



NOV 2020 APPLICATION GUIDE

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GRANT CATEGORIES

I. Health Services Research Grants (HSRG)¹

(A) Aim

Health Services Research (HSR) is the “multidisciplinary field of scientific investigation that studies how social factors, financing systems, organisational structures and processes, health technologies, and personal behaviours affect access to healthcare, the quality and cost of healthcare, and ultimately our health and well-being. Its research domains are individuals, families, organisations, institutions, communities, and populations”. HSR can improve policy formulation and practice by studying health delivery and outcomes, and providing rigorous scientific evidence for process improvements in applied healthcare settings.

To achieve a higher impact on healthcare delivery and outcomes, the HSR Grant (HSRG) aims to fund HSR in topic areas aligned with MOH priorities to more directly address key challenges of the healthcare system. With a demographically ageing population and increasing chronic disease burden, the demands on the healthcare system are set to further increase, and the healthcare system can rapidly become unsustainable in terms of both healthcare cost and manpower. To meet these challenges, efforts should be prioritised on transforming care, containing healthcare cost inflation and increasing the efficiency of our limited manpower. Research projects funded by the HSRG can include research into healthcare systems (i.e. not limited to “health services” per se), and should have a relatively short period from research findings to adoption (i.e. within 2 to 3 years upon study completion). HSR should also focus on translating knowledge to not just action but impact, and should result in practical measures that can be implemented across the healthcare system. This can include the adaptation of good practices overseas in the local context. Submitted proposals to the HSRG should focus on solutions with sector- or systems-level impact.

(B) Eligibility criteria

- Each HSRG application must be led by a PI fulfilling the eligibility criteria listed below. Only one Principal Investigator (PI) is allowed per application.
- PI must have a PhD and/or MBBS/BDS/PharmD/MD and/or other appropriate Postgraduate Qualification (at least a Master’s Degree). For proposals involving patients, either the PI or co-I should be SMC-registered; or should be able to demonstrate ability to access patients through SMC-registered collaborators. It is recognized that some studies may not require patient involvement.
- The PI should, at the point of application, also fulfill the following additional eligibility criteria:

Additional Eligibility criteria:

- (a) Hold a primary appointment in a local publicly funded institution and salaried by the institution.

¹ Grant Call for HSRG/HNIG will be made twice a year with closing dates in June and December.

- (b) Be an independent PI with a demonstrated track record of research as evidenced by the award of nationally competitive funding (international funding to be considered on a case by case basis) or substantial publication record.
- (c) Have a laboratory or research program that carries out research in Singapore.
- (d) Hold a minimum of 9 months' employment with a local Singapore institution. Upon award, the PI must agree to fulfill at least 6 months of residency in Singapore for each calendar year over the duration of the grant award.
- (e) No outstanding reports from previous BMRC, NMRC grants and other national grants.

(C) Funding Quantum and Duration

- There is no cap in funding quantum or funding duration. However, it should be noted that reasonableness of budget and time taken to implementation form part of the assessment for HSRG applications. Additional 20% indirect costs will be provided to the host institution of the lead PI.

(D) Research Themes

- Proposals submitted under the HSRG should aim to study new models with scientific rigour, with key focus on **population-based outcomes and interventions that are practical and sustainable** (e.g. the inclusion and exclusion criteria should not be so restrictive that the benefits accrue to only a small population). The type of research should be more **action-oriented** rather than lab-based research. The proposals should also incorporate **new elements** outside of traditional healthcare such as **Behavioural Science and Human Factors**. Proposals involving cross cluster collaboration will be given higher priority.
- Proposals related to **Patient-Reported Outcome Measures (PROMs)** are welcome. Proposals could include the development of **self-reported instruments** that can measure the outcomes of patients (including research on validity and reliability of self-reported outcomes vis-à-vis clinician assessed instruments), potential measures and incentives to **improve reporting of patient outcomes, localisation of PROMs** developed elsewhere (especially the testing of PROMs in the vernacular), and **innovative ways of capturing PROMS** (wearables, IT and other methods). Instruments developed should have a **specific area of deployment** and should also **identify clinicians who are willing to enrol patients** in the collection of PROMs.
- The 7th thematic grant call (Nov 2020 Grant Call) is open to proposals that fit the following themes:
 1. **Diabetes**
In Singapore, diabetes has one of the highest disease burdens, where one in nine Singaporean residents aged 18-69 years are affected by diabetes². Diabetes poses an increasing healthcare and economic cost to the country, with research suggesting that the total cost of diabetes for the entire working-age population will more than double from about \$1 billion in 2010 to beyond \$2.5 billion in 2050.

² National Health Survey 2010, SCs and PR, aged 18 – 69 years

Out of the various aspects to be tackled, the most pressing and current issues in diabetes care include: (i) the identification of diabetes patients late after the onset of disease, (ii) faster rate of deterioration of local diabetes patients compared to other countries', and (iii) expensive acute-centric model of care that prolongs lives in disability after patients require acute intervention.

To address these issues, proposals submitted under the diabetes theme can cover HSR in any or all of these areas:

- i. new models to better pick up and manage pre-diabetics,
- ii. new models of primary or shared care to better arrest the rate of deterioration and reduce acute episodes, and
- iii. more cost-effective care across the spectrum of the disease, including elements of secondary and tertiary care aligned with primary prevention efforts.

2. Health Promotion

A rapidly ageing population and increasing chronic disease burden threaten the long-term sustainability of Singapore's healthcare system. Upstream investment in health promotion is a key move that would decrease the onset of non-communicable diseases (NCDs) such as cardiovascular diseases, cancers, and diabetes, and reduce the burden on Singapore's healthcare system and finite resources. This theme will fund HSR that seeks to identify drivers of healthy living, and leads to the development of new models of health promotion intervention, including good nutrition promotion, physical activity promotion (e.g. reducing sedentary behaviour), tobacco use prevention or cessation, increasing screening uptake, mental well-being promotion and studies on cost-effectiveness of health promotion interventions (including measuring the impact of public health interventions on population health outcomes).

This theme also seeks research into clinical models that reduce the risk, delay the onset and/or decelerate the progress of frailty by covering end-to-end care along the trajectory of frailty (i.e. from health promotion intervention to the delivery of clinical services).

3. Community Mental Health

This theme seeks to fund HSR into new models that enable sustainable end-to-end care that (i) allows for early detection, (ii) enables treatment compliance, and (iii) enables patients with mental health conditions, including dementia, to be cared for and stabilised in the community. New models that partner community providers are encouraged.

4. Healthcare Manpower Sustainability

With a demographically ageing population and increasing chronic disease burden, the demands on the healthcare system are set to further increase, and we need to ensure that the healthcare system remains sustainable in terms of healthcare manpower. This theme seeks HSR to improve the sustainability and efficiency of our limited healthcare manpower, including studies that seek to understand and improve healthcare manpower productivity, explore new manpower deployment models and new models of using alternative workforce (e.g. lay extenders), improve labour force participation rates for older workers and out-of-practice groups, and improve sustainability and effectiveness of informal workforce engagement (e.g. volunteers).

(E) Review Process

- All HSRG applications will be evaluated through a two-stage review process comprising international peer review and local review. The review process will take about 6 months after the application closes.

(F) Reporting requirements

- Successful applicants are required to provide an annual report to NMRC and to submit a final report to NMRC within 6 months from the project completion date.

(G) Submission and deadline details

- It is **mandatory** for all applications to be **submitted and endorsed** by Host Institution's Director of Research (DOR) **online via IGMS** by **16 Dec 2020, 5pm**.
- We will not entertain any late submissions or submissions from individual applicants without endorsement from the Host Institution.

II. Subcategory for HSRG New Investigators Grants (HSRG-NIG)

(A) Aim

- HSRG New Investigator Grant (HSRG-NIG) is a sub category of the HSRG to cater for new HSR investigators. The HSRG-NIG is a step for the new investigator to a first independent national level grant. Applicants with substantial research experience will not be accepted under this category.

(B) Eligibility criteria

- Applicants who are applying as new investigators category (HSRG-NIG) have to work with a mentor for guidance in their research. This mentoring will provide support for a period of supervised research leading eventually to the clinical investigators conducting larger scale research projects independently.
- To be eligible for the HSRG-NIG, the following requirements apply in addition to the above eligibility criteria for the HSRG:
 - (i) Applicants must not have held any national grants (e.g., NMRC, A*STAR, NRF, MOE AcRF Tier II, etc) or international grants (e.g., MRC, NIH, NHMRC, etc) as a PI/Co-PI **prior to the award of the NIG**.
 - (ii) Applicants must not have received funding to conduct their own research project which cumulatively exceeds \$300,000. This can be funding from any sources.

(C) Funding Quantum and Duration

- The HSRG-NIG will provide a funding quantum of up to S\$100,000 per project for 2 years with additional 20% indirect costs provided to the host institution of the lead PI.

(D) Research Themes

- The HSRG-NIG is open to application on all research themes. However, please note that applicants will be asked how the proposed research will help to address the key challenges of (i) increasing demand from ageing population, (ii) shrinking workforce, and (iii) healthcare cost inflation.

(E) Review Process

- All HSRG-NIG applications will undergo local review. The review process will take about 6 months after the application closes.

(F) Reporting requirements

- Grantees are required to provide an annual report to NMRC and to submit a final report to NMRC within 3 months from the project completion date.

(G) Submission and deadline details

- It is **mandatory** for all applications to be **submitted and endorsed** by Host Institution's Director of Research (DOR) **online via IGMS** by **16 Dec 2020, 5pm**.
- We will not entertain any late submissions or submissions from individual applicants without endorsement from the Host Institution.

GENERAL INSTRUCTIONS

- Please prepare your application **using the templates available on the IGMS** online submission system and upload these documents to the relevant sections in IGMS:
 - (i) Research Proposal
 - (ii) CVs (PI, Co-I/Collab, Mentor)
 - (iii) Research Team Signatures and Other Supporting Details
- Any softcopy document must be uploaded to IGMS in Word Document or PDF format (please **do not** submit scanned PDF format except for signatures). Please adhere to the number of pages where specified and reformat softcopies such that all blank or irrelevant pages are removed.
- The applicants are required to complete the grant submission using the **IGMS online submission system**.
- For applications involving a mentor, please upload the completed mentor CV and support letter under the Mentor section in IGMS.
- Once you have completed your application in IGMS, please proceed to download a copy for your safekeeping (please refer to IGMS user guide for instructions).
- **Resubmission attempts are capped at two times, and please note that funding is not guaranteed for resubmitted proposals.** (Resubmission refers to proposals resubmitted based on LRP/ External 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).
- In any single grant call, each PI is allowed to submit up to **two applications under HSRG, with a maximum of one application under each theme**.
- **Note that Co-Investigators need to hold at least an adjunct position in a local public institution.** Researchers from overseas institutions or private companies can only participate as collaborators. The terms of collaboration with overseas research institutions and private companies must conform to NMRC's existing policies.
- **PI's CV is limited to 2 pages. Co-Investigators' and Collaborators' CVs are limited to 1 page each. Please indicate NA if the required information is not applicable. Please take note that NMRC will not be responsible for any missing information not provided in the CV.**
- **Mentor's CV is limited to 2 pages (for applications involving a mentor).**
- Use **Arial font size 10** for all attachment/text.
- Plagiarism (without permission from author or reference made to source) will be referred to Host Institution for investigation and may be subjected to disciplinary actions.
- Refer to Appendix 1 for details on Health Research Classification System (HRCS) to complete "Field of Research" in IGMS.
- Refer to Appendix 2 for checklist on Study Design and Statistical Considerations to complete "Methods/Approach" section in the research proposal.

Submission of Application

- It is **mandatory** for all applications to be submitted and endorsed by Host Institution's Director of Research (DOR) via **IGMS** by **16 Dec 2020, 5pm**. Internal Host Institution submission deadlines may apply, please check with your Office of Research (ORE) for more information. We will not entertain any late submissions or submissions from individual applicants without endorsement from the Host Institution. Please note that any clarifications sought by the DOR/ORE will need to be addressed by the PI **prior to submission by 16 Dec 2020, 5pm**.
- NMRC reserves the right to reject the following:
 - Incomplete applications E.g. missing documents such as the research proposal, resubmission materials, progress / final reports for renewal applications, signatures, sections left blank and missing CVs, etc.
 - Applications using incorrect templates (please only use templates from IGMS)
- No late submission or revision to the submitted application will be entertained after the closing date.

Additional document required for Resubmission Applications

- Resubmission refers to proposals resubmitted based on LRP / External 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
- A proposal can only be resubmitted **two times**. A proposal which has been resubmitted for more than two times will be rejected.
- Append the following documents to the end of the application as Annexes:
 - A document itemizing how the revised proposal (i.e. re-submission application) has addressed past reviewers'/panel's comments and highlight new features or merits of the revised proposal (**Annex B**)
 - International Reviewers' reports of previous unsuccessful application (as images inserted in the Annex document); Rebuttal to the international reviewers; Local Reviewers' reports (as images inserted in the Annex document), where applicable; Response to local reviewers (where applicable); Panel's comments (where applicable); and Response to the panel (where applicable) (in the above order as **Annex C**)

Additional document required for Renewal Applications (follow up study from NMRC projects)

- Submit a progress/final report of the existing project to indicate the progress and outputs of the project in the prescribed NMRC reporting format (i.e. progress/ final report) as **Annex D**.
- As this section may be submitted to both overseas and local reviewers, PI is to ensure that all sensitive information on IP issues and such are cleared from the Host Institution before submitting to NMRC.

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, schizophrenia, 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, <i>in vitro</i> 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

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 environmental
- 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	<p>Studies of normal biology including</p> <ul style="list-style-type: none"> ✚ 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	<p>Studies that do not address health directly but cover issues that may have a bearing on health and well-being including</p> <ul style="list-style-type: none"> ✚ 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	<p>Research in chemical and physical sciences that may lead to the future development of diagnostic tools or medical treatments including</p> <ul style="list-style-type: none"> ✚ bioengineering and biophysics ✚ chemical structures, interactions and properties ✚ molecular modelling ✚ material science
1.4 Methodologies and measurement	<p>Development of novel underpinning research measures and analytical methodologies including</p> <ul style="list-style-type: none"> ✚ 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)	<ul style="list-style-type: none"> ✚ 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	<p>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</p> <ul style="list-style-type: none"> + 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	<p>Environmental or external factors associated with the cause, risk or development of disease, conditions or ill health including</p> <ul style="list-style-type: none"> + 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	<p>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</p> <ul style="list-style-type: none"> + individual or group behaviours and lifestyle + cultural or religious beliefs or practices + ethnicity, age and gender differences + socioeconomic factors
2.4 Surveillance and distribution	<p>Observational studies, surveys, registries. and studies that track incidence, prevalence, morbidity, co-morbidity and mortality including ongoing monitoring of large scale cohorts</p>
2.5 Research design and methodologies (aetiology)	<p>Development of aetiological and epidemiological research designs, measures and methodologies including</p> <ul style="list-style-type: none"> + methodological innovation and modelling complex epidemiological data + development and evaluation of novel research designs + development of epidemiological research measurements including outcome 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)	<ul style="list-style-type: none"> + 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

Research Activity Codes

3 Prevention of Disease and Conditions, and Promotion of Well-Being	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 well-being	<p>Development, implementation and evaluation of interventions to modify personal or group behaviours and lifestyles affecting health and well-being including</p> <ul style="list-style-type: none"> + 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	<p>Development, implementation and evaluation of interventions surrounding physical, biological and environmental risk factors including</p> <ul style="list-style-type: none"> + 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	<p>Research on chemopreventative agents and health protective effects of nutrients including</p> <ul style="list-style-type: none"> + 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	<p>Research on vaccines for prevention of disease including</p> <ul style="list-style-type: none"> + 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
3.5 Resources and infrastructure (prevention)	<ul style="list-style-type: none"> + development and/or distribution of resources for use by the research community including equipment, cell lines, tissue and DNA banks + infrastructure to support research trials, networks, consortia and centres

Research Activity Codes

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	<p>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</p> <ul style="list-style-type: none"> + 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	<p>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</p> <ul style="list-style-type: none"> + 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	<p>Studies investigating impact of screening and factors affecting uptake including</p> <ul style="list-style-type: none"> + 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	<p>Studies investigating population screening programmes including</p> <ul style="list-style-type: none"> + 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)	<ul style="list-style-type: none"> + 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

Research Activity Codes

5 Development of Treatments and Therapeutic Interventions	Discovery and development of therapeutic interventions and testing in model systems and preclinical settings
5.1 Pharmaceuticals	<p>Identification and development of pharmaceutical small molecules, therapeutic vaccines, antibodies and hormones including</p> <ul style="list-style-type: none"> ✚ 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	<p>Discovery and development of cellular, tissue and gene therapies including</p> <ul style="list-style-type: none"> ✚ 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	<p>Discovery and development of medical devices including</p> <ul style="list-style-type: none"> ✚ 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	<p>Development of surgical, obstetric and dental interventions including</p> <ul style="list-style-type: none"> ✚ histocompatibility, 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
5.5 Radiotherapy	<p>Discovery and development of interventions including</p> <ul style="list-style-type: none"> ✚ 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	<p>Development of psychological and behavioural interventions including</p> <ul style="list-style-type: none"> ✚ cognitive behavioural therapy, electro-convulsive therapy, counselling, therapy and social interventions ✚ testing in model systems
5.7 Physical	<p>Development of physical interventions including</p> <ul style="list-style-type: none"> ✚ physical therapies, physiotherapy, occupational therapy, speech therapy, dietetics, exercise and osteopathy ✚ mechanisms of action ✚ testing in model systems
5.8 Complementary	<p>Discovery and development of complementary approaches to conventional medical therapies including</p>

	<ul style="list-style-type: none"> ✚ hypnotherapy, meditation, massage, acupuncture and homeopathy ✚ mechanisms of action ✚ testing in model systems
5.9 Resources and infrastructure (development of treatments)	<ul style="list-style-type: none"> ✚ 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

Research Activity Codes

6 Evaluation of Treatments and Therapeutic Interventions	Testing and evaluation of therapeutic interventions in clinical community or applied settings
6.1 Pharmaceuticals	<p>Clinical application and evaluation of pharmaceutical small molecules, therapeutic vaccines, antibodies and hormones in humans including</p> <ul style="list-style-type: none"> ✚ 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	<p>Clinical application and evaluation of cellular, tissue and gene therapies in humans including</p> <ul style="list-style-type: none"> ✚ 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	<p>Application and evaluation of medical devices in humans in a clinical, community or applied setting including</p> <ul style="list-style-type: none"> ✚ implantable devices, mobility aids, dressings, medical equipment and prostheses ✚ validation of design and post market surveillance
6.4 Surgery	<p>Clinical and applied application and evaluation of surgical, obstetric and dental interventions in humans including</p> <ul style="list-style-type: none"> ✚ 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	<p>Clinical application and evaluation of interventions in humans including</p> <ul style="list-style-type: none"> ✚ 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	<p>Application and evaluation of psychological and behavioural interventions in humans in clinical, community and applied settings</p> <ul style="list-style-type: none"> ✚ phase I, II, III and IV trials ✚ cognitive behavioural therapy, electro-convulsive therapy, counselling, therapy and social interventions

6.7 Physical	<p>Testing and evaluation of physical interventions in humans in a clinical, community or applied setting including</p> <ul style="list-style-type: none"> ✚ physical therapies, physiotherapy, occupational therapy, speech therapy, dietetics, osteopathy and exercise
6.8 Complementary	<p>All aspects of testing, evaluation and provision of complementary approaches to conventional medicine in humans in a clinical, community or applied setting including</p> <ul style="list-style-type: none"> ✚ 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)	<ul style="list-style-type: none"> ✚ 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	<p>Studies of patients and service user care needs including</p> <ul style="list-style-type: none"> ✚ 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	<p>Studies involving all issues related to palliative care and end of life care including</p> <ul style="list-style-type: none"> ✚ 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	<p>conditions by health and social care professionals</p> <ul style="list-style-type: none"> ✚ 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)	<p>development and/or distribution of resources and equipment for use by the community including informatics systems</p> <ul style="list-style-type: none"> ✚ 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	<p>Examining the organisation and provision of health and social care services and evaluating factors affecting the quality of care</p> <ul style="list-style-type: none"> + 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	<p>Economic evaluation of health and social care interventions and delivery including</p> <ul style="list-style-type: none"> + 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	<ul style="list-style-type: none"> + 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	<p>Development of research designs and novel methodologies for health care including treatment, management and health services research</p> <ul style="list-style-type: none"> + analytical innovation, methodological research, statistical methods and modelling + development of research measurements including outcome measures + development of methods of research assessment and evaluation

	<ul style="list-style-type: none"> ✚ development and evaluation of research designs and methodologies
8.5 Resources and infrastructure (health services)	<ul style="list-style-type: none"> ✚ 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 statement³.

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 .	
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	

³ 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.

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	