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Executive Summary

The second meeting of the Advisory Group on Research in Emergencies (AGRE) took place at WHO/HQ on 16 April 1999. Dr Tore Godal presented the recommendations of the WHO Working Group on Policies and Strategies to Support WHO in Health Research, established by the Director General. Dr Godal stated that the Advisory Group on Research in Emergencies was welcome, as it aimed to combine research with learning and improved practice.

The inventory of research in emergencies was being prepared for WHO at the Macfarlane Burnet Center for Medical Research. The inventory, if regularly updated, should become an instrument for the group to identify priority research proposals. The researcher had raised some technical questions for the group to consider.

There was an update on the Sphere project, which is now in its second phase. Concerning the conflict in Kosovo, the possibility of applying epidemiological methods to monitoring human rights abuses was also discussed.

The Australian Agency for International Development will co-sponsor a WHO/EHA consultation on crisis-analysis in countries that experience economic crisis and instability. The aim of the consultation would be to develop a framework for action, based on the identification of elements that may have mitigated, or contributed to a decline in health status of the affected population.

The draft ethics framework - primarily the issues of risk-benefit and informed consent - was the main subject of discussion. A persistent question is whether ethics principles require that the beneficiaries and the actual subjects of research are the same population group. This would be a severe constraint for doing research on refugee and displaced populations.
Introduction and Background

The second meeting of the Advisory Group on Research in Emergencies (AGRE) was held on 16 April 1999 at WHO, Geneva. AGRE was set up following a consultation on priorities for health research in emergencies in 1997. The first preparatory meeting, which took place in June 1998 had reviewed the draft terms of reference, defining the role of the Group in relation to its partners and drawn up a plan of activities. On that occasion, participants had stressed the need to develop an ethical framework for research in emergencies.

It was felt that the place of the Group in the research policy of the new WHO had to be looked at, in the light of the reorganisation occurred in WHO during the second half of 1998. The new WHO management brought new teams and ideas and is promoting stronger partnerships with external agencies, as well as enhanced links between and within clusters.

In his opening speech, Dr J.-P. Menu reminded the participants that the optimal function of WHO in the different phases of an emergency is under discussion. The Chair, Dr Ron Waldman, added that the type and extent of research that can be conducted during preparedness, early emergency, transition or post-emergency needs reviewing.

Discussion - Review of action taken on the recommendations and plan of work outlined in June 1998

1.1. Looking at the recommendations, it was observed that:

i. the ethical framework has been drafted (see later in this report);

ii. the position of WHO towards the group has become clearer; now, the Group should be formalised and present a concrete plan of action to the DG;

iii. the Chair and the Secretary of the Group participated in a meeting on reproductive health in emergencies and in its follow-up, as recommended (POA.5. and 6.); the meeting offered an opportunity for interaction between service providers and institutions;

iv. the coordinating role of the group between specialities and sectors of research needs further discussion;

v. the suggestion to develop generic, off-the-shelf research protocols needs reviewing, as it contradicts the view that proposals should be generated in an operational setting;
vi. the members of the Group have still to clarify among themselves whether they feel mandated and capable to judge and certify the quality of the research proposals.

1.2. Looking at the Plan of work:

i. (POA point 1) the report of the meeting, including revised TOR, was prepared and distributed.

ii. (POA. 2. and 3) Donor involvement was deferred until the role of WHO could be made clearer. The proposal for a centralised fund for research is to be considered. The Secretary will contact other clusters (TDR, GPV, EIP) to get details of the mechanisms they use. The Secretary should discuss with the Management Support Unit (MSU/SDE) if a separate budget for research in emergencies is acceptable within the SDE cluster. It seems almost impossible to find "ad hoc" funds to support research during an emergency. Stand-by funds could provide quick support upon ethical clearance, thus providing an incentive for researchers to submit proposals. Another suggestion was for EHA to look for potential sources of funding within WHO, e.g. RBM, although joint proposals from different areas in the Organization are usually favoured.

In any case, if research is to be funded directly, AGRE will have to audit spending. In the case of operational research, this would be very similar to the usual programme support. It could also imply prioritising studies according to their cost-effectiveness. Approved/funded research would have to be monitored to ensure compliance with the protocol. It was felt that setting up this mechanism would be justified if it promoted essential research in emergencies. Only when WHO accepts active involvement in research, will it become a credible partner.

The agenda to be promoted should be shaped by the debate about the role for research in emergencies and by WHO’s future role in emergencies. It should take a medium/long-term approach, reflecting lessons learned and recurrent problems. The epidemiology of human rights abuses was cited as an example. While the group did not wish to become responsive to every single emergency, contextual research remains important to improve the basic response to emergencies. A research inventory is being compiled to help identify priority research questions. Channels should be kept open to consult with internal and external partners (e.g. USAID). It was suggested to invite other clusters to future meetings of the group.

iii. (POA.4.) Professor M. Golden was asked to take action on the email subscriber list.
iv. (POA.7.) Dr P. Perrin and Dr J. Leaning attended the 2\textsuperscript{nd} AGRE meeting as suggested.

v. (POA.8. and 9.) See elsewhere in the report.

**Discussion - The place of the group in the research policy of the new WHO**

Dr Tore Godal presented the recommendations of the WHO Working Group on Policies and Strategies to Support WHO in Health Research, established recently by the Director General. A cabinet paper is in preparation and will be submitted to the Executive Board next June. The Working Group took a broad perspective on research, that should include the following:
- creation of new knowledge
- validation of knowledge
- transformation of knowledge into best practice, including dissemination
- identification of gaps in health knowledge, and initiatives to fill them.

In this context, the AGRE was welcome, as it aimed to combine research with learning and capacity building for health professionals involved in operations. Also, WHO has an important role in developing guidelines for the complex ethical questions surrounding all types of research, and particularly difficult situations have occurred in emergencies.

The WHO Working Group recommended an external review of all programmes in terms of evidence and best practice. Peer review is essential for all research proposals involving WHO. A revision of instruments and procedures relating to research is underway. The current practice of having "expert committees" within the Organization, that are required to get the advice of external "expert panels" can be long and tedious, and also the composition of the external panels needs looking into. The review should extend to the achievements of Collaborating Centres and their contribution to health research.

In countries that are at high risk or undergoing complex emergencies, research in the area of health sector development can help fill the gap between emergency management and sustainable development. Health workers and policy makers who are active in emergency settings should receive adequate support to develop protocols. It would be advisable for EHA to keep a separate research budget, that would allow researchers to initiate their work as soon as their proposals have technical and ethical clearances.

Although the role of WHO in emergencies has already been examined, new opportunities to involve WHO should be explored. Support for AGRE’s recommendations will be easier to obtain if advice can be translated into research activities.

Where new research in emergencies is envisaged, AGRE wants to be assertive in its interaction with other departments and clusters. Related work is ongoing in Roll Back Malaria (RBM) and Child and Adolescent Health and the AGRE should stay informed on
these initiatives. The Group has no defined criteria for its involvement as yet. Should there still be a review process for research protocols that have already been applied outside emergencies? Should research conducted during transition be included?

**Discussion - How to prepare, plan, and mitigate the health impact of complex humanitarian emergencies**

A plan for crisis-analysis, was outlined, that would aim at building/strengthening or preserving capacities in affected countries. This will be the subject of a third consultation sponsored by the Australian Agency for International Development (AusAID) and facilitated by Dr M. Toole, planned for late October 1999.

The aim is to develop a framework for action by identifying the elements that have helped to mitigate or have contributed to, a decline in the health status of populations during economic crisis and/or instability. The proposed method is to aggregate information on countries that have experienced crises, either making a successful transition from crisis to recovery, or failing to preserve population health, and on countries currently at risk of economic and socio-political crisis. Analysis should focus on health and health systems in an economic context. With appropriate support, local institutions could provide most of the required data. Since aiming at conflict prevention would anyway be too ambitious, the political components should be broadly sketched in the preface, and not analysed in depth.

In the short time before the consultation, it would only be possible to collate and analyse existing data. WHO works through governments, which constitute important parts of the problem in a national crisis. Even with supporting evidence, it would be delicate for WHO to point this out to its members. The study methodology should therefore avoid political implications. It might be possible to detect precursors of a decline in health indicators. Analysis of past emergencies would also be less threatening for the countries’ institutions.

The group agreed to follow-up the discussion by email, with Dr M. Toole as the co-ordinator. The format of the study and the choice of countries to include in the study should be finalised by early June.

**Discussion - Inventory of research in emergencies**

At the request of EHA, Ms Beverley Snell, Macfarlane Burnet Center for Medical Research, Australia, is compiling an inventory of research in emergencies. Subject categories are the same as those used for the working groups at the consultation on research priorities in 1997, with studies on Mortality added separately. When the study is
complete, the full-text version will be electronically accessible. A partial draft inventory was presented. The group was asked to discuss the following issues:

i. Classification: the subject categories are relevant. Women’s issues should be entered separate from reproductive health. Dual classification and double entry should be accepted.

ii. Style of summary: the standard format for each entry is title, study method, findings (caveats), and relevance to emergency relief. A mechanism is needed allowing to enter keywords to search the database.

iii. What is research?: a first selection to exclude "bad research" is made by the researcher doing the inventory, but the scope of the inventory needs to be defined. It might be worthwhile to consult unpublished studies from NGOs and other grey literature. The Refugee Studies Programme in Oxford has a large database, which will become electronically accessible. AGRE could ask agencies for relevant studies, explaining the how and why of the inventory.

iv. Non-English papers : studies that have a summary in English, or have been translated, can be included.

v. Surveillance reports: although raw surveillance data do not constitute research, they may be useful for further research. If the methodology is acceptable, they should be included in the inventory. The same goes for data from nutritional and other surveys, which can be combined and scientifically analysed.

vi. The Group was asked to what to do with incomplete studies. No agreement was reached on the inclusion, or not, of ongoing or abandoned studies.

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**Discussion - Update on the SPHERE project**

The project, which aims to improve the quality and accountability of humanitarian response, is now in its second phase. The output of phase one was a draft handbook (500 copies), composed of a humanitarian charter and the minimum standards. The handbook can be consulted and copied from the Web: [http://www.sphereproject.org](http://www.sphereproject.org)

In the second phase, the handbook was distributed for field review by operational organisations, as well as academic and research institutions, in order to test the applicability of the standards. The review indicates shortfalls in the standards with regard to gender issues and protection. Advice will be sought from the networks that reviewed
the various sections in phase one. SPHERE is also looking into a protocol for handling complaints.

Discussion - Epidemiology of Human Rights violations in Kosovo

Concerning the conflict in Kosovo, there were many questions on public health that had received minimal, anecdotal attention from the media. Quantitative information on disease incidence and comparative mortality was very limited. A consolidated needs assessment had not yet been carried out at the time of the meeting.

The Group agreed that, given the context, the possibility of monitoring human rights abuses, as part of the essential surveillance system should be explored. This kind of information gathering and dissemination may not qualify as research, but it is most important to allow a quantitative estimate of the problem. Complementary, compatible and comparable systems should be set up as early as possible in an emergency, and information should be shared. When registering displaced populations, a minimum data set related to health might be included in the registration forms; a protocol could be developed for this purpose.

The organisation "Physicians for Human Rights" wanted to explore methods to establish the epidemiology of human rights violations. They were planning a randomised survey of the Kosovan refugees to find people who have suffered, witnessed, or heard of human rights violations. The study would be descriptive, to establish temporal, spatial, age and gender distribution. The nature of violations would be specified, though it could be hard to substantiate non-physical abuse. The planned method was to take a systematic random sample of households in refugee camps. The interviewer would list the composition of the household before the events, then ask about the fate of each of the members. The interview would be complemented by questions, in order to establish what happened, where and when.

AGRE felt that the legal value of such information as potential evidence in court should be considered. It was thought important to remember that each reported/documented violation should lead to action for the victim, i.e. to stop its occurrence and to prevent further violations. Indicators have to be developed with this in mind and should exclude cultural practice that cannot be challenged under the circumstances.

Although it was deemed impossible to set thresholds in this matter, the terms "genocide" and "targeted expulsion" might evoke a question of scale. If services are to be provided, information for planning is essential. With adapted tools, epidemiological methods can be used to investigate the public health aspects of human rights abuses. Good practice will include the avoidance of sampling bias. Quantitative measurements can be problematic, when the identity of victims has to be protected. Validation of methods, where no standard exists, poses another dilemma.
The NGO Médecins Sans Frontières was also embarking on several similar studies in Macedonia and other countries receiving Kosovar refugees.

**Discussion - The use of data from research in emergencies**

**The use of data from research in emergencies**

This item was brought onto the agenda because of recent findings in anthropometric surveys in Sudan. On the basis of these data, the validity of BMI in some population groups has been questioned. Revised criteria might result in a reduction of food aid, which in turn could cause aggression against aid workers.

It was noted that a nutritional survey in itself is not research, but a tool for planning to be used in conjunction with other indicators. However, the use of the data to develop new reference values would indeed be research. Anyway, the Group felt that it should not become part of any political debate nor set itself to not control information. Since research is a scientific product, the Group should make sure that a piece of information is scientifically valid.

**Discussion - An ethics framework for research in emergencies**

In the 1997 Consultation on Applied Health Research Priorities in Emergencies, the working group on Ethics looked at the general principles that apply to research, to see how these relate to refugees and internally displaced people. It was then found that from the perspective of research, refugees and IDPs belong to a different category of vulnerability. They are in fact more vulnerable than most other groups – e.g. elderly and mentally retarded persons addressed in documents on the responsibilities of researchers.

The key point regarding research on IDPs and refugees is that they have no protection from the State. If there is a violation to their rights as subjects of research, they have no legal recourse. Refugees have at least protection from UNHCR, though this would be individual and ad hoc, as there are no specific provisions to deal with research violations. Additionally, IDPs and refugees are subject to a high level of insecurity in the future. They are highly mobile, and from the security standpoint, may be harmed by participating in research. Therefore there is accrued need for informed consent, risk-benefit and confidentiality. The proposed template states the conditions that must be met for a research proposal to attend to the ethics of refugees and IDP populations.

The template sets a list of conditions, that the Group should rank in order of priority. It is based on a document that was produced at the 1997 Consultation. The wording is in line with the normative language of ethics, but some of it is deliberately kept practical, to suit
the purpose. The elements of the template should be used when reviewing a research proposal. A further issue is the question of metrics. This requires an instrument that allows ethics reviewers to measure whether or not the set criteria are fulfilled, i.e. to move from standards to metrics, to measures and to indicators.

i. Risk-benefit.

(Point.1) Benefits derived from research must accrue directly to the subject of research. In therapeutic research, benefits may either go to the subject itself, or to future populations. Since refugees have an uncertain future, the model of therapeutic research that benefits the actual subjects applies.

This statement was questioned by group members, who mentioned a real example of proposed research (i.e. to see if systematic treatment with antibiotics can benefit all children in therapeutic feeding centres). A study like this can be done in a non-refugee setting, but large numbers of malnourished children are more likely to be found among refugees or IDPs. Therefore, the argument was not based on accessibility, which should not be used as a reason to conduct research in emergencies.

The discussion focused on whether or not the beneficiaries of research should be the actual subjects. Any research goes through a process of data collection, analysis and dissemination, which cannot be accelerated to suit the length of stay of the refugee population. The principle as formulated would almost preclude any intervention research; e.g. comparison of the effectiveness of different treatment schedules for the same condition. It was suggested to flag the controversial issues and bring in classic ethicists and epidemiologist researchers to settle the argument.

The risk-benefit issue could raise much broader controversy, especially in emergency settings. The argument hinges on the design of a study, and goes back to the standard that a control group could not be subjected to a treatment, less than what is known as the current optimum. This standard does not take account of local conditions, and has already caused controversy over research on AIDS treatment in less developed countries. It was pointed out that the greater good of the population could not be used in such circumstances to justify the neglect of the individual. On the contrary, individual protection should be bolstered.

It would be possible and useful to make a ranking of vulnerability, which would help to choose the setting for research related to vulnerable groups. For example, refugees in a camp administered by UNHCR are less vulnerable than an IDP population. However, operational and methodological constraints, on top of the ethical criteria can make it very difficult to carry out any research. Taking the previous example of research on therapeutic feeding, it is unlikely that one would find the required numbers of severely malnourished children in a well-managed camp.

Ethical principles and practical constraints can contradict each other, and a compromise between the two might be necessary. The template should be phrased in a way that
promotes research that is mindful of ethics principles. Every effort should be made to have the study designed in such a way as to result in full implementation within the life of the camp. Still the group thought that the expression used in the template (actual subject) would be hard to fulfil with mobile populations. Another important aspect of research in emergencies is the need to monitor – and the capacity thereof - the effects that having been engaged in the study has on subjects and collaborators

(point 2) The question investigated could not be answered outside a refugee setting. It might be acceptable to study the effectiveness in a camp setting of a proven safe vaccine, though vaccine trials would not be ethical. The design should then take care to ensure that it was impossible to decide who would get the vaccine.

(point 3) The subject should not only understand the activities s/he takes part in, but also the element of investigation in it. Risk has to be explained and understood, possible uncertainties due to language issues or fear of subjects must be dealt with.

ii. Informed consent

(points 1-3) The highest standards of informed consent should be upheld. The template should refer to the relevant text in documents on ethics and research (Helsinki declaration, Nuremberg code, Belmont Report, NIH, CIOMS documents), all insisting on unforced, voluntary consent, without bribes. Prisoners are automatically ruled out as subjects of research. International conventions define the rights of refugees, but IDPs are often entirely unprotected. Their behaviour may resemble that of a compliant prisoner, thus excluding freedom of consent. In some settings, discussing with community representatives may help find out when and how research would not be perceived as coercive. It was noted that just the presence of a researcher, perceived as rich in poor environment, would often lead the subjects to expect benefits.

The NIH differentiates between high-risk and low-risk research. Observational research is much less invasive than interventions. Expert ethicists could look at case studies to interpret the methods used and if they were possibly coercive. AGRE may need training to ensure that reviews are ethically sound. It should also be remembered that the remit of the Group concerns emergencies and is not limited to research on refugees and displaced persons.

The issue of informed consent is paramount for studies that involve randomisation, a minority in emergency research. On the other hand, such rules ought to apply to programmes as well. Measles vaccination has been established as a priority for all refugee children, but no informed consent of parents is obtained for before vaccinating. The same applies to supplements of vitamin A. In these discussions other kinds of imperatives are considered to override the ethical human rights argument.

The distinction between research and programme assessment/evaluation can be hard to make. It is essential to define criteria to distinguish what is research and what is programme management. This is even more important in the emergency context, where
shifting a study from research to programme management could leave subjects unprotected against misconduct. Case-control studies are routine in an outbreak investigation, and no informed consent is deemed necessary, as the investigation is good public health practice, though it was argued that such investigations are on the edge of research. Since subjects are asked to contribute in some way to the investigation, they can refuse, assuming implied consent. Unless explicitly stated by Law, Public Health authorities cannot override the individuals’ right to choose whether to participate or not. When working with refugees and IDPs, this would require a legal framework to deal with issues such as DOTS for the treatment of tuberculosis in displaced populations.

Evaluation could be classified in four stages:

i. - descriptive
ii. - comparative to best practice
iii. - related to outcome
iv. - comparative to a population where no intervention took place
v. - comparative to a population where a different intervention took place

The first three stages would remain in the domain of programme management, whereas the last two should be considered as research. There were doubts about the potential ethical aspects of outcome evaluation, and the degree to which some of it could be classified as research. It was therefore suggested to revise the template to reflect the different types of programme evaluation and research (from observation to intervention), and the ethical considerations that apply to each category.

Against all this, the Group wished to consider the ethics of not doing research. What are the outcomes of programmes that are not based on good evidence? The 1997 Consultation underscored the feeling that doing research in emergencies was a must, the same as developing a hierarchy of ethical principles to contain, guide and discipline that research. Probably one reason for the scarce research in refugee populations is its hazardous ethical nature.

The "AGRE template" will have to be acceptable in ethical terms without blocking research. This would imply the use of positive language. An introductory statement should specify that it has become unscientific and unethical to continue emergency interventions, without assessing their impact on the community. Many common practices have not been adequately validated. Programmes and research must be based on sound assessments and the work must be subject to peer review, scientific criticism and evaluation. The research that needs promoting would essentially be ethically sound validation and evaluation of current practice. The template should make reference to specific types of research with real examples, to illustrate that some sections mainly refer to intervention research and not to operational research. One should therefore take a contextual approach, remembering that this is an ethical template for intervention research. Taking the priorities from the 1997 Consultation as the context, most of the research under discussion will be operational.
(Points 4-5) The need to obtain informed consent from a village chief can only be assessed by the researcher who is familiar with the situation, not by any distant committee. Consent by a family member or village chief should not substitute for consent by the subject. A person from the community, who speaks the language of the researcher and is prepared to interact with her/him, is probably not representative for that community. Engaging this person might still be important to avoid linguistic confusion.

The principles of confidentiality, fairness and dignity are more applicable to observational research than the principles already discussed. They are also more open to interpretation. The principle on dignity refers to the Universal Declaration of Human Rights and the Convention on the Rights of the Child. The latter document sets high standards for promotion, enhancement and respect of the dignity of the child, which could be of use to modify and improve protocols.

The group has to consider who is going to take on the ethical review of proposals. Should it decide to take this responsibility upon itself, then training will be necessary. Dr Waldman proposed to accompany Dr Leaning to meet expert ethicists at Harvard for further discussions on the framework. Some guidance for reviewers could be added to it, indicating when an individual reviewer should seek the opinion of other expert reviewers, and whom to address.

The role of WHO/EHA in this endeavour seems appropriate, since it has been stated on many occasions that WHO should not supply direct services in emergencies, but have a normative function. To set ethical standards for review of research is part of that normative role and a service that WHO can provide to the community and to its operational partners. Some countries have IRBs and Medical Research Councils, to whom international standards concerning special population groups may be helpful. UNHCR/ protection unit will be contacted to find out if standards exist for conducting research on refugees. WHO Representatives at field level should be invited to take part in this discussion. They need to be informed and eventually trained on the subject.

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**Discussion - Secretariat. Correspondence and funding**

The Secretariat will handle the requests for information received up to now. At the moment, there is no mechanism to fund approved research. The group agreed to draft a letter of support to reply to researchers who have already submitted proposals. To facilitate the group’s task of reviewing proposals, researchers will be asked to prepare their proposals in a standard format that includes the ethical template. A draft support letter and format outline will be prepared by Dr Toole and Dr Waldman, and circulated. Final clearance of the format will be sought from Dr T. Godal.

To streamline the process of approval for emergency proposals, the ethical template, when finalised, could be given to Institutional Research Boards (IRBs). It was noted that
NGOs do not require permission for research, so that other ways to ensure ethical review will remain necessary.

EHA needs to decide on the level of commitment it intends to assign to the Secretariat. There should be sufficient capacity to screen proposals. On reception of proposals, the Secretariat should decide if initial criteria are fulfilled before returning or forwarding it. The screened proposal would go to an individual reviewer first, and be circulated for group approval next. Reviewers are to be identified, using contacts from the working groups of the 1997 Consultation. This process should be completed within one month. The precise procedures will be developed between the Chair and the Secretariat. Discussions are needed on whether, to what extent and how to involve Regional offices in the process.

A list of possible funding bodies is to be drawn up. Since organisations have funding review cycles, the need for shortcuts was re-emphasised, i.e. for EHA to have a separate budget for research in emergencies.

**Recommendations for follow-up**

1. The co-Chair to take action on the email subscriber list. (Action Professor M. Golden)

2. The Chair and Secretary to continue exploring opportunities for joint visits and meetings with donors and operational agencies. (Action Dr R. Waldman and Dr D. Deboutte)

3. Dr M. Toole to co-ordinate follow-up of the email discussion on prevention and mitigation of the health consequences of crisis (Oct-November 1999 meeting).

4. Dr R. Waldman and Dr J. Leaning to meet expert ethicists at Harvard for further discussions on the template.

5. Dr M. Toole and Dr R. Waldman to prepare a draft letter of support for researchers and to outline a format for submission of proposals.

6. The Secretary to contact other clusters in WHO (TDR, GPV, EIP) to get details of their funding mechanisms for research. (Action Dr D. Deboutte)

7. The Chair to distribute a message to agencies, asking to release relevant studies, explaining the how and why of the research inventory. (Action Dr D. Deboutte to draft message, Dr R. Waldman to distribute)
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Annex - Ethics Template

Submitted by Jennifer Leaning, M.D., S.M.H.
(With acknowledgements to discussions with Sisella Bok, Ph.D.
and Ruth A. Barron, M.D.)

The Template is based on the report of the WHO ethics working group meeting of the Consultation on Applied Health Research in Emergencies, October 1997. (See summary on page 15 & 16 of the Consultation report)

The subject of concern is the need to create ethical guidelines to use when designing and conducting research on populations of refugees and internally displace persons. By their status and situation, refugees and IDPs lack the customary protections of the state, are dependent for their vital needs on the efforts of others, often speak a different language and come from a different culture than that of those charged with their protection, and frequently have experienced recent drastic physical and psychological losses.

The major principles addressed in the ethics report arising from the WHO October 1997 meeting are beneficence, autonomy, and justice. When framed in an ethics template, these principles in their operational form can be stated as issues of risk-benefit, informed consent and confidentiality, dignity, and fairness.

The template states the conditions that must be met under each category of principle in order to assure that the research design and implementation conforms to the highest standards of research ethics.

Risk-Benefit:

1) The benefit derived from the research must accrue directly and temporally to the actual subjects of the research.

2) The research must be directed at questions that could not be answered in a non-emergency or non-refugee setting.

3) The risks to the individual subjects, their community, and their future security must be kept to an absolute minimum. These risks must be extensively and comprehensively detailed in the research protocol and also embedded in the protocol for obtaining informed consent. All anticipated risks should be identified and mechanisms described to monitor for adverse outcomes. A threshold must be defined for intervention and, if needed, interruption of the study. Mechanisms to treat those in whom adverse outcomes develop must be described. The feedback methods by which this monitoring system will be operationalized must be described.
Informed Consent:

1) Attention to the highest standards of informed consent must perfuse the study design.

2) All possible efforts must be made to obtain from each individual subject a valid and reliable informed consent.

3) A full explanation, in terms and language understandable to the study subject, must be given regarding the specific investigational aspects of the research. The subject must be seen to understand what aspects of the research are based on known and proven science, and what aspects of the research are in fact investigational. This explanation must be delivered in an oral and written form.

4) Informed consent may need to be obtained as well from the village chief or community leader, or from the head of the household. This consent must be considered additional to and not a substitute for the informed consent obtained from the individual subject. All points relating to obtaining valid and reliable informed consent apply in this group context as well. Under no circumstances can consent from a community leader or head of house hold be construed as replacing the need to obtain as well a fully independent and informed consent from the individual study subject.

5) To provide greater assurance that informed consent has indeed been obtained according to the standards described above, the research team should include as a full member of its staff for the duration of the study at least one person (from the community that provides the study subjects and who speaks all relevant languages) who is given the responsibility of monitoring the informed consent process and content.

Confidentiality:

1) The privacy of the individual subject and the individual’s family must be assured in all aspects of the study design and implementation.

2) All information relating to or traceable to an individual, the individual’s family, or an identifiable group must be kept completely confidential at all levels of research implementation, extending through the process of data analysis, preparation of reports, and publication.

3) The identity and identifying characteristics of the site of temporary settlement or the refugee camp must also remain confidential and be known only to the few members of the research team who for logistic purposes must know this information.

4) The research protocol must address the question of security by discussing the possible short and long-term risks of exposure, for the individual or group, and by describing the methods of monitoring and surveillance, over time, that the research team intends to keep in place in order to assure that no harm subsequently befalls the subject or the group that can be related to the fact that the individual or the group participated in the study.
Dignity:

1) The research protocol must explicitly state the ways in which all interactions with the study subjects and their community will be conducted according to the high standards defined in the Universal Declaration of Human Rights and the Convention on the Rights of the Child.

2) The research protocol must demonstrate that the ways in which those conducting the research and the ways in which the resulting information will be handled and used supports the dignity and autonomy of the individual subject and, wherever relevant, the individual’s family and the group.

3) Every opportunity should be taken to promote and if possible enhance the study subject’s sense of well being, dignity, and autonomy throughout the research enterprise from the choice of question, to the design and continuing through the implementation and publication of results.

Fairness:

1) The research must address an urgent and important problem whose solution would provide immediate benefit for the individuals in the community who are to be recruited for the study. Thus the study rational must explicitly explain and justify its choice of question and its choice of site and population in these terms.

2) Subjects of the research must be selected on the basis of scientific principles without bias introduced by issues of accessibility, cost, or malleability.