National Health Research Policy
2006
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Preface:

Health research is defined as generation of new knowledge using scientific approach. It is a systematic scientific method aiming at identifying and solving health problems. Health research adds to the scientific knowledge and guide to provision of information needed as a base for planning and decision making, leading to improvement of the community health both locally and nationwide.

Since 1978 the Eastern Mediterranean Regional Office of WHO established a unit under the name of Research Promotion and Development. Late the unit was renamed The Research Policy and Cooperation (RPC) Unit. The aim of RPC is to support health research and development (HR&D) in EMR Member States through policy advice, capacity building of national health research systems, generation of appropriate knowledge and its utilization towards improved health.

In 1988, a Global Commission was created to look at the status of health in the world. It was discovered that, while more than 80% of all the health problems and diseases were in the developing world, more than 90% of resources directed to health research were in the developed world. As first pointed out by the Commission on Health Research for Development in 1990, only about 10% of health research funding is allocated to 90% of the world’s health problems (the 10/90 gap).

The Commission recommended that each country, no matter how poor, should conduct research in health as a strategic component of its national development. This was called Essential National Health Research (ENHR). The main strategies of the ENHR process are advocacy, consensus building, capacity development, and networking and sustainability mechanisms.

The Commission further recommended that, in implementing this concept, each country should encourage consensus building and all-inclusiveness as a national strategy for implementing health research.

In 1990, a Global Task Force on Health Research for Development was formed to implement the recommendations of the 1988 Global Commission on ENHR. Eighteen countries began to apply the ENHR strategy between January 1991 and March 1993.

At the end of the life of the Task Force, it was recommended that a Council on Health Research for Development (COHRED) be established to continue the work started by the Commission and further developed by the Task Force.

During the last decade several of the international agencies involved in funding health research, including WHO, have tried to seriously examine
the role of health research as an important contributor to sustainable human development. They have also attempted to look at how governance of research at national, regional and global levels can be made more effective and efficient. As a result of these deliberations, it was decided to hold an International Conference on Health Research for Development.

This landmark conference, which was held in Bangkok, Thailand, in October 2000, and attended by over 700 participants, was preceded by a year of intensive preparatory work including consultation with countries. The conference recognized that the research efforts in many countries were fragmented with a lot of duplication and were not focused on national needs and priorities. This has led to the emergence of a vision of a systems approach to health research driven by equity, focused on national goals and priorities and operating within an interactive regional and global framework. In September 2000, at the conclusion of the Millennium Summit, world leaders adopted the “United Nations Millennium Declaration Goals” (MDGs) which contained key development goals. Recommendations outlined to achieve these goals can be more or less efficient and more or less effective in breaking the circle of poverty and ill health, depending on whether they are evidence-based. The role of research is therefore to ensure that the proposed measures are, as far as possible, evidence-based, so that the resources available to finance these measures are used in the most effective way in the fight against poor health and poverty.

**Research Situation in Sudan:**

At the turn of the 20th century, health research in Africa focused on the epidemiology of those diseases which attacked the European missionaries or caused epidemics e.g. malaria (‘the white man’s grave), guinea worm, tuberculosis, meningitis and trypanosomiasis in West and East Africa. In North Africa, the establishment of the Wellcome Tropical Research Laboratories in Khartoum supported early studies on schistosomiasis in Egypt and Sudan.

Sudan's history in conducting medical research could be traced to 1903, when the Welcome Research Laboratories in Khartoum were established as a part of the Gordon Memorial Collage. Policies to conduct research at that time played an important role in the national effort to develop new or improved prevention strategies, diagnostics, and treatments using the information gained from research.

The latter was also used to develop evidence-based guidance for preventive and treatment services, and providing support for the provision of these services.

Currently, the stakeholders in health research in the Sudan could be divided into the following categories:
1. The government:

Under the auspices of the government many ministries i.e. Federal Ministry of Health and States Ministries of Health, Ministry of Science and Technology, Ministry of higher Education, Ministry of Agriculture, Ministry of Animal Resources are involved in conducting health and health related research.

2. The Universities:

Most of the faculties of medicine, pharmacy, dentistry, laboratory technology, paramedical colleges, nursing and imaging technology schools are considered as stakeholders and involved in health research.

Faculty, post and under graduates are major players in health research

4. The private sector:

In recent years the private sector was attracted by certain research centers in universities to contribute to health research either by giving financial support or by participating in the governing boards or both.

5. The United Nations (UN) Agencies:

Such as WHO, UNICEF, UNFPA, UNAIDS and others provide technical and financial support to the health research through existing health programmes

6. The European Union (EU)

Although the contribution of EU to health research is yet not significant it is expected that EU would give support to institutions involved in health research. Such support will be realized by submitting sound research proposals.

7. National and International NGOs:

Few national and international NGOs as actors in the area of health could be considered as stakeholders in health research

8. The community

The local communities do participate in health research; however, their contribution is limited as shown in the Health Research System study carried in Sudan in 2003.

Realizing the importance of research in national development, the Federal Ministry of Health responded to the WHO initiative in establishing a HSR
unit and created a full directorate responsible for research and technical training in 1998.

This document entitled "National Health Research Policy" (NHRP) is the national document for the research policy that regulate the conduct of research related to health and health systems in Sudan. It was updated by the National Task Force Committee (NTFC)) through a long process by reviewing the old research policy document which had been developed since 1999. The overall objective of the updated policy is to contribute to the generation of evidence-based information for use by policy makers and managers at all levels of the health system for strengthening the health systems and services at national and state levels.

**The milestones for preparing the policy:**

- In 1996 Health System Research Unit (HSRU) was established in the FMOH with collaboration of the World Health Organization (WHO). The vision of the unit was effective utilization of the scarce resources for health in solving the priority health problems by research. This mission of the HSRU was to improve the quality, safety, efficiency, and effectiveness of healthcare by solving the health problems facing the health care delivery system by research.

- In 1998 an Undersecretary Decree was issued for the transformation of the HSRU to Research Directorate (RD) which had taken the responsibility of developing health research policy. The latter was developed, approved and the adopted since 1999.

- In 1999 The Ministerial Decree was issued for the formation of Health Research Council (HRC).

- The first policy statements and plans were developed immediately after the establishment of the Research Directorate 1998 without advocacy and endorsement by higher political level

- The policy was approved, endorsed by the Health Research Council (HRC). The latter was formed by an under-secretary ministerial decree in 1999.

- The policy document was then printed and disseminated to the different institutes, academia, NGOs and health related sectors.

- Since adoption of the old policy a lot of responses were translated into plans, strategies and activities both at national and state levels. These
activities were promoted and supported by the WHO Regional Office over the years.

In 1999 Sudan had adopted the ENHR strategy. The most appealing aspect of ENHR is its stated goal of addressing equity and social justice.

A National Conference on Health Research priority setting was held in Khartoum 1999 in collaboration with COHRED and was attended by different stakeholders in the country.

During the last years the FMOH recognized that although the global culture of health research and evidence-based health planning, decision and policy became a prominent feature of the health systems in many countries, Sudan still lacks this culture.

A decision to develop a comprehensive research policy was made by The General Directorate of Planning and Health Development. The Directorate of Research in the FMOH was nominated to take over this task.

A task force was formed in June 2006 headed by the head of the National Technical Committee (NTC) for updating and renewing the old policy.

Expert's opinion through the taskforce meetings consultation and National Policy documents review enrich the information necessary for updating the old policy document.

The Needs for an Updated Health Research Policy

A study carried during 2001-2003 examined the current situation in health research system in Sudan.

The study concluded that research efforts were fragmented with a lot of duplication and were not focused on national needs and priorities. This has led to the emergence of a vision of a systems approach to health research driven by equity, focused on national goals and priorities and operating within an interactive regional and global framework.

The need for a new, strong and clear national health research policy backed by high political commitment became apparent. An updated policy is needed to create appropriate research environment, to strengthen leadership, management and coordination system of research.
. Federalism & Decentralization policy in Sudan has an overall objective to minimize disparities that have been quite wide between federal states and regions, between urban and rural areas, between war affected and more stable areas. Decentralization in Sudan might lead to more equitable, accessible, acceptable quality of health services at the local level. To achieve this goal there is a great need for generation of evidence-based information for use by policy makers and managers at all levels of the health system through conduct of research and application of results as evidence for policy and health programmes.

. After the signing of a peace agreement, Sudan demands newer and better mandates to provide better services especially in health as health is the most important asset that directly affects the life, security and prosperity of the population. Peace era has to be kept by specific well developed and definite measures, to assure its sustainability and further improvement. Health is a major issue and a demand to assure stability.

Decision- making in health care provision should be evidence-based and health research is the main pillar of providing information for health decisions.

. However, it is felt that intensified efforts are needed now to enable the FMOH to develop its health research systems further and to use research increasingly to provide evidence for policy-making and health actions, especially in reducing health inequalities and in addressing the health problems of the poorer segments of the population.

It was in this context that the Ministry of Health formulated an ad-hoc committee in 2006 for updating the old research policy through a series of meetings and consultations.

Introduction:

Health research is defined as generation of new knowledge using scientific approach. It is a systematic scientific method aiming at identifying and solving health problems. Health research adds to the scientific knowledge and guide to provision of information needed as a base for planning and decision making, leading to improvement of the community health both locally and nationwide.

Sudan, like many other developing countries, has high morbidity and mortality rates affecting its population of all ages but especially children aged less than 5 years.

Although a significant proportion of this morbidity and mortality is due to infectious conditions, many other non-infectious factors also play a role. These include chronic diseases like asthma, cardiac disorders including
hypertension, malignancies, and also economic deprivation resulting in poverty, malnutrition, and inadequate or inappropriate health care.

Sudan’s history in conduction of medical research could be traced to 1903, when the Welcome Research Laboratories in Khartoum were established as a part of the Gordon Memorial Collage. Policies to conduct research at that time played an important role in the national effort to develop new or improved prevention strategies, diagnostics, and treatments using the information gained from research.

The latter was also used to develop evidence-based guidance for preventive and treatment services, and providing support for the provision of these services.

1.1 Current Health Research Situation in Sudan:

The Research Directorate was established as a health system research unit at 1996 as a WHO initiative.

It is noted up to 1996 that there were a lot of problems facing health research in Sudan and justifying national research policy to be set. Those problems are summarized as follows:

. Research activities have often lacked a national focus, and have tended to be individualized efforts within hospitals, universities, research institutes, government departments, or within private or nongovernmental organizations without reference to the critical national needs.

. Researchers concentrate on clinical and biomedical research both of which need to be strengthened.

. Although the global culture of health research and evidence-based health planning became a prominent feature of the health systems in many countries, Sudan still lacks this culture.

. Inadequate allocation of national resources for health research makes scientists so heavily dependents on foreign grants that they tend to ignore national priorities in favour of lucrative contracts from foreign sponsors.

. Most of the researches are conducted in academic purposes with no consideration to the health system priority problems.

. Even in situations where ample research has been undertaken, major issues in research methodology and utility such as selection of research questions, subject selection, and measurement of outcomes and cost-effectiveness have not been adequately addressed.

Additional problems are summarized as follows:
Inadequate political commitment

Lack of adequate financial incentives for health research.

An unfavourable research environment

Lack of leadership and weak management and coordination of research activity at different levels.

Near absence of linkages and networking among scientists

Limited developed research capacity building.

Research results are poorly utilized for policy formulation.

Restricted publication of research results.

Since 1999 the Directorate of Research developed a policy document for research.

The first policy statements and plans were developed immediately after the establishment of the Research Directorate 1998. The policy was approved, endorsed by the Health Research Council (HRC), printed and disseminated to the different institutes, academia, NGOs and health related sectors. Since adoption of the old policy a lot of responses were translated into strategic plans and activities:

In the field of research advocacy and coordination, a Ministerial Resolution was issued for the formation of the Health Research Council, the National Ethical Committee and the National Technical Committee (1999-2002).

Members of these committees are representing the different stakeholders in research in the country.

A Manual of Research Methodology, both English and Arabic versions were published by the Directorate in collaboration with the World Health Organization (WHO) distributed to the academics and used as research training manual.

A monthly seminar was organized since 1999 by the FMOH in which health directorates and research institutes and universities are invited to contribute in presenting their research findings.

Training thematic areas covered proposals writing, data management, data analysis and health research ethics and project management.
Calls for proposals for small grants for junior researchers to the Federal priority areas were executed in collaboration with WHO.

Health research priority setting exercise was undertaken in 2000 in collaboration with Council on Health Research for Development (COHRED) in which a national and state lists of research priorities were identified.

In the area of coordination a conference on coordination of research supported by COHRED was held in Khartoum in 2004.

A scheme of small grants was established in 2005 in collaboration with Research and Coordination (RPC) Advisory Committee in WHO Regional Office to encourage junior researchers and postgraduate university students to conduct research.

A quarterly newsletter was issued since 1999 as a tool to advocate for research and to facilitate the publication of results of research results.

More intensive work has to be done in the field of coordination and collaboration with other research partners, strengthening the national health research capacity and promotion of the utilization of research results so as to achieve the goals of the updated research policy.

1 – 2 – 1 Vision

Effort and endeavor to direct scientific research towards achieving fruitful life-hood for a population enjoying good health and well being.

1 – 2 – 2 Mission

Utilization of scientific knowledge and medical technologies for the improvement of the quality, safety, efficiency and effectiveness of performance of the health care delivery system for all Sudanese, so as to prevail safety, security and effective contribution of sustainable development

Guiding principles of health research policy:

The Health Research Policy is guided by and supports the:

1- Comprehensive Strategic Plan goals of the Federal Ministry of Health (FMOH). In the field of research the Strategic Plan states that:

- Health planning, decision and policies should be evidence-based.

- Critical mass of researchers at all levels should be reached at 2010.
Funds raising for priority health research topics.

2- The vision of the research policy is also guided by the values and principles of Sudan National Health Policy which states that: Health systems research should be strengthened to promote equitable health and health care through sustainable health research system.

1 – 3 General objectives:

To identify new and emerging trends in health research, knowledge generation and technology development that have a strong potential for improving health, and supporting their utilization to strengthen health systems at both national and state levels.

1 – 4 Specific Objectives: -

1- To Provide support and technical assistance to build capacities and resources for improved health research conduct and its utilization at the national and state.

2- To Support health research in priority areas of public health and developing effective mechanisms to disseminate and share knowledge and information.

3- To Promote and advocate adherence to ethical practices, moral values and principles of equity and fairness in health research at national and state levels.

4- To develop effective linkages and partnerships with national and international health research institutes to augment the national health research capability.

5- To develop new tools (e.g. rapid diagnostic tests); cost-effective solutions (e.g. oral rehydration solution replacing intravenous fluids, ambulatory treatment of tuberculosis more effective than in-patient management and hospitalization); and helps to define options and opportunities in health systems.

Chapter Two

Health Research Ethics

The Declaration of Helsinki issued by the World Medical Association in 1964 and its amendments in the future, the International Ethical Guidelines for Biomedical Research Involving Human Subjects prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). The International Ethical Guidelines for Biomedical Research Involving Human Subjects (An
Islamic Perspective) Prepared by The Council for International Organizations of Medical Sciences (CIOMS) in cooperation with WHO and the Islamic Organization for Medical Sciences (IOMS) are accepted as fundamental documents for ethics and ethical principles in research involving human subjects.

In the field of ethics Health Research Policy:

- stresses that the ethics and ethical principles are to be adapted to the religious values and the Sudanese socio-cultural and traditional context.

- emphasizes the importance and application of ethics and ethical principles in all stages of research involving human subjects.

- ensures addressing of ethics and ethical principles in research involving human subjects for protection of the well fare and rights of the participants in research.

- emphasizes ethical considerations as germane to good research as are scientific considerations. Ethical inadequacies in a research proposal are as significant as scientific inadequacies. Scientific inadequacies also have ethical implications. Projects without scientific merit are wasteful of resources and unnecessary subject participants to risks.

- stresses an essential condition of the ethical acceptability of research is the determination that the scientific quality of a proposal, the skill and experience of the researchers are such that the objectives of the proposal can reasonably be expected to be achieved.

- ensures the ethical and scientific quality standard for proposal, design, conduct, recording and reporting results of clinical and preventive trials involving human subjects.

- Research must be conducted and supervised only by persons or teams with experience, qualifications and competence appropriate to the research.

- Research must only be conducted using facilities appropriate for the research and where there are appropriate skills and resources for dealing with any contingencies that may affect participants.
Chapter Three:

Research Training Policy

To adopt the right strategy for training in research, it is necessary to build up a proper system for training to raise the capacity in Health Research.

One of the policy objectives is to promote appropriate training in Health research at Federal and State levels besides institutional and universities as long as the other partners.

The government recognizes the need for training to encourage and support training in priority areas as identified by the concerned bodies and support training in Health Research at the National, State and institutional levels.

Research directorate is responsible for planning supervision of training besides raising capacity in research at national and state levels.

*Training by Federal Research Directorate should be conducted at the same level and

Training by states and institutions should be conducted by trainers from the same levels.

State governments should allocate resources for training in Health Research to be under the responsibility of research units at the state levels.

The policy emphasizes co-ordination between different sectors at the Federal and state levels in the field of training.

Chapter Four

Research to Action Policy

4- 1. Publication and Dissemination of research findings:

The policy emphasizes that publication/dissemination of research findings significantly contributes to health policy formulation, advancement of knowledge and medical practice.

Health Research Ethics and Technical Committees should be satisfied that researchers have the appropriate ways for publication and dissemination and of their research findings.
The results of the research whether publicly or privately funded and the methodology used should normally be disseminated in ways that contribute to public knowledge.

Where personal information about participants is collected, stored, used or disposed, the researcher must ensure the respect of their privacy, confidentiality and cultural sensitivity.

Health Research Ethics and Technical Committees should be satisfied that the processes of collection, storage, access and use of personal information are adequate to preserve the protection of the participants.

Results of the research must not be published in a form that permits identification of individual participants and must be published in a form which gives due regards to cultural and other sensitivities.

The policy emphasizes that participants have the right to now the research results in which they have participated.

4- 2. Utilization of research findings:

The policy:

- encourages the utilization of quality research findings for national health policies made by government ministers, officials, local health service managers, and clinical guidelines from professional bodies.

- ensures the utilization of quality research in agenda settings, policy formulation and implementation, monitoring and evaluation

- ensures the importance of research in setting clinical policies and the national policies for better performance of the health care delivery system as well.

- emphasizes the importance of links and partnerships between researchers in different research institutes and universities and the policymakers to pave the way for effective utilization of research findings in policy formulation.

- Interactions across the interface between policy makers and researchers are important in transferring and translating the research findings for policy formulation.
Chapter Six:

Research Financing

The Policy envisages an increase in Government-funded health research to a level of up to 2 percent.

Domestic medical research would be focused on new therapeutic drugs and vaccines for tropical diseases, such as TB and Malaria.

Research programmes taken up by the Government in these priority areas would be conducted in a mission mode. Emphasis would also be laid on time-bound applied research for developing operational applications. This would ensure the cost-effective dissemination of existing / future therapeutic drugs/vaccines in the general population.

Private entrepreneurship will be encouraged in the field of medical research for new molecules / vaccines, inter alia, through fiscal incentives.

Chapter Seven:

Institutional Structure

Federal Ministry of Health

Office of the Minister

Ministerial decree No. 11

The Federal Minster of Health,

In reference to the item no. 81 of the Public Health Law for the Year 1975, and in accordance with the directions and policies of the Federal Ministry of Health towards promotion and development of scientific research in Health, through coordination of health research activities and development of research infrastructure and in contribution to scientific research dissemination and promotion of its usage in planning and decision-making;

Has decreed:

First: Name of Ministerial Decree and date of validity

The decree's name will be: Decree for establishment of Health Research Council and will be valid from the date of its signature.

Second: Cancellation
This Decree will cancel the Decree no. 60, issued in 1998, on establishment of Council for Health Research.

**Third: Council for Health Research**

(i) Establishment, Mandate, composition and meetings of Council for Health Research

A Council for Health Research to be established in Sudan,

The Mandate of Council for Health Research will be:

1. Policy- and general strategies setting for health research in Sudan and follow-up of their implementation;

2. Endorsement of the National Health Research Plan and follow-up of its implementation reports; and

3. Fund-raising for Health System Research.

A Council for Health Research is to be composed from the following entities:

Undersecretary of the Federal Ministry of Health Chair

The executive Secretary of the Council for Health Research Reporter

Director of the General-Directorate of Preventive Medicine Member

Director of the General-Directorate of Curative Medicine Member

Director of the General-Directorate of Preventive Medicine Member

Director of the General-Directorate of Pharmacy Member

Director of the General-Directorate of Training and Human resources Development Member

Director of the General-Directorate of Health Planning & Development, Member

Director of the General-Directorate of International Health Member

Director of the General-Directorate of National Laboratories & Blood Transfusion Services
The Council for Health Research is to convene regular meetings every six months, while the Chair has the right to call for a meeting whenever he estimates it necessary.

Fourth: Executive Board

Establishment, composition and meetings of the executive board is as follows:

(a) An Executive Board for the Council for Health Research is to be established
(b) Mandate of the Executive Board to be as follows:

1. Setting national plans for health research in Sudan and follow-up of their implementation;

2. Coordination of the work of the Council for Health Research;

3. Setting the priority list for health research in Sudan; and

4. Supervision and follow-up of affiliated committees and institute.

(c) Composition of the Executive Board for the Council for Health Research is to be as follows:

1. A full-time Secretary-General, to be nominated by the Council for Health Research;

2. A Director for the Health System Research Institute, a member

3. Other members to be nominated by the Secretary-General, in consultation with Executive Secretary Council for Health Research.

(d) The Executive Board is to meet 2-weekly on a regular basis.

(i) The following bodies will be affiliated to and under supervision of the Executive Board for the Council for Health Research, which will follow-up its implementation activities:

A. Health System Research Institute:

Functions are as follows:

1. Training on health system research Methodology;

2. Conduction or assistance in conduction of health system research;

3. Building relations with international health research bodies;

4. Provision of health research tools & logistics; and

5. Advocacy for health system and support for researchers.

B. Committee for Health Research Ethics:

Mandate and Functions:

(a) Setting ethical guidelines for conducting health research;
(b) Involvement in ethical approval for national research or research involving or submitted to international entities; and

(c) Approval and delegation of mandate to the States' and institutional ethics committees.

Establishment of the Committee for Health Research Ethics is to be as follows:

(a) A Chair, to be nominated by the Director of the Council for Health Research;

(b) An Executive Secretary for the Council for Health Research, Reporter, and

(c) 10 members, representing main specialties.

C. Consultative Technical Committee:

Mandate and Functions:

(a) Setting directions for technical endorsement of health research;

(b) Involvement in technical approval for national research or research involving or submitted to international entities; and

(c) Approval and delegation of mandate to the States' and institutional technical committees.

Composition of Consultative Technical Committee: as follows

(a) A Chair, to be nominated by the Director of the Council for Health Research;

(b) An Executive Secretary for the Health System research Institute, Reporter, and

(c) 5 members, representing main specialties.

Issued under my signatures, on the 6th of Ramadan 1423 H., according the 11th of November 2002.

Signed:

Dr Ahmed Bilal Osman

Federal Minister of Health
**Administrative Structure:**

1. **Health Research Council (HRC):**

   **Functions of the council:**

   (a) Formulating the health research policy, work plan and follow-up of their implementation.

   (b) Setting principles of co-ordination and collaboration between all sectors involved in research.

   **Members of the council:**

   (a) Representatives of all directors of the Federal M.O.H.

   (b) State ministers of health.

   (c) Representatives of the universities and health intuitions.

   (d) Research experts.

   (e) Representatives of health-related sectors.

   (f) Representatives of NGOs.

   (g) representatives of the community.

   The chairman of the council is the Undersecretary of the Federal Ministry of Health and the reporter is the Director of Research Directorate.

   The council members meet yearly in the Federal Ministry of Health.

2. **Advisory Committee:**

   This includes some researchers and experts, and it provides the necessary advice for the Research Directorate to perform its role in an effective, efficient and scientific manner.

3. **Research Directorate (R D):**

   Consists of the following units:

   **A) Administrative and financial Units:**

   This units carries out all Administrative and financial work within the directorate.
B ) Training unit :

Its activities include the following :

2. Preparation of the research methodology manual .

3. Working with the concerned parties to incorporate research methodology course in the curricula of medical institutions and schools .


C ) Documentation and Information Unit :

Its activities include the following :

1. Establishing a data-base system for health research and health research institutions .

2. Provision of means for continuous collection of health research .

3. Publishing of a biannual journal and a bimonthly newsletter .

D ) Research Implementation Unit :

1. Upgrading of the Research Directorate and creation of research units at state level .

2. Setting of a priority list for health research .

3. Implementation of selected health research projects at federal level .

4. Reviewing and approving research proposals scientifically and ethically .