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PAHO/WHO REGIONAL PROGRAM ON
ACTION-ORIENTED RESEARCH IN NUTRITION THROUGH
PRIMARY HEALTH CARE SERVICES

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PAHO/WHO REGIONAL PROGRAM ON
ACTION-ORIENTED RESEARCH IN NUTRITION THROUGH
PRIMARY HEALTH CARE SERVICES

(Guidelines for the formulation, organization, and
management of project proposals

DIVISION OF COMPREHENSIVE HEALTH SERVICES

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1. Introduction

It is widely recognized that nutrition is an important determinant of health status, particularly in early childhood. Energy-protein malnutrition and other specific nutritional deficiencies continue to be a major public health problem in developing countries, despite the implementation of nutrition plans and programs in many of them. Although the ultimate solution for malnutrition will come only through overall social and economic development, it is clear that improvement of the existing situation need not, and must not, wait for the effects of long-term development plans; furthermore, experience has shown that socioeconomic development per se does not necessarily bring improvement in nutritional conditions.

There is some evidence to indicate that it is indeed possible to improve the nutritional status of populations at risk, through well designed health care activities, without waiting for definite changes in the socioeconomic status of people as a whole; therefore, specific actions targeted to nutritional improvement are imperative as part of the effort to reach the goal of Health for All by the Year 2000.

Past research in nutrition has provided a body of knowledge and technology not fully translated into effective actions at the community level. There is now sufficient knowledge which, if applied, can help in the control and prevention of nutritional deficiencies to a considerable extent. The major limitations to action appear to be of logistic and operational nature which preclude the application of the existing knowledge to the solution of the nutritional problems. Unfortunately, the type of applied and operational research needed to translate knowledge into viable action programs had not received adequate attention and emphasis until recently.

It was in recognition of this that the Subcommittee of the WHO Global Advisory Committee on Medical Research (ACMR) recommended in 1979 (ACMR 21/79.8) the development of an action-oriented research program in nutrition to identify and facilitate practical actions capable of implementation at the community level within the context of existing economic and social constraints. Given that the primary health care (PHC) approach is regarded as a key to achieving health for all and overcoming the problems of coverage, and since nutrition is one of the essential elements of primary health care, it was proposed that a basic feature of such action-oriented research should be its integration within the primary health care services.

If nutrition activities within primary health care are to be effective, the challenge is to reach the priority groups at greatest risk (infants and young children) and to develop the technology appropriate to local conditions. Thus, the major objective of the action-oriented research program in nutrition is to formulate a basic nutrition component of primary health care, and to develop effective and suitable strategies

and technologies to deliver that nutritional package to the community. The prevention of energy-protein malnutrition in infants and young children (below three years of age), by improving their dietary practices with the maximum utilization of local resources (self-reliance in child feeding) was recommended as the first priority area. Not only is the age of 0-3 years by far the most critical one, but also the period in which it is believed that significant improvements in dietary practices can be made under the present socioeconomic conditions and with the food available to the community. Actions at the primary level of health care are expected to be more implementable if an appropriate technology can be developed.

While many other nonnutritional activities (control of infectious diseases, appropriate birth spacing, etc.) are also required for the prevention of malnutrition in young children, this program is specifically addressed to the dietary component of the problem, realizing, of course, that there must be an integrated approach to primary health care as a whole.

The strategy of the program is one of problem-solving, action-oriented research aiming at contributing to a better nutritional care of children at the primary health care level, with actual community involvement and active participation, by:

- a) identifying, on a continuing basis, the priority problems and needs at the community level;
- b) translating these problems into identifiable research questions;
- c) promoting the research to address these questions;
- d) translating findings into approaches that can be implemented at the community level;
- e) promoting research on the implementation of these approaches.

In 1980 the PAHO/ACMR recommended the implementation of the action-oriented research program in nutrition at the Regional level, and stated that means had to be found to implement it. Steps in the same direction were taken by AFRO, AMRO, and SEARO between 1979 and 1980. Progress reports on the matter were the subject of the WHO Global ACMR in October 1980 (ACMR 22/80.8).

The PAHO/ACMR in June 1981, recommended that strong support should be given to the Regional Program of Action-oriented Research in Nutrition, following the strategies and plan of action drawn by the Technical Group of PAHO/WHO which met in Bogota, Colombia, in June 1980. Therefore, such program was launched in 1981 on a Regional basis. As the program goes on,

however, the need has been felt for clarification of a number of issues and the establishment of general guidelines for both the preparation of protocols and necessary administrative aspects of program organization and management.

2. SCOPE OF THE PROGRAM

For the purpose of the PAHO/WHO sponsored program, action-oriented research is defined as research explicitly addressed to the development and testing of appropriate technologies for the improvement of feeding practices in infants and young children, with active community participation and making use of locally available resources. These technologies must be an integral part of the nutrition component of primary health care.

The scope of the program is therefore restricted to research projects that:

- a) focus specifically (although not exclusively) on the problem of inadequate feeding (quantity or quality) of infants and young children during the weaning and postweaning periods;
- b) are responsive to the actual needs at the community level, providing mechanisms to assess these needs and translate them into specific questions to be researched in such a manner, that the results may be converted into community action by using locally available resources more effectively to relieve local problems;
- c) develop and field test appropriate technologies for the improvement of dietary practices, simple enough to be incorporated into the package of primary health care activities;
- d) are implemented within the existing primary health care services with the active involvement of the primary health care or community workers, and ensuring the extended implementation of the appropriate technologies in nutrition developed as part of the package of primary health care.

3. RESEARCH PRIORITIES

Establishing priorities for the research projects to be developed within the program is mandatory, not only to make the best use of limited resources to support highly relevant projects, but also to concentrate the effort as much as possible on those issues regarded as most pressing needs for action implementation in nutrition. The priority areas recommended are:

1. Research on the determinants of the existing infant and young child feeding patterns with emphasis on prevalent weaning practices, their appropriateness, the sociocultural, ethnographic, biological, and other determining factors, and identification of problem areas in infant feeding, e.g. diet when afflicted with infectious diseases and during the convalescent period. This line of research is a prerequisite for the development and field testing of appropriate methodologies to improve child feeding through primary health care.
2. Operational research on the definition, design, implementation, and evaluation of activities to improve infant feeding as part of the nutrition component of a primary health care package. The activities to be chosen and the tasks that they involve should be tested for feasibility, effectiveness, and impact under conditions that are normal in the operation of regular primary health care programs.
3. Research areas dealing with the implementation of food and nutrition activities within primary health care, such as training and supervision of primary health and community workers and methodology of nutrition education. The community health worker (CHW) should be able to show how improved weaning foods and feeding practices can be introduced by utilizing the ordinary foods available at home; therefore, educational techniques and tools must be developed and taught to the CHW so he/she can bring about the awareness that leads to a desire to acquire knowledge and to changes of attitude and behavior.

Ideal projects would be as comprehensive as possible dealing with the assessment of feeding practices and their determinants, as well as with the identification of problem areas and the design, field testing, and evaluation of primary health care activities addressed to correct faulty practices and improve the child's dietary intake.

4. GUIDELINES FOR THE RESEARCH PROTOCOLS

Given the diversity of action-oriented nutrition research projects that may eventually meet the priorities stated for the program, it is not possible to recommend a standard protocol. However, general guidelines on the type and content of research protocols may be of help in the preparation of proposals to be submitted for funding.

The research protocol should contain, as a general rule, the following major headings: 1. purpose and significance of the study; 2. review of relevant background; 3. study design; 4. general procedures and methods of data collection; 5. outline of data analysis; 6. feasibility; 7. institutional arrangements to be carried out to ensure the extensive application of the findings; and 8. resources required (available and unavailable) and estimated budget for the proposal.

4.1. Purpose and Significance of the Study

These should be stated clearly but briefly and should leave no doubt as to why the study should be undertaken, what additional knowledge, methodologies or technologies, will provide at its successful conclusion, and how these will contribute to the improvement of infant and young child feeding practices of populations at risk.

Examples of the overall purpose of different types of hypothetical projects are given below:

- to test the feasibility and effectiveness of improving infant and child nutrition by a specific infant feeding component of the nutritional package of primary health care;
- to test the feasibility and effectiveness of a given nutrition intervention integrated to primary health care;
- to design and test the effectiveness of different methodologies for education on infant and young child feeding (behavioral modification techniques) to be used by primary health care workers;
- to design and test the efficiency of simple tools for the identification of children at risk of dietary inadequacies to be used by primary health care workers;
- to test the effectiveness of different approaches to improving breastfeeding and weaning practices through primary health care actions;
- to develop appropriate technologies for improving current home-prepared weaning foods, and to test the efficiency of methods for introducing home-prepared nutritionally sound weaning foods, in the regular infant diet through primary health care actions.

4.2. Review of Relevant Background

This should provide the knowledge based upon which the research proposal is built, with the appropriate bibliographic references. The uncertainties in our understanding or the gaps in knowledge, that the proposed project is supposed to fill out, should be identified.

4.3. Study Design

A summary statement of the general approach to be used in the study provides a skeleton framework upon which appropriate research methodology must be built. The general nature and approach of the study should be

stated first, followed by details of how it is to be constructed and conducted. A variety of different research designs could be used depending on the particular purpose of the study.

However, the relatively restricted scope of the action-oriented nutrition research program calls for intervention (experimental or quasi-experimental) designs of a prospective nature, or even for the operational research modality, rather than for cross-sectional or longitudinal purely descriptive or even analytical type of studies. In fact, priority should be given to intervention-type projects with a clearly specified evaluation component to test the effectiveness of simple methods for improving infant and young child feeding through primary health care. Therefore, it is expected that the proposed research project should have a clearly defined action component (preceded or not by a basic or descriptive research component as needed) to be tested for feasibility and effectiveness.

Admittedly, in order to devise effective actions aimed at improving infant and young child feeding practices, basic information is required on the characteristics of such patterns as well as on their determinant factors, particularly of sociocultural nature (beliefs and attitudes toward infant and young child feeding in health and disease). Thus, in some cases an initial phase of the action-oriented research project is required to gather such information by means of descriptive and/or analytical studies.

As has been mentioned above, sufficient knowledge on the feeding patterns of small children, and the sociocultural, ethnographic, biologic, and other factors that determine them, is a prerequisite for designing effective nutritional activities through primary health care. In other instances such basic research component might not be needed. It has been suggested that a useful approach could be the examination of the nutrition content of ongoing primary health care programs to see what the bottlenecks are, introduce the nutritional inputs which are thought to be appropriate for the conditions under which the program operates, and test them for feasibility and effectiveness (WHO-NUT/81.1).

Most of the research designs meeting the objectives of the action-oriented research program will fall into the category of intervention studies, either strictly experimental or, more often, quasi-experimental. They are prospective in nature and should follow the general methodologies for the observational cohort studies, with the important difference that the investigator deliberately introduces or carries out well-defined manipulations of the factor under study.

In strictly experimental intervention studies the intervened and control groups are randomly selected or assigned and every effort is made to eliminate all intervening variables except the one under investigation, i.e., the experimental and control groups must be as alike as possible in all ways other than the procedure that is applied to the experimental subjects.

In some instances the operational nature of the research or the field conditions under which it is implemented may preclude the use of rigid experimental designs; this may happen either because of operational difficulties or ethical problems in the formation of an appropriate control group, or because of the need to introduce successive modifications in the intervention implementation as a result of ongoing evaluation feedback. While the lack of a randomly selected control group may allow only the use of quasi-experimental designs, the changing nature of the intervention is a key feature of the so-called "operational research." Both types of research design, however, would be suitable for the purposes of the action-oriented research program, provided that it is adequately addressed to well-defined research questions.

Quasi-experimental designs, although less likely to control for some of the confounding variables, are frequently the only ones feasible. There are two modalities of this type of research design that would probably meet the objectives of the action-oriented research approach without presenting insoluble feasibility problems:

- a) The experimental and control community(s) design, which simulates a pure experimental design, except that total comparison groups or communities, rather than individuals, are randomly allocated. This is the case when one or more communities are randomly assigned as intervened and control, the former being subjected to the experimental intervention or program, and the other not. Major problems likely to jeopardize the internal validity of this design are the difficulties in ensuring comparability between communities in variables likely to affect the outcome, and the operational and eventual ethical problems derived from the need to refrain from intervening in the control community(s). This last problem may be of lesser importance when the experimental intervention is an addition, or a new implementation modality, to an ongoing program which continues to be implemented in the control communities.
- b) The one-group (or community) prospective design in which after a baseline measurement, the experimental intervention or program is implemented, or the new modality or delivery system is introduced, and periodic evaluations are carried out to assess intervention outcomes. There already is an action-oriented nutrition research project using this design in Colombia. This type of design may often be used for operational research in which the intervention program is adjusted or its implementation procedures modified over time as a result of feedback from periodic evaluations.

The lack of appropriate control groups poses for one-group designs some internal validity problems, which may weaken their efficiency in permitting valid inferences on intervention effectiveness. This may be

obviated by controlling confounding variables or taking them into account in the analysis. For a discussion on the validity problems inherent to this type of quasi-experimental designs, see Campbell, D.B., "Experimental and Non-Experimental Designs for Research."

In summary, different research designs may be used for projects meeting the requirements of the action-oriented research program; however, it is envisioned that they mostly will be intervention studies using quasi-experimental designs such as the experimental and control community(s) or program(s) or the one-group (or community) type of designs.

As an example, operational research may be planned at the country, regional or local level to make a situation analysis for identifying the "nutrition component" of primary health care as they operate in the field, and on the basis of this analysis to develop effective and suitable strategies for the delivery of a nutritional package or intervention at the community level as a component of primary health care services. Such new strategies, with a concrete action content, may be introduced at random in certain communities or programs and not in others; baseline and successive further evaluations of the program operation in the experimental communities will allow the assessment of the feasibility and efficiency of program delivery (operational research), and comparisons between intervened (new strategies and/or activities) and control (old or none strategies and/or activities) communities in specified outcomes (e.g., assessment of infant feeding practices or food intake) will serve to ascertain program effectiveness (impact).

We should not discard the possibility of undertaking noninterventional research projects dealing with highly practical issues, by means of descriptive and analytical studies. As an example, it has been often suggested that a relevant line of research would be a comparative study of apparently normal and malnourished children belonging to poor socioeconomic groups for the identification of factors underlying the differences between them, with particular emphasis on those likely to be dealt with through primary health care (e.g., feeding practices). This can be done by means of carefully designed observational studies, preferentially prospective. However, a final stage of the project should develop and test a suitable corrective intervention program within primary health care.

Another line of research requiring descriptive-analytical strategies followed by some sort of intervention study is the identification of acceptable low-cost weaning foods (or the development of appropriate technology to use them) with special consideration as to how to overcome practical problems in promoting their use. Such a project would be analytical at its first stages, including laboratory and eventually food technology studies, and interventional in the long run, possible involving the development and evaluation of educational strategies, techniques, and materials to be used in primary health care services.

4.4 General Procedures and Methods of Data Collection

This chapter of the research protocol should focus primarily on three points:

- a) Description of the study population, as well as the sampling frame and the sampling procedures (selection, size, allocation, etc.), when applicable. Both the study population (that in which the study will be carried out and from which eventually a sample is taken for measurement and evaluation purposes) and the reference population (that to which the study findings can be properly applied through generalization), should be clearly identified. The questions to be answered are who and where.

When a sample and not the total study population is to be studied, procedures for sample selection and management should be described in detail, including sample frame, sampling techniques, estimations of sample size, and procedures for sample recruitment, eventual group assignment, and follow-up. Random sampling (stratified or not) is usually recommended, by using well-known techniques which should be clearly set-up in advance and carefully followed to avoid selection bias.

Since the study results need to be analyzed statistically, the study groups must be sufficiently large to reach the desired level of statistical "significance." They should not be larger than necessary, however, to avoid unnecessary expense. This almost always requires that a decision be made on sample size at the stage of protocol development before the study begins. A statistician can calculate the sample sizes needed for various research purposes if the investigator can provide him with certain estimates and the level of statistical confidence that is needed to rule out mere chance.

- b) Procedures for the implementation of the intervention program, techniques or specific activities, when an intervention study is being planned. In some instances, intervention strategies or techniques, or the program content and implementation procedures, are well-defined in advance and can be described in detail as part of the research protocol. In some others, only a general description of the intervention approach, strategies, alternate ways of delivery, and content could be provided; this is particularly true when the first phases of the project are just devoted to descriptive and analytical studies out of which an intervention mode and/or content is identified or developed to be applied in later stages. This might be the case in projects aimed at identifying nutrition education strategies and methods based on the analysis of feeding practices and their

sociocultural determinants, or in those dealing with the identification of suitable weaning foods to be promoted or the development and test of appropriate technologies for home use to improve the quality of the weaning diet. On the overall, such description of intervention procedures should answer the question of what and how it is to be delivered to the population or sample (who) in the geographical area (where) already indicated.

- c) The design of appropriate data collection procedures is a very important component of the research protocol. First, data to be collected should be carefully thought of so as to include all relevant (but only relevant) information, according to the objectives of the study and to the particular research design, having always in mind the specific purpose of collecting every single piece of data; the questions to be asked always in regard to each data item are "what for?" and "what is the relevance of this particular item to the goals of the study?" In dealing with intervention studies objective information should be gathered on the "input" (intervention program or technique) in such a way that the concrete "package" to which the study population was exposed to can be defined and hopefully quantitatively described.

By the same token, the expected intervention outcome should be defined in advance so that measures of program impact could be obtained. A careful selection of outcome measures is mandatory; some apparent failures of programs to demonstrate effectiveness in impact evaluations are most probably due to an inadequate identification and measurement of the true program outcome.

Questionnaires design is a sophisticated skill, and should be undertaken only by someone with experience. Only a limited number of relevant questions should be asked. Problems relate to the phrasing and ordering of questions, the inclusion of confirmatory questions, coding of responses for subsequent analysis, and the overall length of the questionnaire. A pretest or "pilot" trial of a questionnaire is always desirable before a final commitment is made.

An important feature of the research protocol and its implementation is the establishment of adequate data quality control procedures. A systematic sequence of data quality control procedures should be introduced at all stages of data collection and handling. Those at the data gathering phase include appropriate training, standardization, and field supervision of the personnel responsible for collecting data.

Data handling must be planned and arranged at the time of protocol development. Hand tabulation and analysis are suitable and may be preferable for smaller studies and those with limited data sets, but if computer processing is thought to be necessary, the availability of suitable equipment ("hardware"), the format of data for computer entry (including coding), computer programming ("software"), and the analytical procedures to be used must all be considered.

Adequate procedures must be incorporated into the protocol to ensure the health and safety of study participants. Note that the withholding of an "accepted" remedy or prophylactic may be as unethical as the administration of a possibly hazardous new one. Subjects must be reasonably informed of the nature and implication of the study, and an "informed consent" form may have to be signed. The participants must be free to withdraw from the study at anytime they wish to do so. For the protection of both study participants and investigators, all research protocols dealing with human subjects should be reviewed and approved by an Ethical Review Committee.

4.5 Outline of Data Analysis

The statistical procedures to be used for the analysis of data must be specified in the protocol in detail; it is not sufficient to plan "data to be analyzed by standard statistical methods." A competent statistician should be consulted if the investigator does not have the necessary skills.

4.6 Feasibility of the study

The translation of a good research idea into a practical research project requires much more than the availability of adequate funding. The principal investigator must be assured that: permission to undertake the work has been given by all relevant governmental, organizational, and institutional authorities; needed equipment, including laboratory and computer facilities, are available for use; skilled personnel, including such special competence as statistical expertise, can be found; the numbers of individual cases, controls, or other study subjects are adequate; the time frame is reasonable and there is a reasonable probability that the study subjects will continue under observation for the time required; and the logistical plans for subject recruitment, travel, specimen collection, etc., are practicable.

An important aspect of feasibility relates to the institutional arrangements necessary to ensure the active involvement of the Ministry of Health (national and/or regional level) and in the project; its implementation as an integral part of the primary health care services. The active participation and commitment of the health authorities is deemed crucial to increase the likelihood of the extended application of the research findings within the existing health infrastructure.

4.7 Institutional Arrangements

Action-oriented research projects in nutrition should ideally be developed and carried out by the health services or jointly with research institutions. The latter may provide some of the research capabilities required and, not infrequently, they take the initiative to undertake the study. Joint projects carried out by research and health services institutions may be of mutual benefit provided that a clear understanding of common purposes and interests is reached through an active participation of both partners in all stages of project development (planning, execution, and evaluation).

There may be some instances in which the research capabilities of the health services are adequate enough to make it feasible to accomplish good quality research projects. If this is not the case, joint projects with research institutions may often be the only feasible option. On the other hand, research projects to be carried out by research institutions independently can not be supported within the framework of this action-oriented research program, since active involvement of the primary health services is crucial for the action component operation and, most important, for extended application of findings.

4.8 Budget

A description of all material and human resources for the project should be followed by an enumeration of those already available and the estimated costs of those for which financial support is asked. The latter should be translated into an itemized budget for the proposal with appropriate justification.

4.9 Examples of Research Protocols

Strengthening the research capability in the Region is often a prerequisite for carrying out sound research projects. This is an important component program and PAHO/WHO will seek ways to provide the critical inputs (technical and financial support) needed for strengthening institutions and individual capabilities as part of the promotional activities of the program, so that a strong and durable infrastructure for action-oriented nutrition research can be promoted in the countries of the Region. This can be partially achieved through stimulating technical cooperation among countries (TCDC), as well as through provision of facilities and opportunities for training in nutrition, epidemiology, and public health. Some preliminary explorations have already been made to identify potential resources (institutions, groups, and individuals), for the development of the PAHO/WHO Regional Program on Action-oriented Research in Nutrition. An action-oriented research project for the improvement of infant and young child feeding practices through primary health care services with active community participation in a rural area of Colombia is already

underway as a joint project between the State Health Department of Cundinamarca and the Javeriana University. Some other research proposals have been submitted to PAHO/WHO and it is expected that more well-developed research projects will be forthcoming.

As a useful example, general protocols for some projects on the priority areas selected for the program are appended to this document; they provide suggested outlines on which detailed protocols may be worked out. These protocols adapted from those prepared by an interdisciplinary working group convened by SEARO, deal with the following highly relevant areas of action-oriented research in nutrition through primary health care services (Appendix I):

1. Situation analysis of the current status with regard to content and implementation of the nutrition component of the primary health care.
2. Assessment and development of a nutrition education program at community level in relation to its effectiveness and relevance to community needs.
3. Development and evaluation of simple procedures of food and nutrition surveillance for the identification of mothers and children at risk, and the monitoring and evaluation of nutrition programs at community level by primary health workers.
4. Identification of practical problems in promoting acceptability of low-cost weaning foods among poor rural communities, and of practical approaches to overcome them.

5. PROGRAM MANAGEMENT AND ORGANIZATION

5.1 Purpose of the Program

The overall objective of the PAHO/WHO Regional Program of Action-oriented Research in Nutrition through primary health care services is to promote and support in the countries of the Region the development of action-oriented research projects, the application of the findings, and the extension of results to other areas in each particular country.

5.2 Specific Objectives

- 5.2.1 Identification of interested institutions, groups and individuals in the countries of the Region with potentiality to carry out innovative research along the guidelines of the program. This should include the identification of suitable national programs of primary health care where action-oriented nutrition research activities may be undertaken.

- 5.2.2 Promotion of the program within the Region, through distribution of documents and visits by PAHO/WHO staff to ministries of health, academic and scientific institutions, and researchers already identified.
- 5.2.3 Strengthening the research capabilities of health institutions and individuals engaged in nutrition research in the Region, by providing critical inputs such as formal and informal training, and technical advice for the development of protocols and the implementation of the research projects, including field procedures for data collection and processing, training of field personnel, and statistical advice for data analysis.
- 5.2.4 Promoting the program among potential financial donor agencies, and searching for funds from external sources for the implementation of country research projects.
- 5.2.5 Designation of a Project Review Board (PRB) to assess research proposals and provide technical assistance to possible grantees in the development of appropriate research protocols when necessary. This body may also serve as task force for institutional strengthening, as well as in guiding the search for the necessary funds.
- 5.2.6 Provision of technical support to the projects as needed, and periodic supervision of those having partial or total support from program funds, by PAHO/WHO staff at the headquarters and country offices.
- 5.2.7 Promotion of an active interaction and communication between country project managers to review the progress, share experiences, interchange findings and promote their extended application within the country or in other interested countries. This interaction may also be used to strengthen the research capabilities of other researchers who wish to design and develop projects in their own countries.
- 5.2.8 Actions to promote, facilitate, and support dialogue and interchange of information between personnel involved in research, planning, and administration of health and nutrition programs, as a means to ensure that the results of the projects are quickly applied within primary health care services. This may include interdisciplinary meetings at country and/or regional level.
- 5.2.9 Active cooperation with other WHO regions and Headquarters to ensure optimum utilization of current resources, and effective search for new sources of support.

5.3 Organization of the Program

To fulfill its objectives, the PAHO/WHO Regional Program of Action-oriented Research in Nutrition through primary health care services is organized as follows:

- 5.3.1 The program management^a is ascribed to the Division of Comprehensive Health Services (CHS), in close collaboration with the Unit of Research Promotion and Coordination, Division of Human Resources and Research (HRR), and other Divisions of PAHO. Ultimate responsibility for the program development is on the Regional Advisor in Nutrition (Program Manager), who acts as the Executive Secretary of the Project Review Board.
- 5.3.2 The Project Review Board (PRB) is the technical advisory body to the Regional Program and has the following responsibilities:
- a) to review, discuss, and give specific recommendations on the technical documents prepared by the program: guidelines for research protocols, program organization and management, working plans, technical reports, etc.;
 - b) to act as a steering committee in charge of reviewing research proposals submitted for financial support from budgetary or extrabudgetary funds;
 - c) to provide technical assistance to possible grantees in the development of appropriate research protocols of solid scientific quality;
 - d) to cooperate in actions aimed at institutional research strengthening;
 - e) members of the PRB are the Regional Advisor in Nutrition, the Chief of the Unit of Research Promotion and Coordination, and the Regional Advisor in Primary Health Care. Other members of the PRB may be appointed regularly or invited to specific meetings.
- 5.3.3 Project research proposals following the program guidelines and the PAHO standard format should be addressed to:

Regional Advisor in Nutrition
Division of Comprehensive Health Services
Panamerican Health Organization
525-23rd Street, N.W.
Washington, D.C. 20037
USA

- 5.3.4 Research proposals received by the Program Secretariat will be reviewed by the Project Review Board which, when judged appropriate, may seek the opinion of independent reviewers who are experts in the relevant field of research. The final decision regarding funding of the proposal will be based on availability of funds, after the Project Review Board approves it.
- 5.3.5 The Project Review Board (PRB) will judge the proposals on the basis of:
- a) congruence with the objectives and priorities established by the program;
 - b) scientific quality (research design and procedures);
 - c) evidence of feasibility and extensive application of results (e.g., health services involvement); and
 - d) costs.
- 5.3.6 Approved projects will be funded through a Contractual Technical Services Agreement (CTS), between PAHO/WHO and the country institution(s) responsible for the project. Funds will be usually allotted on a yearly basis subject to their availability; projects not exceeding two years may be funded completely; projects requiring more than two years may be recommended for up to three years of support subject to satisfactory progress and availability of funds.
- 5.3.7 All country projects will be overseen by a local Coordination Committee formed by representatives of the research institutions and the corresponding national health authority at national and/or intermediate level, and the PAHO Country Representative.
- 5.3.8 The Principal Investigator is the individual who shall be responsible on behalf of the institution for all technical and administrative aspects of the work referred to in the CTS agreement. The Institution is the organization with which the Principal Investigator is associated and to which he is responsible.
- 5.3.9 The Principal Investigator shall submit an Annual Progress Report, in the required format, at the time specified, to the PAHO/WHO Program Manager. This report constitutes a part of the project evaluation and is essential for continuation of the support to the project. Final Reports are required on

completion of the Project and should summarize the course of the research and give in some detail the findings of the work in relation to the objectives of the Program. The PAHO/WHO Program Manager must be informed promptly of any major changes or significant deviations from the activities covered by the original Agreement. Additional reports may be required.

- 5.3.10 Institutions and/or Principal Investigators may publish in any scientific journal the results of work supported by the Program, although the responsibility for the direction of the work should not be ascribed to PAHO/WHO. In the case of a collaborative research project involving more than one institution, it is recommended that investigators obtain PAHO/WHO's approval prior to publication. All publications should have a footnote identifying PAHO/WHO and/or the Program as having supported the research, for example:

"This investigation received financial support from the PAHO/WHO Action-oriented Research Program in Nutrition through Primary Health Care Services." In the event of publication, 25 off-prints or copies should be sent to PAHO unless another number is agreed upon. PAHO/WHO funds may be used for publication costs only when specific arrangements are made with the Program Manager.

- 5.3.11 It is the responsibility of the Institution and the Principal Investigator to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from PAHO/WHO in accordance with the appropriate national code of ethics or legislation. Funds may be used only to support investigations where: a) the rights and welfare of the subjects involved in the research are adequately protected; b) freely given informed consent has been obtained; and c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts at the Institution.

The Investigator must submit to PAHO/WHO the written approval of an Institutional Panel to carry out the proposed research involving human subjects. For countries with national ethical review bodies for research involving human subjects, written agreement from such a body must be submitted to PAHO/WHO with the research proposal. In the absence of national ethical review bodies, the Investigator shall be guided by the Declaration of Helsinki supplemented

by the revised and extended version of the Declaration adopted by the Twenty-ninth World Medical Assembly in Tokyo (October 1975) and by Article 7 of the International Covenant of Civil and Political Rights, adopted by the United Nations General Assembly on 16 December 1966. PAHO/WHO will, on request, advise scientists regarding the ethical aspects of planned research projects.

Protocols for projects involving human subjects must be reviewed and approved by an independent institutional ethical body prior to formal submission to PAHO/WHO (attach documentation of approval).

National bodies for the regulation of human experimentation, if they exist, should review and clear the proposal prior to formal submission to PAHO/WHO (attach documentation of approval).

For all protocols or projects involving human subjects:

- i. indicate the benefits and any known risks or inconveniences to the subjects involved in the study;
- ii. describe precisely the information which will be conveyed to potential subjects of the study and the manner, oral or written, by which this information is to be conveyed. If a written consent form is to be used, attach a sample. Include the name(s) and status of the project staff member(s) that it is understood and that the consent is given freely by the subject;
- iii. indicate any special incentives or treatment the subjects receive for their participation (e.g., money for transportation, stipends for participation, food, medication, etc.). Whenever payment is involved, specify amounts, manner, and timing;
- iv. indicate how the confidentiality of all information obtained during the course of the study, relating to participants included in the study, will be maintained.

6. WORK PLAN FOR 1982 - 1985
 - 6.1 Presentation to PAHO/ACMR the "Guidelines for the formulation, organization, and management of project proposals."
 - 6.2 Review of the Guidelines by the Project Review Board (PRB), and distribution of final drafts.
 - 6.3 Continuation of promotional activities throughout the Region, as well as closer contacts with institutions and individuals already interested in carrying out action-oriented research in nutrition (e.g., Brasil, Guatemala, Jamaica, Nicaragua, and Peru) with a major emphasis in assessing research opportunities within ongoing primary health care programs.
 - 6.4 Strengthening the research capabilities and provision of technical support to interested groups or individuals in the preparation of research protocols.
 - 6.5 Initiation of the Mexican Project and continuation of technical and financial support to the Colombian Project; field supervision, promotional activities, and dissemination of project findings.
 - 6.6 Development and implementation of 2 to 3 projects per year contingent upon availability of funds.
 - 6.7 Promotional activities among potential financial agencies and search for extrabudgetary funding. Letters of agreement will be signed with funding agencies interested in supporting action-oriented research in nutrition (e.g., Nestle Coordination Center for Nutrition; International Development Research Centre (IDRC), Canada; W. K. Kellogg Foundation; Swedish International Development Authority (SIDA), Sweden; United States Agency for International Development (USAID), etc.).
 - 6.8 Annual Regional Meeting of Principal Investigators of ongoing projects to review experiences and methodologies with the participation of other interested researchers from institutions and countries with potentialities for undertaking action-oriented research in nutrition projects.
 - 6.9 Progress reports to PAHO/ACMR and global WHO/ACMR when required.