MINISTRY OF HEALTH

INDUSTRY ALIGNMENT FUND

(MOH IAF)

CATEGORY 1

APPLICATION GUIDE

I. MOH INDUSTRY ALIGNMENT FUND CATEGORY 1 (MOH IAF CATEGORY 1)

1. Aim

1.1 The MOH IAF programme aims to facilitate partnerships between researchers and industry in pre-clinical and clinical research.

1.2 The **MOH IAF Category 1** aims to support researchers in their pre-clinical and clinical research projects carried out in collaboration with the industry. This is to encourage:

(i) Commercially relevant research;
(ii) Fostering new directions in translational biomedical research;
(iii) Multi-disciplinary and multi-institutional collaborations that will bring new perspectives to the field.

1.3 They can be composed of:

(i) Multiple individual projects involving multiple local research partners and multiple industry partners, forming comprehensive, long-term collaborations with a high probability of leading to substantive R&D programs or impactful outcomes.

- Under this type of partnership, it is expected that there will be multiple individual projects.

- The Principal Investigator (PI) of each individual project shall apply individually, indicating the name of the "Strategic Partnership" and its projects in the Application Form

(ii) Individual projects that are of significance to the national Biomedical Sciences (BMS) research agenda and industry relevance.

2. Funding Criteria

2.1 The pre-requisite for application is PI's ability to obtain industry contribution of **at least 70%** of the Total Project Cost. In-kind and cash contributions from industry partner can be included.

2.2 This industry contribution should be clearly indicated in the "Industry Contribution" section/tab of the application in nGager and must be supported by a **Research Collaborative Agreement (RCA)** (to be uploaded in the "Supporting Documents" section/tab in nGager).

3. Funding Quantum

3.1 The PI may apply to MOH IAF Category 1 for funding of the remaining **up to 30%** of the Total Project Costs.

3.2 Funding support will be capped at (inclusive of 20% indirect costs):

(i) **S$500,000** per project for **pre-clinical** projects;

(ii) **S$1mil** for **clinical** projects;

(iii) In the case of translational projects involving both **pre-clinical and clinical** elements, a cap of **S$1.5mil** will apply.

3.3 The funds will be awarded to the lead institution[1], which can claim for but will also be responsible for reimbursing costs incurred by collaborating institutions[2]. No reimbursements will be made to the industry partner.

4. Funding Duration

4.1 Projects should last no longer than two years, with the potential for a one year extension subject to approval by the review panel.

5. Grant Call

5.1 This scheme is **open for application throughout the year**, i.e. no formal grant calls will be held. Applicants can submit their applications **via nGager** at any time.

*** NOTE (NEW): The last date of submission will be 31 Dec 2015.**

nGager will not accept any applications from this date onwards.

6. Eligibility Criteria

6.1 Only research conducted in Singapore may be funded under the MOH IAF Category 1.

6.2 **New projects and expansions/addendums made to RCAs of existing projects** commencing any time **from 1 January 2013** are eligible.

Individuals Eligible to be the Principal Investigator

6.3 Only one Principal Investigator (PI) is allowed per application. The PI is expected to be actively involved in the overall management of the project and will be accountable for the project and its deliverables.

6.4 Each grant application must be submitted by a :

- **Clinical or Non-clinical PI**[3] for **pre-clinical** projects
- **Clinical PI** for **clinical projects**

who has to fulfil the eligibility criteria listed below at the point of application.

(i) Non-clinical PI should possess a minimum academic qualification of a PhD at the point of application.

(ii) Clinical PI must be clinically qualified (i.e. with MD/MBBS/BDS) and with post-graduate clinical training and experience. For proposals involving patients, the clinical PI should be SMC registered; or the PI should be able to demonstrate ability to access patients through SMC registered collaborators.

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[1] The lead institution must be a local public hospital/public health institution/national specialty centre/public universities/academic medical centre

[2] The collaborating institution must be a local public hospital/public health institution/national specialty centre/public universities/academic medical centre

[3] **Definition of Principal Investigator (PI)**: The lead researcher who has the appropriate level of authority and the responsibility to direct the **project** being supported by the grant. He or she is responsible and accountable for the proper conduct of the **project**.

(Note: For projects involving clinical trials, CTG criteria of clinical specialty certification applies).

(iii) PI must hold a primary appointment and be full time employed in a local public hospital/public health institution/national specialty centre/public universities/academic medical centre, and salaried by the institution.

(iv) PI must 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), and substantial publication record.

(v) PI must have a laboratory or clinical research program that carries out research in Singapore.

(vi) PI must fulfil a minimum of 9 months employment with a local Singapore institution. Upon award, the PI must agree to fulfil at least 6 months of residency in Singapore for each calendar year over the duration of the grant award

(Note: For projects involving clinical trials, CTG criteria of full time residency applies).

(vii) No outstanding reports from previous NMRC, BMRC grants and other national grants.

7. Review Assessment Criteria

7.1 The proposal will be selected based on the assessment criteria listed below:

- Research team
- Industry partner involvement and contribution
- Scientific and intellectual contribution
- Industry/commercial relevance and potential
- Overall impact in local context – eg. health outcomes, likelihood for project to exert a sustained, powerful influence on the research fields involved and on expanding the local presence of the industry partner, in R&D or related activities.

8. Review Process

8.1 All applications will undergo a common streamlined review process that covers areas such as the research team, industry partner involvement and contribution, scientific and intellectual contribution, industry/commercial relevance and potential, and overall impact in local context eg. on expanding the local presence of the industry partner, in R&D or related activities.

8.2 Successful applicants will be informed by the NMRC.

8.3 The review process is expected to take less than 3 months.

9. Reporting Requirements

9.1 Grantees are required to provide an annual progress report to NMRC.

- Milestones reported will be subjected to review based on projected milestones in the application proposal.
- If the milestones projected cannot be reached, NMRC reserves the right to withhold the funding if necessary.

9.2 Grantees are required to submit a final report to NMRC within 3 months from the project completion date.

9.3 During the term of award, any variation to the approved grant has to be reported to NMRC under specific conditions.

9.4 NMRC is agreeable to publications of research results and findings, but would require acknowledgement of MOH IAF funding and host institution's submission of the copy of publication to us within 1 month of publish. NMRC support should also be acknowledged orally during all conference presentations, news and media interviews.

9.5 For more details and other reporting requirements please refer to the 'Policy Document on Admin Requirement'.[4] Information and reporting requirements on third party collaborations can be found in the 'Policy Document on Third Party Collaborations'[5].

10. Submission Details

10.1 It is mandatory for all applications to be submitted online via **nGager**. Please download the nGager User Guide at http://www.nmrc.gov.sg/content/nmrc_internet/home/ngager.html**.**

10.2 This scheme is **open for application throughout the year**, i.e. no formal grant calls will be held. Applicants can submit their applications via nGager at any time.

*** NOTE (NEW): The last date of submission will be 31 Dec 2015.**

nGager will not accept any applications from this date onwards.

11. Enquiries

11.1 For further enquiries, you may contact Dr Sharon Ling at Sharon_Ling@moh.gov.sg or Ms Jennifer Lee at Jennifer_A_Lee@moh.gov.sg.

12. Changes to MOH IAF Cat 1 Application Guidelines

12.1 NMRC reserves the right to make changes to the above guidelines and any submission templates relating to the MOH IAF Cat 1, as and when it deems fit.

[4] http://www.nmrc.gov.sg/content/dam/nmrc_internet/documents/policiesAndGuidelines/Policy%20Document%20on%20Admin%20Requirements.pdf

[5] http://www.nmrc.gov.sg/content/dam/nmrc_internet/documents/policiesAndGuidelines/Policy%20Document%20on%20Third%20Party%20Collaborations.pdf

II. GENERAL INSTRUCTIONS

1. **Resubmission attempts are capped at up to two times. Funding is not guaranteed for resubmitted proposal.** (Resubmission refers to proposals resubmitted based on Review Panel's 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).

2. There is no limit to the number of Co-Investigators (Co-Is)[6] or Collaborators[7]. **Please specify and describe clearly the roles of Co-Investigators and Collaborators in the relevant section.**

3. **Note that Co-Is 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.

4. Use **Arial font size 10** for all attachment/text.

5. 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.

6. Applicants are required to complete the grant submission using the nGager online submission system.

7. Please complete all sections in the nGager and indicate "**NA**" where a particular section is not applicable**.**

8. Please prepare your application using the templates available on the nGager online submission system and upload these documents to the relevant sections in nGager:
   (i) Research proposal template
   (ii) CV (PI, Co-I, Collab) template
   (iii) Research team signatories' template
   (iv) Other support template

9. Please adhere to the number of pages where specified and reformat softcopy such that all blank or irrelevant pages are removed.

10. Please upload Research Collaborative Agreements (RCAs) and the Clinical Trial Certificates (CTCs) at the "Supporting Documents" tab. The submission of RCA(s) is mandatory for MOH IAF Cat 1 applications. The provision of CTC(s) only applies for clinical trials (may submit at point of application if available).

11. Any softcopy document must be uploaded to nGager as 1 file at each uploading tab either in Word DOC or PDF format (please do not submit scanned PDF format except for signatories).

12. Please refer to Appendix 1 for details on Health Research Classification System (HRCS) to complete "Field of Research" in nGager.

13. Please refer to Appendix 2 for checklist on Study Design and Statistical Considerations to complete "Methods/Approach" section in nGager.

14. Please refer and adhere to the NMRC financial guidelines and list of fundable and non-fundable items available for download here[8].

[6] **Definition of Co-Investigator (Co-I)**: 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 as compared to a collaborator and is considered a key personnel.

[7] **Definition of Collaborator**: An individual involved in the scientific development and execution of project. A collaborator would typically devote a specific percent of effort to the project.

Submission of application

15. Once you have completed your application form in nGager, please download the form in PDF format for your safekeeping.

16. The submitted application form in nGager will be routed to your Host Institution's Research Office for endorsement before it is submitted to NMRC.

[8] http://www.nmrc.gov.sg/content/dam/nmrc_internet/documents/policiesAndGuidelines/Policy%20document%20on%20Finance%20Regulations.pdf

Appendix 1

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

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	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
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

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	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

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	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
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

Research Activity Codes

6 Evaluation of Treatments and Therapeutic Interventions	**Testing and evaluation of therapeutic interventions in clinical community or applied settings**
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
6.1 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
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

Appendix 2

*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[9].

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 -	Method used to generate the random allocation	

[9] 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.

Sequence generation	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	