Institutional Research Policy

Armauer Hansen Research Institute

Final Version

August 2023

Contents

1. Background

The Armauer Hansen Research Institute (AHRI) is a health research institute established in 1970 by the Government of Ethiopia in collaboration with the Save the Children Organizations of Norway and Sweden.

AHRI was initially established to investigate the pathogenesis and human immune responses to leprosy. But now, it undertakes medical research in a wide range of diseases such as tuberculosis, malaria, NTDs, HIV and other viruses, antimicrobial resistance, as well as various cancers and other non-communicable conditions. In 2022, as a result of Proclamation Number 1263/2021 issued for the Definition of Powers and Duties of Executive Organs of the Federal Democratic Republic of Ethiopia, the mandate of the research institute is expanded by including responsibilities related with research, development and production of vaccines, diagnostics, therapeutics, traditional medicine, nutraceutical and other pharmaceuticals. The Institute further continues to be responsive to the challenges of emerging and reemerging diseases through medical research and innovation.

As a result developing the institutional research policy document, which is aligned with the institute's strategic plan became important. This policy document will guide the institute in its navigation and focus towards developing research plan, protocol and execution. It narrates the research priority areas of the Institute.

2. Research Administration structure

Research and Innovation wing of the institute organized, coordinated and conducted under the following six directorates: Communicable and Non-Communicable Diseases Research Directorate, Clinical Trial Directorate (CTD), Knowledge Management Directorate (KMD), Vaccine, Diagnostics, Medical Device Research and Development Directorate, Traditional and Modern Drug Research and Development Directorate, and Pharmaceutical and Biological Product Development Directorate.

3. Goal and objectives of the research policy

The overall purpose of this Research Policy is to provide a framework for the governance and conduct of research in AHRI. Furthermore, the policy details the mechanisms of support

available for research activities and provides guidelines regarding internal procedures when developing a research project.

The specific objectives are to:

- Prioritize research projects
- Introduce end to end thinking/principles while project planning
- Determine the percentage of clinical, biomedical, epidemiological and product-oriented research to be conducted/financed for each directorate
- Align postgraduate students' projects to match with the institute's mission
- Streamline research activities
- Create an enabling environment for the conduct of research
- Strengthen research management and coordination
- Improve research culture and practice
- Mobilize and manage funds for quality research and innovations; and
- Increase the returns for the conduct of research to achieve international researcher visibility and attract of both human and financial resources to the institute.

4. Scope

This policy shall apply to all researchers and projects under the authority of Armauer Hansen Research Institute.

5. Research Policy Guidelines

5.1. Principles of the policy

1. Focus: Most, if not all, projects should be in line with the mission of AHRI. Hence, both staff, as well as postgraduate student's projects should contribute to the targets /goals of the Institute.
2. Continuity of research: Research shall be thematic and by the end of the project, findings from all single projects should add up to answer one big research question/problem.
3. Projects embedded within the same/existing cohort, where possible: Planning projects around a well-established cohort would give every possible benefit to scientific excellence/quality and impact

4. Product-oriented: The relevance/significance of the research, particularly in LMIC should target research findings that have direct significance to public health. The product can include policy, treatment guidelines/algorithm, devices, vaccines, diagnostics, therapeutics; new or improved, technology transfer and adaptation, etc,
5. Proportion: The proportion of the nature of research i.e., operational, epidemiological, clinical, basic biomedical, product development, tech transfer, etc should be balanced across the research directorates
6. Inter-directorate collaboration: Depending on the nature of the research project, more than one directorate may work together by defining their individual directorate roles and responsibilities, which shall be implemented in a case-by-case approach
7. Funding shall not dictate the type of research: The institute shall not lose focus solely based on the availability of funding or should not only be donor-oriented. Even though the Institute receives grants from international agencies, a lot more is contributed from the Ethiopian government in terms of tax exemption, laboratory facility, staff, and general service support, etc. Therefore, research questions should be prioritized based on the relevance for Ethiopian public health than the availability of fund.
8. Postgraduate students will be attached and get support if and only if their research project contributes to the mission of AHRI
9. Research partnership: the selection of partnership shall be in alignment with the mission of AHRI. We shall avoid haphazard network/partnership as it will be overwhelming by their interest and lead to loss of focus. The same is true for grant applications. The core should not be just to get grants but grants that can support our defined projects.

5.2. **Research Priorities**

Research agenda are set to be defined by the Federal Ministry of Health. Notwithstanding the Institute will undertake research, based on the national health research agenda, on priority to health and nutrition problems related with communicable and non-communicable diseases and generate, accelerate, absorb and disseminate scientific and technological knowledge to improve clinical care, health and well-being of the public. It will promote health innovations and undertake research on traditional medicines, vaccines, diagnostics and therapeutic tools and strategies. The Institute will further, promote and strengthen local production of medicine, vaccines, diagnostics, therapeutics, traditional medicine, nutraceutical and other pharmaceutical

products to improve access to healthcare products through quality production. It will serve as a hub for knowledge and technology transfer in health research and development. The institute will continue to conduct clinical trials and bioequivalence studies. It is also the responsibility of the institute to build national human capacity in health research and development through supporting postgraduate trainees when project ideas align with the institute's mission and the research agenda set by the Ministry.

Each research directorate should identify research priority areas of the directive from this policy's Principles perspective as shown under Clause 5.1. They should list thematic areas and show the degree of priority.

5.3. Research Planning and Administrative

Research has to be performed within a clear framework with targets, responsibilities, indicators and outputs. To maximize the use of available scarce resources and avoid duplication, AHRI shall therefore:

i. Strengthen the infrastructure in all research directorates conducting research.
ii. Strengthen further the current critical mass of researchers who have qualifications in Research coordination and management.
iii. Leverage more resources and emphasize strengthening the capacity for research planning at all levels.
iv. Strengthen further the current mechanism by which AHRI staff can be motivated to conduct research. Implement the 3R principle i.e., recruit the best, reward the best (which includes the fringe benefit and other motivation mechanisms) and retain the best.
v. Sustain the current arrangements of multidisciplinary approach to research.

5.4. Sourcing and Management of Research Funds

It is recognized that for sustainability and relevance, main source of research funds will be from government of Ethiopia. Nonetheless, for the purpose of increasing the institute's international impact and recognition and the career development of the researchers of the institute at international level, the institute is highly encouraged to cover its research project costs from

competitive research grants secured from national and international funders. As result the institute adhere to the following activities to encourage securing competitive research grants

i. Timely disseminate information to staff members and students about the budget allocated by the government for research.
ii. Create conducive environment for staff members and students to write research proposals to get funding.
iii. Continue to solicit funds from different partners to support a research fund for members of staff and students.
iv. Sustain sourcing and provision of general information on possible sources and modes of research funding both within and outside the institute on regular basis.

5.4.1. Disbursement of Research Funds

The management of research fund in a transparent manner is important for the successful implementation of research projects. AHRI shall therefore continue to:

i. Ensure that Disbursement of funds follows approved accounting procedures.
ii. Ensure all research funds are deposited in the institute account (USD or National account).
iii. Ensure that funds are disbursed by installments as impress, the management of which shall be decided by the relevant institute administrators and the grant agreement.
iv. Ensure that funds are disbursed according to the approved budgetary and time allocation.
v. Re-budgeting among major cost categories will not be allowed unless prior approval is obtained from the funding agency.
vi. Require that recipient of Research Funds produce both technical and financial reports.

5.5. Procedures for Approval, Control and Monitoring of Research Process

AHRI needs to put in place an operational mechanism of conducting research such that there is uniformity in the process yet set flexible grounds to enable researchers follow scientific rigor in producing results

Ensuring quality of research

Quality in scientific undertakings is something that can be compromised. Therefore the institute has to ensure quality through:

i. Making sure that projects have approved and updated laboratory standard operating procedures
ii. Use institutional log books to document any data generated in the process and submit the log books to AHRI upon completing their projects
iii. Availing quality reagents
iv. Ensuring that researchers are trained and certified internally to conduct the research
v. Introduce Good Laboratory Practice (GLP) in the Institute

5.5.1. Procedures for Approval

AHRI shall therefore emphatically sustain a process to:

i. Ensure that staff is well aware of the national research agenda and participate in translating it into their respective research project.
ii. Follow one general framework guiding for the preparations and approval of research projects. The framework should addresses the following issues/ processes:
    - Initiation of a research project;
    - Formats of research proposals; Scrutiny and approval process for research proposals shall focus on quality, relevance, need, soundness and resource requirements (including financial resources). This will clearly spell out the roles and powers of different units within the relevant institutional administrative hierarchy;
    - Planning and budgeting guidelines, including applicable rates for cost estimates;
    - Financial regulations governing the financing of research;
    - Procurement of equipment and consumables. These have to be within relevant institutional and national procurement policies and procedures. In principle all equipment procured for research is the property of AHRI;
    - Registration of research projects - whether internally or externally funded; Standard contracts between the funding agency, the Institute; Progress reporting requirements, control, and monitoring; Regulations regarding employment within research projects.

- Formats for final research reports;

iii. Ensure that all research proposals are subjected to AHRI approval process before being accepted for funding.

iv. Enter into a research contract with the researcher when the project has been approved irrespective of the source of funding.

v. Where there is an interest of joint ownership of research results/output, the contract shall be between the researcher as one party and joint financiers as the other party.

vi. Scrutinize all contractual requirements after a proposal has been funded.

5.5.2. Control and Monitoring of Research Process

Management of research has to ensure that the research is well planned so as to provide reliable research output. In this regard, AHRI shall continue to:

i. Develop and disseminate research quality control and monitoring guidelines.

ii. Ensure that applications for research funds are in line with the guidelines.

iii. Ensure that approval of applications for research funds takes into considerations the relevant research quality checklists.

iv. Monitor quality and number of publications resulting from research done by staff;

v. Monitor the dissemination of research results.

vi. Conduct surveys to obtain feedback on quality and value of research results.

vii. Conduct impact assessment every 5 years.

5.4.2.1. The necessity of Institutional Review Board/Ethics Committee for the Control and Monitoring of Research Process

i. The Institute upholds the necessity of verifying the scientific rigor and protection of research participants under every research. Therefore, the Institute obliges all research protocols to be reviewed by the Institutional Review Board/Ethics Committee.

ii. The functions and procedure of review is regulated by an independent Institutional Review Board/Ethics Committee Guideline.

iii. The Institute accepts ethical approvals from other Institutions having the same level Institutional Review Board/Ethics Committee, to avoid being reviewed by different institutions and avoid duplication of efforts.

5.6. Collaborative Research

There is a need to forge strategic partnerships and collaboration within and between the university, the Government, other research institutes and the private sector in the country and beyond. Therefore, the Institute will continue to:

i. Promote collaborative research where there are potential benefits to the institute and the public interest
ii. Promote external collaboration within and outside Ethiopia.
iii. Require that a full-time employee of the institute serve as the Principal or Co-Investigator.
iv. Encourage internal collaborative projects to be multi-disciplinary in nature.

5.7. Dissemination of Research Results

Dissemination of research results may entail sharing research findings with research peers, sponsors and the larger community through publications, seminars and conferences. Subject to the Intellectual Property Policy, AHRI shall continue to:

i. Encourage the incorporation of a specific section on dissemination plan of research results in the research proposals. Different ways of sharing research results should be through seminars, workshops, annual research meetings etc
ii. Require that research proposals include at least one local seminar/ workshop to ensure local 'ownership' of research findings. For large research projects, local conferences/symposia shall be organized.
iii. Ensure that research reports are produced according to the agreed format. Depending on the level of research and the funding agency, research reports may be reviewed at Directorates and General Directorates level.
iv. Subject all research reports to peer-review before depositing them in the data bank.
v. Require that AHRI organize at least one research workshop annually to review research plans, progress and outputs. Annual research workshop shall also include presentations of academic papers, to which key stakeholders shall be invited. Prepare and submit to policy makers research abstracts/policy briefs for the purpose of informing policy.

vi. Encourage and support dissemination of research results through regular local and international fora. Encourage and support the inclusion of research findings/publications in accessible electronic databases,

vii. Encourage the publication of popular versions of research findings in the local media with the permission of the institute management. Popularize research findings in languages that people can understand.

viii. Disseminate research findings through national/international exhibitions in line with National Research Ethics Policy.

ix. Strengthen report-back to the community where studies have been conducted

5.8. Research on Animals

i. All research, research training, experimentation, biological testing, and related protocols involving live, vertebrate animals conducted in the institute, or at another institute as a consequence of sub-granting or subcontracting, shall comply with internationally acceptable standards on humane care and use of laboratory animals.

ii. AHRI will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand the applicable laws and regulations pertaining to animal care and use. The institute will also monitor and ensure compliance at individual and collective levels.

iii. All research on laboratory animals must be reviewed and approved by AHRI Ethics Committee.

iv. The institute and all individuals involved in animal care and use must comply with occupational health and safety procedures for personnel who work in laboratory animal facilities or have frequent contact with animals.

5.9. Bio-hazardous Agents

i. The appropriate department from the institute will be designated to review the institute's research activities and facilities involving the acquisition, use, storage and disposal of bio-hazardous agents.

ii. The institute shall endeavor to provide appropriate training in the safe handling and management of biological and chemical hazard agents used in research studies.

Researchers and personnel working or handling bio-hazard agents shall first receive appropriate training and get certified.

iii. Research proposals involving the use of bio-hazardous agents shall include a section on the handling of bio-hazardous materials.

5.10. Intellectual Property Rights

All participating researchers including students and visiting scholars must follow the AHRI's Intellectual Property Policy and procedures annexed to this document. For researchers wishing to send study samples abroad, either for analysis or other research purposes, they should sign the National Material Transfer Agreement

5.11. Use and disposal of research project Resources

i. Sponsored project agreements must always include the terms and conditions for the disposal of tangible property (e.g. equipment, vehicles, reports, theses or dissertations) or intangible properties such as rights to data, copyrights, and inventions. Except as otherwise expressly provided, all equipment purchased within a research project is the property of AHRI. National laws, policies and procedures governing the disposal of the institute's property (obsolete or otherwise) should be applied.

ii. During the life of a project, all equipment or goods purchased with research funds will not be sold, ceded, exchanged or otherwise disposed of without the prior approval of the institute.

iii. On completion or termination of a project/program, the institute will retain the title to all equipment purchased for the project or program. The unit/researcher that had these resources should be given priority in the disposal of research resources when the project is completed.

5.12. Confidentiality of data

i. Researchers are entitled to keep data sets confidential before publication.

ii. After publication, when the research is in the public domain, the data should, upon request, be available to other researchers by the Principal Investigator/corresponding author. It is recognized that there may be technical or cost problems which prevent it being freely available, but the principle is that

there should be the opportunity for checking any data on which material in the public domain is based.

iii. In no way do the requirements for data availability override the right to confidentiality and privacy of individuals or organizations who are the subjects of research.

iv. Non-disclosure agreement need to be signed by all parties who are involved in product development projects.

5.13. **Authorship**

The principles in this section of this Policy are based on part of the Vancouver Protocol, originally developed at a meeting in Vancouver by a group of editors of medical journals. Further,

i. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

ii. One or more of the authors, as corresponding author, should take responsibility for the integrity of the work as a whole.

iii. Credit as an author should be based only on participation in each of the following aspects of the work:

a) Substantial contribution to conception and design, or acquisition of data, or analysis and interpretation of data.

b) Either drafting the article or commenting critically on the draft.

c) Approving the final version, to the extent that each author is prepared to take joint responsibility for it. The acquisition of funding, the collection of data, or the general supervision of the research group, does not, by themselves, justify authorship. Such contributions should be listed in the acknowledgements.

d) The order of authorship should be a joint decision of authors, decided at an early stage of drafting the paper.

e) In most fields of research, the first author is recognized as having made the most significant contribution. This is the preferred style unless the conventions of the field of research require another ordering.

f) In joint publications of graduate student and her/his supervisor, the graduate student should be first author unless the supervisor's contribution goes well beyond material on which the graduate student has worked.

Additionally,

i. Students shall take the first author position in their respective research projects.
ii. MoH, Norad and Sida must be acknowledged in all publications as core funders of the researches in the Institute.

5.14. Citation and acknowledgement

It is important in all publications, including such documents as research proposals, to cite all sources properly. The form of citation is usually specified by the journal in which the article is published. Citations serve two purposes

a) To direct the reader to further information;
b) To give due credit to the source of ideas, quotations, or data;

Any of the following require appropriate citation of the source:

a) Direct quotations of published material – longer quotations may require a release from the copyright holder;
b) The description, summarizing, or paraphrasing of any previous work;
c) Use of previously published data presented in any form, such as graphs, calculations, or tables. Use of such data also requires permission in the form of clearance from the holder of the copyright.
d) Ideas that originate from other published or unpublished sources

6. Miscellaneous Clause

This policy document is effective for 5 years from the date of final signature by the Director General.

Approved by:

SIGNATURE:

PROF. AFEWORK KASSU
DIRECTOR GENERAL
ARMAUER HANSEN RESEARCH INSTITUTE

ANNEX 1

No	Research Area	Specific Priority of Research Area	Level of Priority
1)	Mycobacteria and Other Bacterial Diseases research	Antimicrobial Resistance	
		Development of in-house diagnostic assays	
		Understanding the aetiology, pathogenesis, and molecular epidemiology of infectious diseases	
		Assessing vaccine efficacy	
2)	HIV and other viral diseases research	Understanding and characterization of viral etiologies of public health importance	
		Development of simple and low-cost in-house assays for viral diseases diagnosis and monitoring	
		Understanding the interplay of host-virus interaction, host immune and vaccines responses	
		Understanding mechanism of antiviral drug resistance and mutational pathways	
3)	Malaria and Neglected Tropical Diseases Research	Research related to Malaria Elimination	
		Research to improve the current Malaria treatment	
		Research related to Neglected tropical disease	
		Research on malaria parasite and antimicrobial resistance	
		Research that uses evidence to test new products in malaria treatment	
4)	Cancer and other non-communicable diseases research	Understanding burdens and patterns of NCDs	
		Understanding risk-factors of NCDs (Genetics, social factors, nutrition…	
		Generate evidence for improving diagnosis and treatment of NCDs	
5)	Clinical Trials for development of Therapeutics to	Drugs trial for the treatment of communicable and non-communicable diseases of public health priorities	

	communicable & non-communicable diseases	such as TB, Malaria, NTD, CVD, Diabetes, cancer, etc	
		Biologicals trial for the treatment of communicable and non-communicable diseases of public health priorities	
		Medical devices trial for management of communicable & non-communicable diseases	
		Trials on local therapeutic innovations including TM/herbal products	
6)	Clinical Trials for development of **vaccines** to communicable & non-communicable diseases	Vaccines trial for to infectious diseases of public health priorities such as TB, Malaria, HIV, NTD, emerging infections, etc	
		Improving the vaccine trial capacities	
7)	Clinical Trials for development of **diagnostics** to communicable & non-communicable diseases	Trials on clinical validity of kits for the diagnosis of communicable and non-communicable diseases of public health priority	
		Trials on clinical validity of devices for the diagnosis of communicable and non-communicable diseases of public health priority	
		Improve the clinical development landscape of local innovations for diagnostics	
8)	**Bioequivalence** and clinical pharmacology studies	BE Clinical studies	
		BE bioanalytical services	
		Clinical pharmacology studies	
		Creating enabling capacities for BE services in Ethiopia	
9)	Improving the clinical trials landscape in Ethiopia & beyond	Excellence in Trials management and quality	
		Capacity building: training and trial sites development	
		Trials Methodology	
10)	Vaccine Research and	Genetic mapping of circulating different priority	

	Development	pathogens, design antigen for disease of interest, antigen screening and evaluation for vaccine development.	
		Pre-clinical studies and clinical trials of new vaccines against priority diseases.	
		Clinical evaluations of existing vaccines for new indications, schedules, and age groups, and evaluation of vaccine delivery.	
		Research to monitor vaccine effectiveness and safety	
11)	Diagnostic research and development	Conduct diagnostic product design, product prototype development, and production.	
		Develop new, clinically relevant biomarkers and assays, validations and reference range establishment for existing or new assays, and technology transfer of advanced technologies and emerging concept.	
		Diagnostic kit evaluation.	
12)	Medical devices and equipment research and development	Work with all stakeholders to turn medical device research and innovation into real benefits for health care providers, patients and society.	
		Work to deliver safe, effective health care device innovations that cover the entire spectrum of care from prevention to diagnosis and treatment focusing on the areas where there is unmet public health need.	
		Conduct preclinical and clinical studies of medical devices.	
13)	Traditional medicines and nutriceuticals Research and development	Analytical testing of herbal material and herbal products.	
		Identification and Isolation of bioactive or marker compound.	
		Standardization of herbal products	

		Establishment of Medicinal plant botanical garden and herbarium for further research and development activity.	
14)	Modern medicine and in silico research and development	Documentation of ethno-medical information of medicinal plants/practices and scientific publications.	
		Development of Ethiopian traditional medicine database	
		Development of monograph, pharmacopeia and Atlas on Ethiopian medicinal plants.	
		Undertake Pharmacokinetic, pharmacodynamic and pharmacovigilance, toxicovigilance studies on Modern medicine.	
		Undertake computational drug discovery and development studies on promising medicinal plants through the applications of Artificial intelligence, cheminformatics and bioinformatics tool.	
15)	Safety and Efficacy research and development	Safety testing of commonly utilized Ethiopian traditional medicine.	
		Safety and efficacy evaluation of medicinal plants used for the treatment of diseases of public health importance.	
		Undertake microbiological quality analysis of herbal medicine, nutraceuticals and other source of natural products.	
		Establish and conduct the pharmacodynamics and pharmacokinetics of herbal and other source of natural products.	
16)	Product formulation research and development	Studies on value-added safe and standardized herbal products, nutraceuticals and other source of natural products.	

		Study methods of production of traditional medicines of proven therapeutic efficacy, safety and quality.	
		Development of appropriate dosage forms from validated and standardized herbal products, nutraceuticals and other source of natural products.	
		Develop Ethiopian herbal products, nutraceuticals and other source of natural products recipe (Product Packages).	
		Pre-formulation studies of pharmaceutical or herbal products.	
		Carry out studies the quality (physic-chemical, adulterants/substandard) of modern medicines and herbal medicine in the Ethiopian market.	
17)	API Development and Synthesis	Development of new and improved manufacturing processes for APIs	
		Synthesis of novel APIs with enhanced efficacy, safety, or stability	
		Optimization of existing API synthesis methods for improved efficiency and cost-effectiveness	
		Development of sustainable and environmentally friendly API synthesis approaches	
18)	Excipient Innovation and Formulation	Research on novel excipients with improved functionality, stability, and biocompatibility	
		Development of excipients for modified-release formulations, taste masking, or targeted drug delivery	
		Compatibility studies between APIs and excipients to ensure formulation stability	
		Investigation of excipient-related factors influencing bioavailability and therapeutic efficacy	
19)	Packaging Material Development	Research on advanced packaging materials with improved drug protection and stability	
		Development of innovative packaging technologies to enhance drug shelf life and patient safety	
		Investigation of packaging material interactions with drugs and their impact on drug stability	
		Development of sustainable and eco-friendly packaging solutions	
20)	Process Optimization and Scale-	Optimization of manufacturing processes for APIs and	

	up	excipients to improve efficiency and yield	
		Scale-up studies and process validation for commercial production of pharmaceutical inputs	
		Investigation of process parameters and conditions to ensure consistent product quality and reproducibility	
		Research on continuous manufacturing approaches for pharmaceutical inputs	
21)	Nanotechnology and Advanced Drug Delivery Systems	Development of nanoscale drug delivery systems for enhanced bioavailability and targeted delivery	
		Research on nanomaterials as excipients or carriers for APIs	
		Investigation of nanotechnology-based approaches to improve stability and solubility of poorly soluble APIs	
		Evaluation of safety and toxicity aspects of nanomaterial used in pharmaceutical inputs	
22)	Market Research and Analysis	Analysis of healthcare market trends, patient demographics, and disease prevalence	
		Assessment of market dynamics, including competitive landscape and pricing strategies	
		Identification of unmet medical needs and potential market opportunities	
		Investigation of market access barriers and strategies to improve access to pharmaceutical products	
		Evaluation of health economic aspects of pharmaceutical products and their value proposition	
23)	Manufacturing and Supply Chain Optimization	Research on efficient and cost-effective manufacturing processes for pharmaceutical products	
		Development of novel manufacturing technologies and equipment	
		Optimization of supply chain management strategies to ensure product quality, safety, and availability	
		Evaluation of sustainability and environmental impact of pharmaceutical manufacturing and supply chain operations	
24)	Emerging Technologies and Innovation	Research on emerging technologies with potential applications in the pharmaceutical industry (e.g., AI, machine learning, nanotechnology)	
		Assessment of the impact of digital health and telemedicine on pharmaceutical products and services	
		Investigation of innovative drug delivery systems and formulations	
		Evaluation of emerging therapeutic approaches, such as gene therapy or personalized medicine	
25)	Project Feasibility and	Research on assessing the feasibility of pharmaceutical	

	Investment Analysis	projects, including market demand analysis, financial modeling, and risk assessment.	
		Evaluation of investment strategies, return on investment (ROI), and cost-benefit analysis for pharmaceutical projects.	
		Investigation of funding sources, such as venture capital, public-private partnerships, and government grants for pharmaceutical R&D projects.	
26)	Facility Design and Engineering	Research on facility layout and design for pharmaceutical manufacturing plants, laboratories, and research facilities.	
		Development of engineering solutions for pharmaceutical production processes, including equipment selection, process automation, and process optimization.	
		Investigation of cleanroom design and control strategies to ensure product quality and regulatory compliance	
27)	Process Development and Scale-up	Research on process development and optimization for pharmaceutical manufacturing, including formulation development and technology transfer.	
		Evaluation of scale-up strategies to transition laboratory-scale processes to commercial production, considering factors such as process robustness, efficiency, and cost-effectiveness.	
		Assessment of the impact of intellectual property on innovation, market competition, and market exclusivity	
		Investigation of process analytical technologies (PAT) and real-time monitoring approaches for process control and quality assurance.	
28)	Sustainability and Green Engineering	Research on sustainable practices in pharmaceutical manufacturing, including energy efficiency, waste reduction, and environmental impact mitigation.	
		Evaluation of green engineering approaches and technologies, such as solvent-free processes, eco-friendly solvents, and sustainable packaging.	
		Investigation of life cycle assessment (LCA) methodologies to evaluate the environmental footprint of pharmaceutical products and processes.	
29)	Product quality management and productivity	Problem-solving research to identify and rectify the quality related problems faced by local manufacturers	
		Research to develop new testing methods and process optimization technologies to enhance the quality medicine	
		Development of quality control/assurance, product development in regards to regulatory compliance	
		Quality risk management, manufacturing technology	

		advancements and continuous improvement strategies	
30)	Enhance the production of vaccines and other biological products	**Bio-Pharmaceuticals** Antibiotics, Vaccines, Diagnostic kits, Animal medications, Anticancer medications **Bio-chemicals** Biopolymers, Industrial enzymes and reagents, Enzymes and reagents for research, Bio-cosmetics and home & personal care chemicals **Bio-Foods** Functional health foods, Amino acids, Food additives, Fermented foods **Bio-Environmental** Microbial treatment agents, Measuring apparatus for environmental pollution (service for pollution assessment) **Bio-Process and Equipment** Bioreactors, Biomedical and diagnostic apparatuses, Bioprocess and analysis equipment, and Plant and process design **Bio-Assays, Informatics Service** R&D services (ex. drug development services, Bio-safety and efficacy evaluation services, Bioinformatics services	

**Key Coloring*

Low Priority

Mid Priority

High Priority