

THE CODE SAYS

The AMA *Code of Medical Ethics'* Opinions on International Health and Research

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Although the AMA *Code of Medical Ethics* provides guidance primarily to physicians practicing in the US, these physicians are expected to uphold the *Code's* standard of professionalism when working internationally. Accordingly, the *Code* specifically addresses ethical issues related to physicians' conducting [biomedical or behavioral research outside the US](#). By the same token, physicians practicing in the US are expected to uphold the *Code's* standard of professionalism regardless of their patients' national origins, and the *Code* specifically addresses [safely discharging patients](#) who are noncitizen immigrants.

Opinion 2.077, "Ethical Considerations in International Research" [1], provides guidelines for physicians participating in research in countries with differing cultural traditions, health care systems, and ethical standards. Physicians have ethical obligations to ensure protection of research participants in several ways: first, they must ensure that the research protocol has been developed according to a sound scientific design. In fact, with certain exceptions, US investigators must obtain approval for such protocols from [institutional review boards](#) (IRBs) [2]. What are the specific participant protections addressed by Opinion 2.077?

Opinion 2.077 specifies that IRBs—particularly, physicians who serve on them—must determine that the "ratio of risks to benefits is favorable to participants." The opinion states that when making this evaluation, the IRB "should obtain relevant input from representatives from the host country and from the research population." As with any research protocol, IRBs are required to protect the welfare of individual participants by ensuring that an appropriate and effective [informed consent process](#) will take place. In order for the information presented to be meaningful to the participants, it needs to be communicated in ways that are consistent with local language and customs. Opinion 9.121, "Racial and Ethnic Health Care Disparities" [3], while not discussing research per se, also touches on this point by noting that

Participatory decision making should be encouraged with all patients. This requires trust, which in turn requires effective communication. Physicians should seek to gain greater understanding of cultural or ethnic characteristics that can influence patients' health care decisions.

Physicians should not rely upon stereotypes; they should customize care to meet the needs and preferences of individual patients.

Finally, Opinion 2.077 explains that IRBs must protect from exploitation the population from which participants are recruited by ensuring that the research corresponds to an actual medical need in a region. The research should also have [potential for lasting benefits](#) for the population from which participants are drawn, particularly if the region lacks health care resources. Moreover, physicians conducting human subjects research must encourage research sponsors to continue to provide interventions found by the study to be beneficial to all participants at the conclusion of the study.

Safe Patient Discharge

The *Code* also speaks to international health in cases in which noncitizen immigrant patients are being cared for in US hospitals. Opinion 9.141, “Safe Patient Discharge” [4], provides guidelines for physicians who might face conflicting demands in discharging patients. When a nonpaying, noncitizen patient is being cared for in a US hospital, physicians at that hospital must balance the needs of the patient with those of the greater community. While resources at the US hospital might be limited (e.g., beds, clinical staff, and money), physicians still may not ethically discharge any patient to a resource-poor environment where the patient’s health would be at risk. Similarly, a patient who is ready for discharge may be released into care that is safe and adequate for his or her clinical situation but possibly not ideal. (For example, an ideal care setting might include 24-hour daily care though only 18 hours daily can be provided.) The background report on the opinion explains the factors a physician should consider in these types of circumstances.

Throughout the discharge process, physicians should listen to the concerns of future caretakers and to the preferences of a patient who is not a citizen or legal resident just as they would when planning the discharge of a citizen patient. The physician should consider the caretakers’ and patient’s understanding of the standards of care in their country of citizenship and the social attachments (such as employment or other support systems) that the patient may have in the US, for example. These considerations may be important when physicians assess the adequacy of future care arrangements for the patient. Moreover, the caretakers’ and patient’s involvement in the discussions may very well lead to a helpful consensus about what ought to be done [5].

The background report acknowledges that occasionally, despite the best efforts by a physician and the discharge team, there may be no ethically satisfying decision. If no consensus can be reached about how the patient’s care ought to be handled, a physician

should support the patient's right to seek input from an [ethics committee](#). Should stakeholders continue to fail to reach consensus, a physician should support a patient's right to seek arbitration before a legal body. Consultation with the embassy of the patient's country of origin might also be helpful. It is extremely important to note, as the report does, that "forcing an immigrant to leave the US is a prerogative of the federal government, and should only occur following due process. Physicians should decline to authorize a discharge that would result in the patient's involuntary repatriation, except pursuant to legal process" [5].

References

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2. Protection of human subjects, 45 CFR sec 46.109(a) (2016).
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