal Investigator (Lead PI) to oversee and coordinate the implementation of the Research during the funding period of the Research.

5.6   The Lead PI will serve as the primary point of contact with the Grantor for the purpose of the Healthy Longevity Catalyst Awards. The Lead PI shall make all reasonable efforts to ensure that all Institutions, Investigators and Collaborators in the same Project Team are informed of all matters relating to the Grant.

5.7   The Lead PI must reside in Singapore for at least six (6) months in each calendar year over the duration of the funding period of the Research.

5.8   For administrative purposes, the Project Teams shall identify a Host Institution (HI) with the following roles:

- Host Institutional Director of Research (HI DOR)
- Host Institution Office of Research (HI ORE)
- Host Institution Finance Officer (HI Finance)
- Host Institution Human Resources Officer (HI HR).

If awarded the Grant, the HI shall receive the Funding on behalf of the Project Team. The HI shall in turn make funding arrangements with the other Partner Institutions.

SUPPORT AND FUNDING

Research Funding

6.1   Funding support of up to S$200,000 per project, inclusive of 30% indirect costs, will be provided for a period of up to two years. **Only Singapore-registered Institutions[1] that are institutes of higher learning (IHLs) or non-profit entities, including public healthcare providers, may qualify for support for indirect costs**.

6.2   Project Teams may refer to the Terms and Conditions which is available for download from the National Medical Research Council (NMRC) webpage at (https://go.gov.sg/nmrc-grants-tnc/) for more information. The actual funding quantum for selected Research will be determined upon assessment of the proposal submitted by the applicant.

6.3   All Research must be conducted in Singapore and Funding shall not flow out of Singapore to support overseas entities, including Collaborators.

6.4   The relevant Project Teams will be notified by the Grantor if they are shortlisted for the award of the Grant. Funding shall be granted subject to the mutual agreement between the relevant Project Teams and the Grantor on the terms and conditions of the Grant as set out in a Letter of Award.

6.5   Funding will be administered and reimbursed through the NIC Programme Office.

APPLICATION SUBMISSION

General Instructions

7.1   Capitalised expressions used without definition shall have the meanings assigned to them in the Public Document and Application Guide for the Healthy Longevity Catalyst Awards, as well as the NMRC Research Grant Terms and Conditions and its Annex: Additional Terms and Conditions for Projects Funded under the National Innovation Challenge on Active and Confident Ageing (accessible under clause 6.2 above) unless otherwise expressly stated.

7.2   For the avoidance of doubt, all applicants are assumed to have fully read and understood the Public Document and Application Guide for the Healthy Longevity Catalyst

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[1] The host institution must be registered in Singapore with the Accounting & Corporate Regulatory Authority (ACRA).

Awards and the important notes set out on the README document to apply for the Healthy Longevity Catalyst Awards.

7.3   To submit an application on the Integrated Grant Management System (IGMS), PIs are required to obtain a CorpPass from your institution and this will be used to access IGMS. For more information on how to register your institution's representative as a CorpPass admin or obtain a CorpPass, please visit www.corppass.gov.sg.

If your institution/organisation has not created an institutional account with IGMS, please email Tricia_Teo@moh.gov.sg **at least two weeks before the submission deadline** with the following details:
-    Full Name of Company:
-    Local Company / Foreign Company:
-    Public Company / Private Company:
-    UEN (for Local Company) / Unique Identifier (for Foreign Company):

The Grant Manager will inform you of the next steps.

7.4   The Lead PI, Co-Investigator(s) and Collaborator(s) must fulfil the eligibility criteria specified under Table 1 of this document.

Table 1: Project Team – Role and Eligibility Criteria

Role	Definition	Eligibility criteria
Lead PI	An individual who is expected to be actively involved in overall project management and accountable for deliverables.	He/She must hold a primary appointment in a local public/private institution and salaried by the institution.
Co-Investigator	An individual involved in the scientific development and execution of the project. A co-Investigator typically devotes a higher percentage of effort to the project compared to a collaborator and is considered a key research personnel of the *"Research Team"*. There is no limit on the no. of participating co-Is.	He/She should be a salaried employee of a local public/private institution.
Collaborator	An individual involved in the scientific development and execution of project. A collaborator typically devotes only a specific percentage of effort to the project. There is no limit on the no. of participating collaborators.	He/She can be from local/overseas/public/private institutions.

7.5   The PI should prepare and submit only one application according to the instructions in the 'README' file **using the following templates available on the IGMS**:
(i)   Research proposal
(ii)   CV template (PI, Co-I/Collab)
(iii)   Other Attachments Template (Signatories and Other Support)

Applications that do not adhere to the requirements may be removed from consideration.

7.6   For reference, the application templates and guides can be downloaded from the NMRC website, under the section for the Healthy Longevity Catalyst Awards, as well as the IGMS during the period of grant call.

7.7   Any softcopy document must be uploaded to IGMS at each uploading tab either in Word DOC or PDF format (please do not submit scanned PDF format except for signatories). Please adhere to the number of pages where specified and reformat softcopy such that all blank or irrelevant pages are removed. The applicants are required to complete the grant submission using the IGMS online submission system.

7.8   The applicants are required to complete all sections in the IGMS and indicate 'NA' where a particular section is not application.

7.9   Once you have completed your application form in IGMS, please download a copy for your safekeeping (please refer to the IGMS application guide for instructions).

7.10   **Resubmission attempts are capped at one time. Funding is not guaranteed for resubmitted proposal.** (Resubmission refers to proposals resubmitted based on Reviewers' comments. It is not a re-written proposal from a new perspective. If more than 50% of the proposal is to be revised, it should be submitted as a new application).

7.11   **PI's CV is limited to 3 pages. Co-Investigators' and Collaborators' CV is limited to 1 page. Please indicate NA if the required information is not applicable. Please take note that the NIC Programme Office (NICPO) will not be responsible for any missing information not provided in the CV.**

7.12   Applicants must not use a font smaller than **Arial font size 11** for all attachments/texts.

7.13   Plagiarism (without permission from author or reference made to source) will be referred to HI ORE for investigation and may be subjected to disciplinary actions.

7.14   Refer to Appendix 1 for details on Health Research Classification System (HRCS) to complete "Field of Research" in IGMS.

7.15   Refer to Appendix 2 for a checklist on Study Design and Statistical Considerations to complete "Methodology and Implementation Plan" section in the research proposal.

Submission of Application

7.16   It is mandatory for all applications to be submitted online via **IGMS** by **3 April 2023, 5pm.** Internal Office of Research submission deadlines may apply. Please check with your Office of Research (ORE) for more information.

7.17   *For Host Institution Offices of Research (HI ORE) to take note*: Please ensure that all submissions are endorsed by the corresponding Host Institution's Director of Research (DOR) via IGMS by **3 April 2023, 5pm**. We will not accept any late submissions or submissions without endorsement from the . Please note that any clarifications sought by the DORs/HI OREs will need to be addressed by the PI prior to submission by **3 April 2023, 5pm.**

7.18   The NICPO reserves the right to reject the application if:
- Any of the required documents was not submitted
- Wrong template (e.g. outdated, different programme's) was used for any of the required documents (please use latest templates as available in IGMS)
- Any of the Proposal or CV documents exceeds the page limits

7.19   Project Teams should ensure that all information contained in the Applications and any other information submitted to the Grantor relating to the Healthy Longevity Catalyst Awards is complete, accurate and not misleading. The Grantor reserves the right to reject any requests for additional funding or any changes in the Research or requested funding after the Project Proposal has been submitted to the Grantor.

7.20   No late submission or revision to the submitted application will be entertained after the closing date and time.

Ethics considerations

7.21   Project teams are accountable for the safety and well-being of human subjects during the course of the Research and be responsible for the submission of any applications required for ethics approval before the commencement of human/animal research activities, if necessary.

7.22   PI is required to make Ethics Declarations via IGMS, by selecting the relevant ethics categories that are applicable for the research/study. While Ethics approval(s) is not mandatory at the point of application, these will be required if awarded, before the commencement of project.

EVALUATION AND AWARD

Evaluation

8.1   Applications will be evaluated by an evaluation panel comprising evaluators from multidisciplinary backgrounds, including representatives from MOH.

8.2   The criteria listed below shall be used for the evaluation of the Applications.

Component	Evaluation Criteria
Innovativeness	The extent to which the proposed idea challenges existing paradigms and employs new methodologies or concepts.
Potential for Impact	The extent to which the proposed idea may have a significant impact on the physical, mental, or social well-being of people as they age.
Quality	The extent to which the proposed idea and the research methodology are clearly explained and includes a compelling or well-defined outcome metric.
Scope	The extent to which the proposed idea represents a challenge impacting the entire field, and not solely the interests of the applicant.

8.3   The evaluation panel reserves the right to reject any or all Applications submitted for the Healthy Longevity Catalyst Awards, without being obliged to give any reason thereof.

Moderation

8.4   Where an Application is selected by the evaluation panel for consideration for award, the Project Team, through the Lead PI and HI ORE, will be notified. The terms of the Research, Milestones, KPIs and Funding quantum may be adjusted by the Grantor in agreement with the Project Team.

Award

8.5   The final decision to award the Grant will be made by the Grantor on the evaluation panel's recommendation. The Grantor and the evaluation panel shall not be obliged to enter into any correspondence with any Institution, Investigator or Collaborator regarding reasons for non-acceptance of an Application.

Progress and Final Reports

8.6   Awarded Project Teams will be required to submit to the Grantor annual progress reports as stated in the Letter of Award in relation to all project specific milestones and KPIs, the progress of implementation and any challenges that may impede progress.

8.7   Awarded Project Teams will also be required to submit a final report at the end of the funding period of the project detailing the achievements, learnings made and whether the project has met the desired outcome(s) of the challenge statement. Project Teams should also articulate any plans to bring the project forward (for example, through seeking alternative sources of funding to continue the project or bring it forward into the next phase).

IMPORTANT DATES TO NOTE

9.1   The timeline for key activities under the Healthy Longevity Catalyst Awards is set out below.

Activity	Date
Announcement of Round 4 of the Healthy Longevity Catalyst Awards	February 2023
Public Briefing	22 February 2023
Call for Applications	27 February 2023
Deadline for Project Proposal Submission	3 April 2023
Announcement of Results	September 2023

CONTACT DETAILS

10.1   Any enquiries regarding the NIC and/or the Healthy Longevity Catalyst Awards should be emailed to NIC_Ageing@moh.gov.sg.

HEALTH RESEARCH CLASSIFICATION SYSTEM

The Health Research Classification System is a bespoke system for classifying the full spectrum of biomedical and health research - from basic to applied - across all areas of health and disease. It was developed by the UK Clinical Research Collaboration Partners. It is supported by an online reference source and manual - http://www.hrcsonline.net/".

Health Categories

Category	Includes
Blood	Haematological diseases, anaemia, clotting and normal development and function of platelets and erythrocytes
Cancer	All types of cancers (includes leukaemia)
Cardiovascular	Coronary heart disease, diseases of the vasculature and circulation including the lymphatic system, and normal development and function of the cardiovascular system
Congenital Disorders	Physical abnormalities and syndromes that are not associated with a single type of disease or condition including Down's syndrome and cystic fibrosis
Ear	Deafness and normal ear development and function
Eye	Diseases of the eye and normal eye development and function
Infection	Diseases caused by pathogens, acquired immune deficiency syndrome, sexually transmitted infections and studies of infection and infectious agents
Inflammatory and Immune System	Rheumatoid arthritis, connective tissue diseases, autoimmune diseases, allergies and normal development and function of the immune system
Injuries and Accidents	Fractures, poisoning and burns
Mental Health	Depression, schizopnrenia, psychosis and personality disorders, addiction, suicide, anxiety, eating disorders, learning disabilities, autistic spectrum disorders and studies of normal psychology, cognitive function and behavior
Metabolic and Endocrine	Diabetes, thyroid disease, metabolic disorders and normal metabolism and endocrine development and function
Musculoskeletal	Osteoporosis, osteoarthritis, muscular and skeletal disorders and normal musculoskeletal and cartilage development and function
Neurological	Dementias, transmissible spongiform encephalopathies, Parkinson's disease, neurodegenerative diseases, Alzheimer's disease, epilepsy, multiple sclerosis and studies of the normal brain and nervous system
Oral and Gastrointestinal	Inflammatory bowel disease, Crohn's disease, diseases of the mouth, teeth, oesophagus, digestive system including liver and colon, and normal oral and gastrointestinal development and function

Renal and Urogenital	Kidney disease, pelvic inflammatory disease, renal and genital disorders, and normal development and function of male and female renal and urogenital system
Reproductive Health and Childbirth	Fertility, contraception, abortion, *in vitro* fertilisation, pregnancy, mammary gland development, menstruation and menopause, breast feeding, antenatal care, childbirth and complications of newborns
Respiratory	Asthma, chronic obstructive pulmonary disease, respiratory diseases and normal development and function of the respiratory system
Skin	Dermatological conditions and normal skin development and function
Stroke	Ischaemic and haemorrhagic
Generic Health Relevance	Research applicable to all diseases and conditions or to general health and wellbeing of individuals. Public health research, epidemiology and health services research that is not focused on specific conditions. Underpinning biological, psychosocial, economic or methodological studies that are not specific to individual diseases or conditions
Other	Conditions of unknown or disputed aetiology (such as chronic fatigue syndrome! myalgic encephalomyelitis), or research that is not of generic health relevance and not applicable to specific health categories listed above

Overview of the Research Activity Codes

1   Underpinning Research
- 1.1   Normal biological development and functioning
- 1.2   Psychological and socioeconomic process
- 1.3   Chemical and physical sciences
- 1.4   Methodologies and measurements
- 1.5   Resources and infrastructure (underpinning)

2   Aetiology
- 2.1   Biological and endogenous factors
- 2.2   Factors relating to physical environental
- 2.3   Psychological, social and economic factors
- 2.4   Surveillance and distribution
- 2.5   Research design and methodologies
- 2.6   Resources and infrastructure

3   Prevention of Disease and Conditions, and Promotion of Well-Being
- 3.1   Primary prevention interventions to modify behaviours or promote well-being
- 3.2   Interventions to alter physical and biological environmental risks
- 3.3   Nutrition and chemoprevention
- 3.4   Vaccines
- 3.5   Resources and infrastructure (prevention)

4   Detection, Screening and Diagnosis
- 4.1   Discovery and preclinical testing of markers and technologies
- 4.2   Evaluation of markers and technologies
- 4.3   Influences and impact
- 4.4   Population screening
- 4.5   Resources and infrastructure (detection)

5   Development of Treatments and Therapeutic Interventions
- 5.1   Pharmaceuticals
- 5.2   Cellular and gene therapies
- 5.3   Medical devices
- 5.4   Surgery
- 5.5   Radiotherapy
- 5.6   Psychological and behavioural
- 5.7   Physical
- 5.8   Complementary
- 5.9   Resources and infrastructure (development of treatments)

6   Evaluation of Treatments and Therapeutic Interventions
- 6.1   Pharmaceuticals
- 6.2   Cellular and gene therapies
- 6.3   Medical services
- 6.4   Surgery
- 6.5   Radiotherapy
- 6.6   Psychological and behavioural
- 6.7   Physical
- 6.8   Complementary
- 6.9   Resources and infrastructure (evaluation of treatments)

7   Management of Diseases and Condition
- 7.1   Individual care needs
- 7.2   End of life care
- 7.3   Management and decision making
- 7.4   Resources and infrastructure (disease management)

8   Health and Social Care Services Research
- 8.1   Organisation and delivery of services
- 8.2   Health and welfare economics
- 8.3   Policy, ethics and research governance
- 8.4   Research design and methodologies
- 8.5   Resources and infrastructure (health services)

Research Activity Codes

1. Underpinning Research	Research that underpins investigations into the cause, development, direction, treatment and management of diseases, conditions and ill health
1.1 Normal biological development and functioning	Studies of normal biology including • genes and gene products • molecular, cellular and physiological structures and function • biological pathways and processes including normal immune function • developmental studies and normal ageing • bioinformatics and structural studies • development and characterisation of model systems
1.2 Psychological and socioeconomic process	Studies that do not address health directly but cover issues that may have a bearing on health and well-being including • perception, cognition and learning processes • social and cultural beliefs • individual or group characteristics and behaviours • politics, economies and urban development • development and characterisation of model systems
1.3 Chemical and physical sciences	Research in chemical and physical sciences that may lead to the future development of diagnostic tools or medical treatments including • bioengineering and biophysics • chemical structures, interactions and properties • molecular modelling • material science
1.4 Methodologies and measurement	Development of novel underpinning research measures and analytical methodologies including • development of statistical methods and algorithms for genomic analysis • development of mapping methodologies and novel data comparison methods • development of biological, psychological and socioeconomic research measures
1.5 Resources and infrastructure (underpinning)	• development and/or distribution of resources for use by the research community including equipment, cell lines, DNA banks, and genomic and proteomic sequence resources • infrastructure to support research networks, consortia and centres

Research Activity Codes

2 Aetiology	Identification of determinants that are involved in the cause, risk or development of disease, conditions and ill health
2.1 Biological and endogenous factors	Identification and characterisation of endogenous factors known or suspected to be involved in the cause, risk or development of disease, conditions or ill health including • genes and gene products, molecular, cellular and physiological structures and functions • biological factors linked to ethnicity, age, gender, pregnancy and body weight • endogenous biological factors or pathways involved in responses to infection or damage by external factors • metastases, degenerative processes, regeneration and repair • complications, reoccurrence and secondary conditions • bioinformatics and structural studies • development and characterisation of models
2.2 Factors relating to physical environment	Environmental or external factors associated with the cause, risk or development of disease, conditions or ill health including • physical agents, occupational hazards, environmental surroundings, radiation and pollution • chemicals and nutrients • infection by pathogens and studies of infectious agents
2.3 Psychological, social and economic factors	Research into psychological conditions, or research into the cause, risk or development of disease, conditions or ill health associated with social, psychological and economic factors including • individual or group behaviours and lifestyle • cultural or religious beliefs or practices • ethnicity, age and gender differences • socioeconomic factors
2.4 Surveillance and distribution	Observational studies, surveys, registries. and studies that track incidence, prevalence, morbidity, co-morbidity and mortality including ongoing monitoring of large scale cohorts
2.5 Research design and methodologies (aetiology)	Development of aetiological and epidemiological research designs, measures and methodologies including • methodological innovation and modelling complex epidemiological data • development and evaluation of novel research designs • development of epidemiological research measurements includingoutcome measures • development of analytical and statistical methods to understand disease cause, susceptibility and risk including genetic linkage and association studies
2.6 Resources and infrastructure (aetiology)	• development and/or distribution of resources for general use by the research community including equipment, cell lines, tissue and DNA banks, and genomic and proteomic sequence resources

	• infrastructure to support research networks, consortia and centres

3 Prevention of Disease and Conditions, and Promotion of WellBeing	Research aimed at the primary prevention of disease, conditions or ill health, or promotion of well-being
3.1 Primary prevention interventions to modify behaviours or promote wellbeing	Development, implementation and evaluation of interventions to modify personal or group behaviours and lifestyles affecting health and well-being including • risk behaviours associated with diet, tobacco use, physical activity, alcohol consumption, sexual health and substance misuse • age, gender, cultural or religious practices • public health policy, health communication and educational interventions • behavioural, psychological, social and physical interventions
3.2 Interventions to alter physical and biological environmental risks	Development, implementation and evaluation of interventions surrounding physical, biological and environmental risk factors including • radiation, second-hand smoke, physical and chemical agents, • occupational hazards and environmental surroundings • contraceptive devices • infectious agents • policy, educational and physical interventions
3.3 Nutrition and chemoprevention	Research on chemopreventative agents and health protective effects of nutrients including • development, characterisation and mechanism of action • chemical contraceptives • testing and evaluation in model systems and clinical, applied and community settings • evaluation of evidence to inform policy
3.4 Vaccines	Research on vaccines for prevention of disease including • discovery, development and testing of vaccines and vaccination in model systems • mechanism of action • development, implementation and evaluation of vaccination programmes and studies to increase uptake • decision making, outcomes from vaccination and evaluation of evidence to inform policy

Research Activity Codes

3.5 Resources and infrastructure (prevention)	• development and/or distribution of resources for use by the research community including equipment, ceil lines, tissue and DNA banks • infrastructure to support research trials, networks, consortia and centres

4 Detection, Screening and Diagnosis	Discovery, development and evaluation of diagnostic, prognostic and predictive markers and technologies
4.1 Discovery and preclinical testing of markers and technologies	Discovery, development and preclinical testing of novel markers (that may be derived from patient samples) and technologies for use in detection, diagnosis, prediction, prognosis and monitoring including • biological and psychological markers • diagnostic and monitoring devices, imaging, scanning, predictive and • diagnostic tests • development and characterisation of models • diagnostic measures and methodologies
4.2 Evaluation of markers and technologies	Testing and evaluation of markers and technologies in humans for use in detection, diagnosis, prediction, prognosis and monitoring in clinical, community or applied settings including • assessment of sensitivity, efficacy, specificity. • predictive and prognostic value, reproducibility and safety • medical devices, imaging, diagnostic and predictive tests • evaluation of diagnostic models, methods and methodologies in clinical or applied settings
4.3 Influences and impact	Studies investigating impact of screening and factors affecting uptake including • attitudes and beliefs including cultural and religious practices • issues relating to gender, age and ethnicity • genetic counselling and decision making • psychological, social and economic factors • development, implementation and evaluation of interventions to promote screening including policy, education and communication
4.4 Population screening	Studies investigating population screening programmes including • feasibility studies, pilot studies and trials • evaluation of effectiveness, benefits and economic evaluation • impact on health services and policy issues

	• models of population surveillance
4.5 Resources and infrastructure (detection)	• development and/or distribution of resources for use by the research community including equipment, cell lines, tissue and DNA banks, and informatics systems • infrastructure support for research trials, networks, consortia and centres

5 Development of Treatments and Therapeutic Interventions	Discovery and development of therapeutic interventions and testing in model systems and preclinical settings
5.1 Pharmaceuticals	Identification and development of pharmaceutical small molecules, therapeutic vaccines, antibodies and hormones including • drug screening and development of delivery systems • mechanism of action including side effects and drug resistance • pharmacogenetics, prediction of genetic variation and responses to drugs • testing in in vitro and in vivo model systems
5.2 Cellular and gene therapies	Discovery and development of cellular, tissue and gene therapies including • gene therapy, stem cells therapy, in vitro fertilisation and tissue engineering • development of delivery systems • development of culture systems • testing in in vitro and in vivo model systems
5.3 Medical devices	Discovery and development of medical devices including • implantable devices, mobility aids, dressings, medical equipment and prostheses • biological safety assessments and investigation of adverse events • sterilisation and decontamination of equipment or surfaces • testing in in vitro and in vivo model systems
5.4 Surgery	Development of surgical, obstetric and dental interventions including • histocompatability, transfusions, transplantations including xenograft studies and bone marrow transplants • mechanisms of recovery, tolerance, rejection and side effects including infection • testing in in vitro and in vivo model systems

Research Activity Codes

5.5 Radiotherapy	Discovery and development of interventions including
	• radiobiology, radiotherapy, radioimmunotherapy, radiosensitisers, microwaves, ultrasound, laser and phototherapy
	• development of delivery systems
	• investigation of mechanisms of action and side effects
	• testing in in vitro and in vivo model systems
5.6 Psychological and behavioural	Development of psychological and behavioural interventions including
	• cognitive behavioural therapy, electro-convulsive therapy, counselling, therapy and social interventions
	• testing in model systems
5.7 Physical	Development of physical interventions including
	• physical therapies, physiotherapy, occupational therapy, speech therapy, dietetics, exercise and osteopathy
	• mechanisms of action
	• testing in model systems
5.8 Complementary	Discovery and development of complementary approaches to conventional medical therapies including
	• hypnotherapy, meditation, massage, acupuncture and homeopathy
	• mechanisms of action
	• testing in model systems
5.9 Resources and infrastructure (development of treatments)	• development and/or distribution of resources for general use by the research community including equipment, cell lines, tissue and DNA banks
	• infrastructure support for networks, consortia and centres

6 Evaluation of Treatments and Therapeutic Interventions	Testing and evaluation of therapeutic interventions in clinical community or applied settings
6.1 Pharmaceuticals	Clinical application and evaluation of pharmaceutical small molecules, therapeutic vaccines, antibodies and hormones in humans including
	• small scale settings and pilot studies
	• phase I, II, III and IV trials
	• assessing sensitivity, efficacy, specificity, relapse, survival, therapeutic value, pharmacokinetics, reproducibility and safety
	• studies monitoring response, outcome, drug resistance and side effects
6.2 Cellular and gene therapies	Clinical application and evaluation of cellular, tissue and gene therapies in humans including
	• small scale and pilot studies
	• phase I, II, III and IV trials
	• gene therapy, stem cell therapy, in vitro fertilisation, tissue engineering
	• evaluation of applied delivery systems
6.3 Medical devices	Application and evaluation of medical devices in humans in a clinical, community or applied setting including
	• implantable devices, mobility aids, dressings, medical equipment and prostheses
	• validation of design and post market surveillance

Research Activity Codes

6.4 Surgery	Clinical and applied application and evaluation of surgical, obstetric and dental interventions in humans including • small scale and pilot studies • phase I, II, III and IV trials • procedures including organ and bone marrow transplantation, tissue grafts and transfusions • monitoring outcomes, side effects and rejection
6.5 Radiotherapy	Clinical application and evaluation of interventions in humans including • small scale and pilot studies • phase I, II, III and IV trials • radiotherapy, radioimmunotherapy and radiosensitisers, microwaves, ultrasound, laser and phototherapy • monitoring side effects
6.6 Psychological and behavioural	Application and evaluation of psychological and behavioural interventions in humans in clinical, community and applied settings • phase I, II, III and IV trials • cognitive behavioural therapy, electro-convulsive therapy, counselling, therapy and social interventions
6.7 Physical	Testing and evaluation of physical interventions in humans in a clinical, community or applied setting including ✚ physical therapies, physiotherapy, occupational therapy, speech therapy, dietetics, osteopathy and exercise
6.8 Complementary	All aspects of testing, evaluation and provision of complementary approaches to conventional medicine in humans in a clinical, community or applied setting including • hypnotherapy, massage, acupuncture and homeopathy • issues relating to health and social services and health care delivery • attitudes and beliefs of patients and health care professionals
6.9 Resources and infrastructure (evaluation of treatments)	• provision and distribution of resources related to clinical and applied therapeutic interventions • infrastructure support for clinical and applied research networks and trials, consortia and centres

Research Activity Codes

7 Management of Diseases and Condition	Research into individual care needs and management of disease, conditions or ill health
7.1 Individual care needs	Studies of patients and service user care needs including • quality of life, management of acute and chronic symptoms, management of side effects, rehabilitation, long term morbidity and reproductive issues • psychological impact of illness • social and economic consequences of ill health • behaviour affecting disease management including secondary • prevention, compliance to treatment and attitudes and beliefs relating to seeking treatment • assessment of social care and health services needs • educational or communication interventions to promote self-care or improve health care by carers • impact on carers
7.2 End of life care	Studies involving all issues related to palliative care and end of life care including • assessment of patient, service user and carer needs • provision and evaluation of palliative and end of life care services • quality of life for patients and carers • evaluation of interventions for health and social care professionals • social, economic and policy issues • pain management for terminally ill people • bereavement
7.3 Management and decision making	conditions by health and social care professionals • attitudes, beliefs and behaviours of health and social care professionals • investigation of decision making including factors influencing diagnosis, treatment, referral and management strategies • educational interventions and communication practices • development of guidelines, interventions or models to assist decision making and management, including identifying symptoms, predicting outcomes and identifying individuals at risk • testing and evaluating management regimes and strategies
7.4 Resources and infrastructure (disease management)	development and/or distribution of resources and equipment for use by the community including informatics systems ✚ infrastructure support for trials, networks, consortia and centres

Research Activity Codes

8 Health and Social Care Services Research	Research into the provision and delivery of health and social care services, health policy and studies of research design, measurements and methodologies
8.1 Organisation and delivery of services	Examining the organisation and provision of health and social care services and evaluating factors affecting the quality of care • workforce and career issues • organisation and management of services • access to health and social care and geographical variations in outcomes • effectiveness of different care settings and models of service delivery • evaluating quality of care including patient safety issues • evaluation of experiences of service users • assessment of current and future health care demands • development and evaluation of interventions to improve services
8.2 Health and welfare economics	Economic evaluation of health and social care interventions and delivery including • cost-benefit analysis of services including economic modelling • cost effectiveness or economic feasibility of implementing new interventions or technologies within health services • economic assessment of service productivity and outcomes • health care costs • development and evaluation of economic models of health care
8.3 Policy. ethics and research governance	• evaluation of local, regional and national healthcare policy • impact of legislation • synthesis and evaluation of evidence to inform policy • dissemination and implementation of research evidence • research ethics including use of personal data and biological material, consent and confidentiality • research governance and regulation processes including interpretation of guidelines • issues surrounding research subjects and donor recruitment
8.4 Research design and methodologies	Development of research designs and novel methodologies for health care including treatment, management and health services research • analytical innovation, methodological research, statistical methods and modelling • development of research measurements including outcome measures • development of methods of research assessment and evaluation • development and evaluation of research designs and methodologies
8.5 Resources and infrastructure (health services)	✚ development and distribution of resources for use by the community including informatics systems ✚ infrastructure support for networks, trials, consortia and centres

Study Design and Statistical Considerations * - Checklist ☑

All applicants must give careful thought to the following study design, methods and statistical considerations, and ensure that they are reflected in the grant application. Consider the following questions for the clinical research study design and methodological planning.

1. Is the main objective exploratory (for which a formal sample size justification is not relevant) or are you testing a quantitative hypothesis?
2. If the former, what are the population parameter/s you are trying to estimate? (E.g. annual incidence of AIDS, prevalence of teenage smokers, relative risk of a relapse etc)
3. If the latter, use the checklist below which could assist you to describe your study design and methods more clearly.
4. Some sample questions related to the check list below: (a) State the primary quantitative hypothesis (e.g. the hazard ratio is 0.5) and the required precision for the estimate in the form of a confidence interval e.g. 95% CI of the HR (0.3, 0.7)? (b) State the sample size required to achieve that precision. Be sure to specify the type 1 error, any other required assumptions needed and the sample size software / formula used in the calculation.

The following checklist provides guidelines for describing the study and design and methods as adapted from the CONSORT statement[2].

Area	Descriptor	Y/N/NA
METHODS Participants	Eligibility criteria for participants' description of settings/ locations where data are collected.	
Recruitment Methods	How will subjects be identified, enrolled and retained?	
Interventions	Detail the interventions intended for each group and how, when and by whom they are to be administered.	
Objectives hypotheses	Provide specific objectives or aims and related specific hypotheses.	
Outcomes	Clearly define primary and secondary outcome measures, AND when applicable, methods to enhance measurements quality (*e.g.*, multiple observations, assessor training).	
Sample size	How was sample size determined ? When applicable, explain any interim analyses and stopping rules.	

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[2] The CONSORT is primarily for randomized controlled trials, but nevertheless has many features that would apply more generally to other types of clinical research projects. Visit http://www.consort-statement.org/index.aspx?o=1017 for more details.

Randomization - Sequence generation	Method used to generate the random allocation sequence, and any restrictions (*e.g.*, blocking, stratification)	
Randomization - Allocation concealment	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone). Clarify whether the sequence will be concealed until interventions to be assigned.	
Randomization - Implementation	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to their groups	
Blinding	How was blinding of the assigned treatment achieved for (i) subjects (ii) care-givers (iii) outcome assessors?	
Data collection	Outline how data will be collected, stored, managed. How will you ensure data quality (e.g. rater drift)?	
Adverse Events	How detected, measured, and managed?	
Study Period	When will enrollment start, stop, when is last data point?	
Statistical analyses for each hypothesis	What specific statistical analysis is planned for each primary and planned secondary hypothesis?	
Statistical Collaboration	Who provides design and statistical collaboration	