OPEN FUND – LARGE COLLABORATIVE GRANT (OF-LCG)

JUN 2021 GRANT CALL

APPLICATION GUIDE FOR FULL PROPOSAL (FP)

I. OPEN FUND – LARGE COLLABORATIVE GRANT

(A) AIM & FUNDING PRINCIPLES

Aim

The Open Fund – Large Collaborative Grant (OF-LCG) aims to bring together the best teams from public institutions to advance human health and wellness, as well as create economic value for Singapore and Singaporeans, through the pursuit of excellence in research and its applications. The purpose of the OF-LCG scheme is to support patient-centric translational[1] research, underpinned by basic[2] and/or applied research[3]. The scheme will not support pure basic science, pure clinical or pure applied research.

Key Elements

- Interdisciplinary collaboration across institutions is preferred and encouraged so as to integrate, coordinate and leverage on the full spectrum of research capabilities in Singapore, from basic science to clinical research.
- LCG programmes should aim to make significant contributions to the advancement of knowledge in therapeutic areas and help establish Singapore as a global leader in these areas.
- They should facilitate the discovery and application of basic science ideas relevant to the advancement of health, as well as the translation of clinical findings into policy and practice. They should also provide opportunities for international partnerships and/or industry collaborations.
- Pathway(s) to impact should be clearly articulated.

Research Themes

Application to the OF-LCG scheme will be through open grant calls. The OF-LCG is open to proposals of the highest quality in all areas, typically involving multi-disciplinary teams. To better realise the goals of HHP domain in Singapore, the following seven areas have been identified as national priorities for research.

a. Cancers and neoplasms
b. Cardiovascular
c. Eye
d. Infection
e. Mental health
f. Metabolic and endocrine
g. Neurological

For each grant call, specific therapeutic areas will be set as priority areas. The HBMS community is encouraged to address these areas. At the same time, proposals in other areas will also be considered.

Funding Quantum and Duration

There are two funding tiers for application:

- Tier 1: Up to $10M inclusive of indirect cost* up to 5 years; and
- Tier 2: Up to $25M inclusive of indirect cost* up to 5 years.

The following categorisation of research activity is based on UK Health Research Classification System (HRCS):
[1] Translational Research: Prevention, Detection and Diagnosis, Treatment Development and Treatment Evaluation
[2] Basic Research: Underpinning and Aetiology
[3] Applied Research: Disease Management and Health Services

**Indirect cost is provided at a fixed percentage of 30% of the project's qualifying direct cost.*

Grant Call Frequency

Once a year, starting from June 2021.

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Jun 2021 OF-LCG Grant Call

For the Jun 2021 OF-LCG grant call, all seven therapeutic areas are set as priority areas:

- **Cancers and neoplasms**
- **Cardiovascular**
- **Eye**
- **Infection**
- **Mental health**
- **Metabolic and endocrine**
- **Neurological**

Besides the 7 therapeutic areas, proposals in other areas will also be considered.

(B) Definitions and Eligibility Criteria

Definitions

Overview: The research programme should comprise no more than 5 research themes, each led by one or more Theme Principal Investigators (PIs). All the Theme PIs should form the Leadership Team, and one of the Theme PIs should be nominated as the Corresponding PI.

Leadership Team: Comprises all Theme PIs. The leadership team share the responsibility in making the OF-LCG programme a success and is essential for implementing programme strategies and achieving desired outcomes.

Corresponding PI: The Theme PI who will coordinate the OF-LCG programme, serve as the main point of contact between NMRC and the OF-LCG Leadership Team, and is accountable to NMRC for the proper conduct of the whole programme. He/ She will work closely with the Theme PIs to resolve any issues which arise during the course of the programme, including the usage of funding, any variations to the scope of the programme etc. Limited to only 1 Corresponding PI per leadership team. *Please note that in IGMS, the Corresponding PI will take on the role of "Lead PI".*

Theme PI: Theme PIs have the responsibility to direct each specific research theme being supported by the grant, and accountable for the proper conduct of the specific research theme. The main Theme PIs (one for each Theme) are responsible for raising budget variation requests, collating and submitting fund requisitions for direct and/or indirect costs; on behalf of the theme to NMRC for the disbursement of funds. There is no limit on the no. of Theme PIs per theme but a cap of 5 themes and one main Theme PI per theme apply. An individual can be a Theme PI for multiple themes.
Please note that in IGMS, the main Theme PIs will take on the role of "Team PI" while the other Theme PIs will take on the role of "Co-Team PI".

Eligibility Criteria

- **Only one Corresponding Principal Investigator (PI) is allowed per application, and there is no cap placed on the number of Theme PIs per theme. However, a cap of 5 themes applies.**

- **The Corresponding PI and Theme PIs form the Leadership Team and are required to fulfil the following criteria at the point of application:**

i. Holds a primary appointment in a local publicly funded institution and salaried by the institution.
ii. Has PhD or MD/MBBS/BDS qualifications (exceptions would be made on a case-by-case basis).
iii. Is an independent investigator (with PI status in institution) 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), substantial publication record in the past 3 years.
iv. Has a laboratory or clinical research program that carries out research in Singapore.
v. Holds a minimum of 9 months employment (per calendar year) with local Singapore institution(s). 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.
vi. Has no outstanding report from previous BMRC, NMRC grants, and other national grants.
vii. For proposals involving patients, the PI should be SMC registered; or should be able to demonstrate ability to access patients through SMC registered Co-Is or collaborators.

(C) Review Process

Overview

The OF-LCG comprises a 2-stage review process. In the first stage, interested applicants are required to submit a letter of Intent (LOI). The LOIs solicited will be put through an internal review process with the OF-LCG Review Panel (OF-LCG RP) that is made up of local and international clinicians and basic scientists, as well as industry experts appointed by NMRC. Based upon a review and selection of the most promising projects, a certain number of applicants will be invited to submit full proposals.

In the second stage, the full proposals will be evaluated by international domain experts followed by the OF-LCG RP. Shortlisted applicants will be invited to submit a rebuttal to address the issues raised by the international reviewers, and will subsequently be interviewed by the OF-LCG RP. The OF-LCG RP will do a collective review/ranking of the proposals and make funding recommendations for endorsement. The number of awards given out for the grant call will depend on the quality of the proposals and the amount of funding available.

Evaluation Criteria

Selection of successful proposals would be based on the following evaluation criteria:

i. High-quality scientific research focusing on patient-centric translational research, supplemented with basic and/or applied research (including Health Services Research). Proposed research must be well-differentiated and highly competitive. It should demonstrate a high potential to be world class.
ii. Proposed research topic should address issues of national importance. These should typically be challenges that no single institution or discipline can solve and require collaborative and interdisciplinary approaches. Provided they are scientifically meritorious, proposals which address the therapeutic areas would be given priority consideration.
iii. Proposed research team should have established track record and research productivity. Proposed governance to manage the programme should be feasible and sustainable.
iv. Proposed programme should contribute to capacity development of human capital and research infrastructure.
v. Demonstrate the potential to improve health outcomes and capture economic value* with a clear indication of pathway(s) to impact.

Translation Pathways to Healthcare and Economic Outcomes are required in the application. For economic value, an industry engagement plan will also be required in the application, and applicants are encouraged to obtain letters of support from the industry.

(D) Reporting Requirements

Reporting requirements are detailed in NMRC's Terms and Conditions and Guidelines for the Management of MOH/NMRC (Grantor) Funding Programmes (available on NMRC's website).

In addition, research programmes funded under the OF-LCG will be required to undergo annual review of their progress by an NMRC-appointed Scientific Advisory Board (SAB) and a mid-term review by an appointed Review Panel. More details will be shared with the grantees at the start of their research programme.

(E) Terms & Conditions

If awarded, all applicants would have read, understood and will abide to **NMRC's Terms and Conditions and Guidelines for the Management of MOH/NMRC (Grantor) Funding Programmes** (available on NMRC's website) upon their acceptance of the grant.

II. GENERAL INSTRUCTIONS

- Please complete all required sections in the IGMS application for the FP application in **Table 1** below.

- Please provide Section 0 – 5 in **MS Word format** (Section 5 - Annex F Industry Support Letters and Section 6 Declaration can be in PDF or Word format).

- Use **Arial font size 10** for all text and attachments. Please follow the instructions for each section closely.

- **The Corresponding PI and Theme PIs must fulfill the eligibility criteria specified in Section I of this application guide.** Please note that in IGMS, the Corresponding PI and the main Theme PIs will take on the role of "Lead PI" and "Team PIs" respectively; the rest of the Theme PIs will take on the role of "Co-Team PIs".

- Each application is limited to only **1 Corresponding PI**. No cap is placed on the number of Theme PIs allowable per theme, but a cap of 5 themes per application and one main Theme PI per theme apply. A Corresponding PI must be a Theme PI. An individual can be a Theme PI for more than 1 theme.

- **Co-Is[4] are required to hold at least an adjunct position at a local public institution. Researchers from overseas institutions or private companies can only participate as Collaborators[5].** The terms of collaboration with overseas research institutions and private companies must conform to NMRC's existing policies.

- There is no limit to the number of Co-Investigators (Co-Is) or Collaborators. **Please list and specify/ describe the roles of Co-Investigators and Collaborators in the relevant section(s).**

- **The page limit for the CVs of the Corresponding PI and Theme PIs is 3 pages; while the page limit for the CVs of the Co-Is and Collaborators is 2 pages.** Please indicate "NA" if the required information is not applicable and note that NMRC will not be responsible for any missing information not provided in the CV.

- **Please note that resubmission attempts are capped at up to two times. Funding is not guaranteed for resubmitted proposals.**
  Note: Resubmission refers to proposal resubmitted based on the OF-LCG Review Panel/ 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 instead of a resubmission.

- 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** of this document for the Health Research Classification System to help complete Section 0 Summary Details - "Research Activity Code".

- Refer to **Appendix 2** of this document for the checklist on Study Design and Statistical Considerations to help complete Section 1.2(v)- "Methods"- of the research proposal template.

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[4] **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 compared to a collaborator and is considered a key research personnel of the research team.
[5] **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.

APPLICATION SUBMISSION

- All applications must be submitted by the Corresponding PI and endorsed by the Corresponding PI's Host Institution through IGMS by **12 Nov 2021 (Fri), 5pm.**

- Internal Host Institution submission deadline may apply, please check with your Research Office for more information.

- The following will be rejected upon submission:

    - Incomplete applications e.g. missing documents such as resubmission/renewal materials required, missing signatures, sections left blank, missing CVs, etc.
    - Outdated/wrong application templates.
    - Proposal, CV or other attachment documents that exceeds the stipulated page limits.

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

- For enquiries, please contact the NMRC OF-LCG secretariat at peh_kah_yim@moh.gov.sg.

III. TABLE 1: REQUIRED SECTIONS OF THE FP APPLICATION

The application will comprise a "Summary Details" section and 6 additional sections (i.e. Sections 1-6), as shown in Table 1.

SECTION	DESCRIPTION	LOCATION OF TEMPLATE IN IGMS	LOCATION TO UPLOAD COMPLETED TEMPLATE IN IGMS *(Snapshots are provided in Pg 11-12)*
-	**Summary Details**	"**Research Proposal**" tab of "**Research Details**" section	"**Research Proposal**" tab of "**Research Details**" section • To upload each section as a separate file
1	**Research Proposal** • Sub-section 1.1 (page limit of 3) • Sub-section 1.2 (page limit of 4 per theme) • Sub-section 1.3 (page limit of 5) • Sub-section 1.4 (page limit of 2) • Sub-section 1.5 (page limit of 14)		
2	**Curriculum Vitae** of the: • Corresponding and Theme PIs (page limit of 3 per CV) • Co-Investigators and Collaborators (page limit of 2 per CV)	"**Research Team**" tab of **"Research Team, Collaborators, Referees"** section	"**Research Team**" tab of **"Research Team, Collaborators, Referees"** section • For Corr PI, Theme PIs and Co-Is: to upload CVs individually into the respective PI/Co-Is' profiles • For Collab: to collate CVs into a zip file and upload to the Corr PI's profile (separate from the Corr PI's CV).

<table>
<tr><td>3</td><td>Industry Parties' Contributions and Other Support</td><td rowspan="3">"Research Proposal" tab of "Research Details" section

(same location as templates for "Summary Details" and "Research Proposal")</td><td rowspan="3">"Attachments" tab of "Other Attachments" section

• To upload each section as a separate file
• To upload each Annex as separate file as well</td></tr>
<tr><td>4</td><td>Expected Outcomes</td></tr>
<tr><td>5</td><td>Annexes

Please note that provision of any supplemental information/data to the proposal, other than the NMRC-specified Annexes, is not allowed.

<table>
<tr><th>Annex</th><th>Description</th></tr>
<tr><td>Annex A
(max. 5 pages)</td><td>Additional Documents for RENEWAL Applications:
i) Summary of achievements of the last funding and if they met the aims and objectives of the previous research programme. Explain unmet goals.
ii) Brief description of plans laid out for the new tranche of funding and how it is a progression from the last funding.</td></tr>
<tr><td>Annex B
(max. 3 pages for (i))</td><td>Additional Documents for RESUBMISSION Applications:
i) Response to past reviewers'/panel's comments (if any)
ii) Original past review reports (inserted as images) (if any)</td></tr>
<tr><td>Annex C</td><td>Research Team Summary and Research Proposal References</td></tr>
<tr><td>Annex D</td><td>Budget Summary</td></tr>
<tr><td>Annex E</td><td>Scientific Abstracts and Supporting Documents for Section 3: Other Support</td></tr>
<tr><td>Annex F</td><td>Industry Support Letters (if any)</td></tr>
</table>
</td></tr>
<tr><td>6</td><td>Declaration by Leadership Team and Host Institution Endorsement.</td></tr>
</table>

The application will comprise a "Summary Details" section and 6 additional sections, as shown in Table 1.

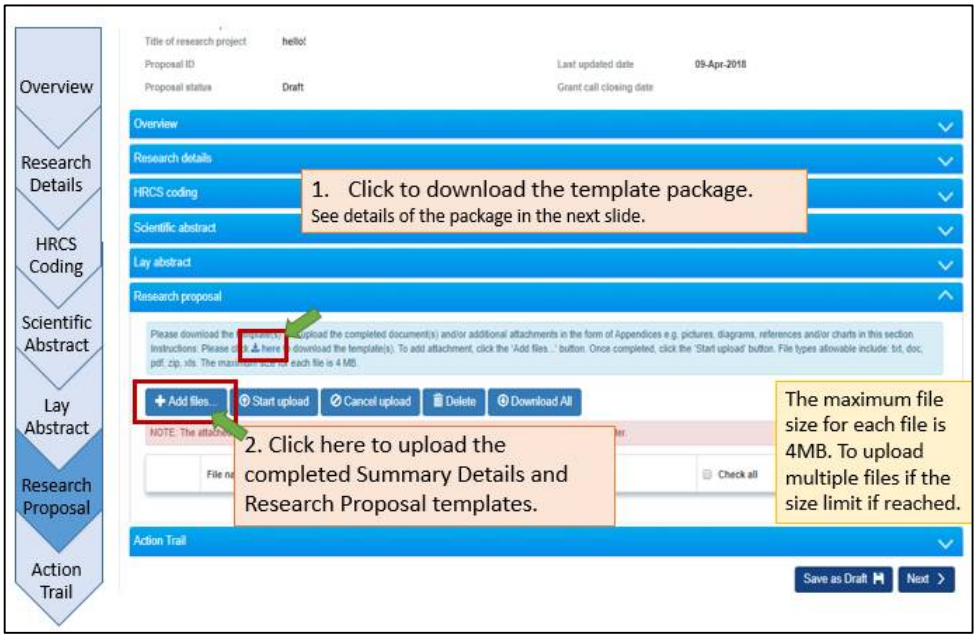
Templates to Download

- For the "Summary Details" Section, Sections 1, and Section 3-6, the templates can be downloaded from the "***Research Proposal***" tab of the "***Research Details***" section.
- For Section 2 (Curriculum vitae of team members), the template can be downloaded from the "***Research Team***" tab of the ***"Research Team, Collaborators, Referees"*** section.

Documents to Upload

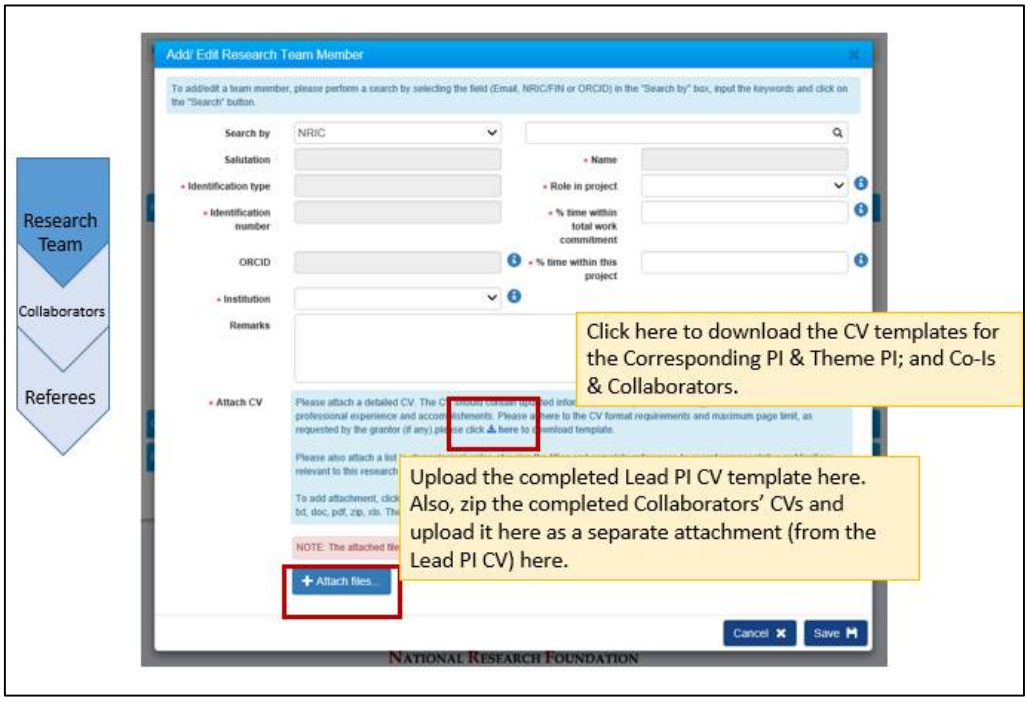
- Completed Summary Details template should be uploaded to the "***Research Proposal***" tab of the "***Research Details***" section.
- Completed Research Proposal template (Section 1) should be uploaded to the "***Research Proposal***" tab of the "***Research Details***" section.

Snapshot of **"Research Proposal**" tab of the "**Research Details**" section



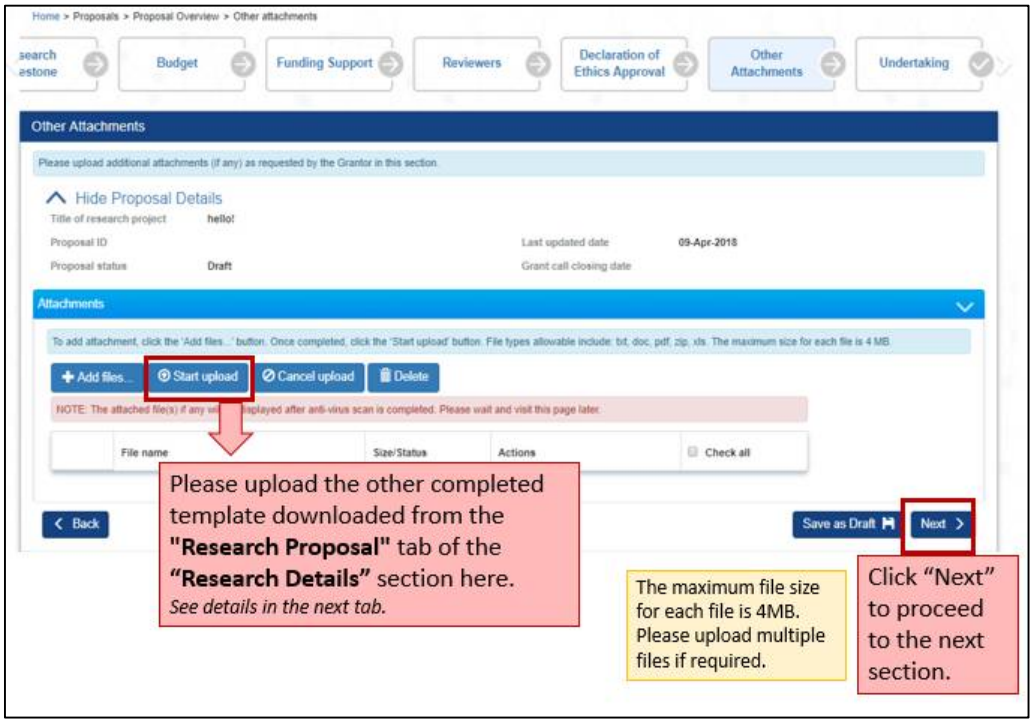
- Completed individual CV template for each team member (Section 2) should be uploaded into the "***Research Team***" tab of the ***"Research Team, Collaborators, Referees"*** section.

Snapshot of "**Research Team**" tab of the "**Research Team, Collaborators, Referees**" section



- The remaining completed templates for Sections 3-6 should be uploaded into the "***Other Attachments***" section.

Snapshot of the "**Attachments**" tab of the "**Other Attachments**" section



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

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[6].

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	
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	

[6] 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.