

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**Recruiting Human Subjects**

**Sample Guidelines for Practice**



**JUNE GIBBS BROWN  
Inspector General**

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# EXECUTIVE SUMMARY

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## PURPOSE

To identify institutional review board and professional medical association human-subject recruitment guidelines that exceed guidelines set forth by the Department of Health and Human Services.

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## BACKGROUND

In our companion report, *Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Research* (OEI-01-97-00195), we indicated that the Department of Health and Human Services (HHS) guidelines do not address the recruitment practices that IRBs and others involved in clinical research find most troubling. In this report, we present other sources of guidance for IRBs and investigators, from such entities as professional medical associations and IRBs. We also include Canadian guidelines on recruitment practices to illustrate how these practices have been addressed by another nation's research community.

This report focuses on guidance provided by IRBs, medical associations, and Canada on recruitment practices *not covered* in HHS guidelines. Specifically, we focus on guidance given by these entities on how three main issues— recruitment incentives, the dual investigator-physician role, and the confidentiality of medical records— should be handled. These particular issues, as discussed in our companion report, have raised many concerns among those involved in clinical research.

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## Recruitment Incentives

Recruitment incentives include bonuses that sponsors give to investigators to boost enrollment and referral fees given to doctors for referring their patients to another investigator's study. Some IRBs prohibit such incentives, claiming that they pose too much of a conflict of interest for investigators. Many professional medical associations, including the American Medical Association, prohibit referral fees, branding them unethical. Other IRBs and medical associations favor investigator disclosure of incentives to potential subjects, allowing the subjects to make their own decisions about the significance of the incentives. Finally, Canada promotes a "proportionate approach," in which an IRB determines the severity of a conflict and metes out safeguards accordingly; minor conflicts may just need to be disclosed to the subject, whereas large ones may require investigators to abandon one of their conflicted interests.

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## Dual Investigator-Physician Role

When an investigator is also the physician of the subject-patient, the investigator may be faced with a conflict between what is best for the subject and what is best for the research protocol. Some IRBs and medical associations assert that this potential conflict must be disclosed to subjects. One medical association goes so far as to suggest using an “uninterested” party to explain the trial to particularly vulnerable subjects. Other medical associations state that if such a conflict should arise, it should always be resolved in the best interest of the patient.

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## Confidentiality of Medical Records

Investigators often search patients’ private medical records to identify and contact potential subjects for clinical trials. Some IRBs prohibit investigators from directly accessing this confidential information unless it pertains to the investigator’s own patients. Professional medical associations do not address this issue explicitly, but do explain the appropriate uses of medical information, divulged in confidence between doctor and patient.

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## CONCLUSION

The guidelines featured in this report have implications for the implementation of the recommendations advanced in our companion report.

### Toward improved practice and a level playing field

One of the key recommendations we set forth in our companion report is for HHS to provide IRBs with direction regarding oversight of recruitment practices. Specifically, we call for HHS to clarify that IRBs have the authority to review certain recruiting practices based on existing Federal regulation and to disseminate guidance on what IRBs can address in their review of recruitment practices. Although all of the IRB guidelines and policies mentioned in this report exceed guidelines specified by Federal oversight agencies, these IRB guidelines are the exception rather than the rule. In order to foster a level playing field, in which sponsors and investigators adhere to common standards in recruiting human subjects, Federal oversight bodies must clarify IRB authority to review recruitment practices and provide them with respective guidance.

A second major recommendation from our companion report is that HHS should facilitate discussion and consensus about appropriate human-subject recruiting practices by convening forums and sponsoring studies, among other initiatives. The guidelines highlighted in this report represent much reflection and deliberation by IRBs, their parent

institutions, professional medical associations, and the Canadian government, on recruitment issues. Any future debate or research on appropriate recruitment practices ought to draw on these and other existing guidelines.

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## **Comments on the Draft Reports**

We received comments on our two draft reports from the Department of Health and Human Services. We also solicited and received comments from the following external parties: the Applied Research Ethics National Association, the Consortium of Independent Review Boards, Pharmaceutical Research and Manufacturers of America, and Public Citizen's Health Research Group. We include the detailed text of all of these comments and our responses to them in our companion report, *Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Research*. In the executive summary of that report, we summarize the thrust of these comments and our responses.

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# INTRODUCTION

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## PURPOSE

To identify institutional review board and professional medical association human-subject recruitment guidelines that exceed guidelines set forth by the Department of Health and Human Services.

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## BACKGROUND

In our companion report, *Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Research* (OEI-01-97-00195), we presented concerns that sponsors, investigators, and IRBs expressed about current practices used to recruit human subjects.<sup>1</sup> In that report, we found that most of the concerns fit into three broad categories: the erosion of informed consent, the compromise of patient confidentiality, and enrolling ineligible subjects. We also noted that many of these concerns are not addressed in guidelines offered by the Food and Drug Administration (FDA) or the National Institutes of Health (NIH), through its Office for the Protection from Research Risks (OPRR).

In fact, we found that the FDA and OPRR guidelines fail to address many of the recruitment practices that IRBs and others involved in clinical research find most troubling. Thus, we set out in this report to find other sources of guidance available to IRBs and investigators. We found that several other entities, such as IRBs and professional medical associations, do provide such guidance. We include examples of these guidelines in this report. We also include guidelines from a collaboration among three Canadian medical research funding agencies, the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*, to illustrate how these recruitment issues have been addressed by another nation's research community.<sup>2</sup>

This report focuses on guidance provided by IRBs and medical associations on recruitment practices *not covered* in HHS guidelines. Specifically, we focus on guidance given by these entities on three main issues: recruitment incentives, the dual investigator-physician role, and the confidentiality of medical records. These three issues parallel the main recruitment strategies set forth in our companion report: offering incentives, targeting one's own patients, and seeking additional patient bases. We have chosen not to highlight guidelines on the fourth recruitment strategy, advertising. Although many IRBs and professional medical associations have their own guidelines on advertisements and subject incentives, there are explicit HHS guidelines for those methods.

## Institutional Review Boards

In our companion report, we explain that many IRBs are uncertain of their authority to review certain recruitment practices, particularly those that take place apart from the investigator-subject interaction. The IRBs whose guidelines and policies are featured in this report have proceeded with the assumption that they have this authority. In fact, many are taking strong stances on some recruitment issues. These IRB or institutional guidelines serve the dual purpose of assisting IRB members when reviewing protocols and guiding investigators as they consider how they will recruit subjects (or how to handle sponsor incentives for boosting enrollment). The guidance falls along a continuum, from merely raising awareness of potential problems associated with a particular recruitment practice to forbidding certain practices.

## Professional Medical Associations

Professional medical associations are another source of guidance regarding ethical conduct of clinical research for both investigators and IRBs,. Guidance from professional associations may not be an obvious resource to those involved in research, but this guidance is, in fact, quite rich and may be gaining in importance.<sup>3</sup> According to a recent article on professional medical associations in the *Journal of the American Medical Association*, “the time is propitious for the medical profession to act responsibly to reaffirm the ethical commitment that grounds physicians’ authenticity. Only then can physicians justify the claim to the moral integrity that patients expect.”<sup>4</sup>

Professional medical association guidance contrasts with IRB and Federal guidance in that it emanates from physicians, who are often themselves investigators. Therefore, this guidance can be seen as a reflection of physicians’ own concerns as well as a form of self-monitoring. The American College of Physicians states that, “although the responsibility for assuring reasonable protection of human research participants resides with the investigators and the local institutional review board, the medical profession as a whole also has responsibilities. Clinical investigation is fraught with opportunities for conflicts to arise.”<sup>5</sup>

Many medical associations have set forth ethical guidelines relating to clinical research. Others have ethical guidelines that relate to general professional conduct, but which could be extrapolated to clinical research. Although many associations have valuable guidance on many aspects of clinical research, we have limited this report to examples focused on recruitment practices. See appendix A for a chart summarizing subject recruitment guidelines mentioned by the 20 professional medical associations covered in this report. See appendix B for a full listing of our sources of these guidelines.



## Methodology

As part of our survey of 200 IRBs, we requested any institutional or IRB guidelines on recruitment issues to which IRBs adhere. We obtained other IRB guidelines during site visits and conversations with IRB representatives. From these, we culled recruitment guidelines that exceeded the scope of Federal guidelines. In addition, we gathered codes of ethics, guidelines, and position papers relevant to subject recruitment from 20 professional medical associations. We selected these medical associations as a sample of the major medical associations; it is not a comprehensive selection. We also thoroughly reviewed the Canadian *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*.

These guidelines do not necessarily represent the best or most suitable response to concerns raised in our other report. Rather, they serve as reference points. These guidelines are intended to stimulate discussion and debate among Federal policymakers, IRBs, sponsors, and investigators over what constitutes appropriate recruitment practices and how to develop guidelines that ensure that appropriate practices are followed. We did not independently evaluate any of the guidelines highlighted in this report. A guideline's inclusion does not mean that it receives our approval, or that it is being used only at the institution that we highlighted. While we have highlighted many guidelines, we may have omitted some useful ones.

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

# Recruitment Incentives

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## ISSUE

Sponsors often offer investigators or their staff incentives to boost subject enrollment. Some of these incentives may be financial, often in the form of a bonus payment per additional subject enrolled. Other incentives include, but are not limited to: granting the investigator authorship on a paper about the study; supplying the research site with office or medical equipment; and offering educational gifts, such as books or conference attendance to research staff.

People involved in clinical research have raised concerns that such incentives could prompt investigators to distort information that they provide to potential subjects during the consent process or pressure potential subjects to enroll in a trial. Some fear that these incentives could cause investigators to stretch eligibility criteria to enroll a potential subject. Finally, some are concerned about whether potential subjects can truly make informed choices about participating in trials without knowing how, and to what extent, investigators are being rewarded for their participation.

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## GUIDELINES

### On the appropriateness of incentives

**IRBs.** The University of Rochester prohibits bonus payments to investigators and research administrators that are intended to encourage subject recruitment, saying:

Bonus payments for subject recruitment may compromise the integrity of that study by giving an appearance of affecting the judgment of the investigator/research team and in some cases may violate regulations and institutional policies.<sup>6</sup>

However, the institution does permit additional, per-subject payments made to investigators if these payments cover additional expenses incurred by the investigator to accelerate enrollment (e.g., for additional advertisements).

Partners Healthcare System, Inc., which is comprised of Massachusetts General Hospital and Brigham and Women's Hospital, prohibits finder's fees given to a physician for referring a potential subject to an investigator. It also prohibits financial incentives given to investigators to accelerate enrollment. It claims that both of these practices pose a conflict of interest.

St. Vincent Mercy Medical Center IRB assesses all additional payments given to investigators during the course of a trial to determine whether these payments reflect “reasonable payment for bona fide services performed.”<sup>7</sup> If the Board finds that the additional payments fail to meet this criteria, but rather, these payments are merely for enrolling subjects, the Board will not allow them.

**Medical Associations.** Many medical associations also provide guidance on financial incentives to investigators. The American Medical Association asserts that “offering or accepting payment for referring patients to research studies (finder’s fees) is unethical.”<sup>8</sup> Similarly, the American College of Physicians asserts that these finder’s fees “generate an unethical conflict of interest.”<sup>9</sup> In addition, five other medical associations (see Appendix A) note that fees paid to doctors for referring patients to another physician are unethical; one could interpret this warning to apply to clinical research, in addition to general medical practice.

The American Academy of Orthopaedic Surgeons and the American Academy of Pediatrics both warn investigators against accepting unreasonable compensation for conducting a trial. The American Academy of Pediatrics states that, “it is important to avoid undue rewards to health care providers that may constitute an undue incentive for coercing patients to participate in a study.”<sup>10</sup> Finally, the American Academy of Ophthalmology and the American College of Physicians recommend using the British Royal College of Physicians guideline for determining the appropriateness of a financial arrangement; that is, “would I be willing to have these arrangements generally known?”

## Disclosure

**IRBs.** UCLA, as a result of a recent legal case, requires that a physician “disclose personal interest unrelated to the patient’s health, whether research or economic, that may affect the physician’s professional judgment,” or risk legal action taken on behalf of the subject for “performing medical procedures without consent or breach of confidentiality.”<sup>11</sup>

Partners Healthcare System, Inc., requires “full disclosure of any financial arrangements that may encourage physicians to recruit patients for research participation that may not be in their best interests.”<sup>12</sup>

**Medical Associations.** The American College of Emergency Physicians advises that investigators disclose to subjects payments from the biomedical industry, while the American Psychiatric Association suggests that investigators disclose the funding *source* to subjects. Six other associations have guidelines for physicians’ disclosure to patients of financial interests in general commercial ventures, if they seem to pose conflicts of interest. One could infer from these guidelines that financial conflicts of interest in clinical research should be disclosed to potential subjects as well.

**Canada.** An entire section of the *Canadian Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* is devoted to conflict of interest issues.<sup>13</sup> In this section, it states that researchers hold trust relationships with research subjects and that these trust relationships “can be put at risk by conflicts of interest that may compromise independence, objectivity or ethical duties of loyalty.” The policy asserts that, though these potential conflicts are not new, “pressures to commercialize research have led to increased concerns.” The policy proposes IRB guidelines for “actual, perceived and potential” conflicts of interest, which include investigator incentives. It recommends that IRBs take a “proportionate approach” to reviewing conflicts of interest. If the IRB perceives a potential conflict to be relatively small, then the IRB should merely require the investigator to disclose this conflict. However, if the IRB perceives a potential conflict to be large, then the IRB should require the investigator to abandon one of the interests in conflict, either by withdrawing from the research or authorizing someone else to make certain decisions about the research.

# Dual Investigator-Physician Role

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## ISSUE

Many investigators recruit subjects from their own patient populations. In such scenarios, the physician-investigator must both consider the best interest of the patient-subject and remain objective in order to foster scientific advancement and discovery. One of the main concerns raised about this practice is that the distinction between physician and investigator will be blurred, as will the distinction between patient and subject. Patient-subjects may become confused as to whether they are involved in therapy or research.

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## GUIDELINES

### Acknowledging and separating the dual roles

**IRBs.** UCLA recognizes the potential conflict of interest that faces an investigator who is also the physician of the subject-patient. Thus, the University requires that investigators in this situation disclose their possible conflicts to subjects at the top of the informed consent form, using the following wording:

Your health care provider may be an investigator of this research protocol, and as an investigator, is interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your doctor.<sup>14</sup>

In some cases, the UCLA IRB may discourage investigators from directly approaching their patients. Instead, the Board will suggest that the investigator place information about a trial in the waiting room and wait to be approached by the patient about participating.

**Medical Associations.** The American Academy of Neurology clearly acknowledges the threat that the doctor-patient relationship may pose on the objectivity of the consent process. The Academy suggests precautions that IRBs and researchers may want to take to mitigate this threat when trying to recruit particularly vulnerable subjects, such as people with severe, progressive or terminal neurological illnesses:

Experienced physicians and researchers know that some patients will accede, on the basis of trust, to just about any medical requests their physicians make. Therefore, particular problems may arise when the researcher has a long-standing doctor-patient relationship with a person who also enrolls in his or her research protocol. Physicians and researchers must be vigilant about their relationships with these patients/subjects because the distinction between standard medical care and experimental treatment may become blurred. In such cases, researchers and IRBs may want to consider additional safeguards. For example, the IRB may request that an 'uninterested' individual, such as a clinical neurologist not involved in the research, discuss with prospective subjects the research study and other clinical or research alternatives.<sup>15</sup>

Both the American College of Physicians and the American Medical Association recommend that physician-investigators handle their dual role by always placing the health and welfare of their patients first, before their value as study subjects.

**Canada.** The Canadian Tri-Council Policy directs physician-investigators to disclose their dual roles to potential subjects, stating that:

[Researchers have] relevant ethical duties that govern potential or actual conflicts of interest, as they relate to the free and informed consent of subjects. To preserve and not abuse the trust on which many professional relations reside, researchers should separate their roles as therapists...If a researcher is acting in dual roles, this fact must always be disclosed to the subject. Researchers should disassociate their role as researcher from other roles, in the recruitment process and throughout the project.<sup>16</sup>

# Confidentiality of Medical Records

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## ISSUE

Investigators and their staff may use patient medical records to identify potential subjects for clinical trials and then may contact these patients to inquire about their interest in participation. Sometimes other researchers who are not the patients' physician will have access to these same patient databases and may use them for the same recruitment purposes.

Concerns relate to how private medical information, divulged in confidence by patients to their physician, ought to be used. Specifically, people question whether using this information for purposes other than treating or diagnosing, or transmitting this information to a third party, constitutes a breach of confidentiality.

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## GUIDELINES

**IRBs.** Some IRBs have guidelines about accessing confidential medical information through a physician's or hospital's database. Others have guidelines for investigators' use of information to contact potential subjects.

The Medical College of Ohio states that:

Review of departmental log books, medical charts, and databases for potential subjects is not an acceptable practice prior to IRB review and approval...Persons with access to patient names and diagnoses should not, nor should they be asked to, provide such lists for an investigator to use to contact potential participants who could view such an unexpected communication to be an invasion of privacy and a breach of doctor-patient confidentiality...If an investigator plans to recruit subjects that are not his own patients or not from his department's clinic(s), s/he should enlist the assistance of potential participants' own physicians to introduce the study.<sup>17</sup>

UCLA emphasizes that investigators must take care to ensure the confidentiality and privacy of potential research subjects when identifying eligible subjects for their research:

In order to avoid a breach of the potential subject's privacy, investigators should not ask institutions, or their employees, such as physicians or case workers to directly identify potential subjects for a research study. Instead, an investigator should ask the physician, case worker, etc., to first approach potential subjects (or their parent/guardian, as appropriate).<sup>18</sup>

Likewise, Partners HealthCare System, Inc. and the University of Rochester also prohibit anyone who lacks legitimate access to the potential subjects' private medical records, generally the primary care-giver, from contacting these subjects for recruitment purposes.

The University of Washington recommends that when investigators lack legitimate access to private medical records that they use a neutral "intermediary" whose sole job is to ask the potential subject whether the subject's name and contact information could be released to the investigator. The investigator would then be allowed to contact the subject directly.

If an investigator intends to use private medical records to find potential subjects for a study, the Mobile Infirmiry Medical Center instructs its IRB to ascertain whether the investigator is allowed access to the records by the institution or the physician. Once the permissibility of the investigator's access is determined, the investigator must accept responsibility for protecting the potential subjects' privacy.

**Medical Associations.** No medical associations in our sample have guidelines specifically relating to the use of medical records for identifying and contacting research subjects. However, many have guidelines regarding how private medical information *should* be used, and indicate that all other uses are impermissible unless specifically agreed upon by the patient. For example, the American Academy of Family Physicians states that:

Historically, the privileged nature of communications between physician and patient has been a safeguard for the patient's personal privacy and constitutional rights. However, new forces in the medical marketplace, including the proliferation of electronically linked data bases and a growing demand for health care data of all types by...academic and commercial researchers...are encroaching upon that relationship...No physician should disclose in individually identifiable form any information about the individual without the individual's explicit authorization.<sup>19</sup>

Similarly, the American Medical Association maintains that:

Patients divulge information to their physicians only for purposes of diagnosis and treatment. If other uses are to be made of the information, patients must give their permission after being fully informed about the purpose of such disclosures. If permission is not obtained, physicians violate patient confidentiality by sharing specific and intimate information from patients' records with commercial interests.<sup>20</sup>



# CONCLUSION

The additional guidelines featured in this report provide further evidence of the pervasiveness of concerns about certain recruitment practices among both IRBs and professional medical associations. More importantly, these guidelines have implications for implementing the recommendations advanced in our companion report.

## **Toward improved practice and a level playing field**

One of the key recommendations we set forth in our companion report is for HHS to provide IRBs with direction regarding oversight of recruitment practices. Specifically, we call for HHS to clarify that IRBs have the authority to review certain recruiting practices based on existing Federal regulation and to disseminate guidance on what IRBs can address in their review of recruitment practices. All of the IRB guidelines and policies mentioned in this report exceed guidelines specified by Federal oversight agencies. These IRB guidelines indicate that some IRBs believe that recruitment practices raise enough concern to warrant a more rigorous review than called for by Federal guidelines. Yet, these IRBs, according to data from our IRB survey mentioned in the companion report, are the exception rather than the rule. In order to foster a level playing field, in which sponsors and investigators adhere to a common standard in recruiting human subjects, Federal oversight bodies must clarify IRB authority to review recruitment practices and provide appropriate guidance. Otherwise, only the exceptional IRB is likely to add this extra layer to their standard protocol review, as it may be to their competitive disadvantage to do so.

A second major recommendation that we make in our companion report is that HHS should facilitate discussion and consensus about appropriate human-subject recruiting practices by convening forums and sponsoring studies, among other initiatives. The guidelines highlighted in this report represent much reflection and deliberation by IRBs, their parent institutions, professional medical associations, and the Canadian government on recruitment issues. Any future debate or research on appropriate recruitment practices ought to draw on these and other existing guidelines, including any incidents that led to the guidelines' creation and the discussions that preceded their adoption. These guidelines, and the debate that led to them, represent a rich source of material that should be tapped by Federal bodies in exploring recruitment issues.

**Professional Medical Association Guidelines**

The following chart indicates which medical associations have such guidelines or codes of ethics. Guidelines that specifically pertain to clinical trials are denoted by a ✓. Associations that have general medical practice guidelines or codes of ethics that could have *implications* for clinical research are denoted by a ✪.

	Incentives			Dual Role	Confidential Records	Other Guidance		
	referral fees	disclosure to subjects of financial arrangements	Compensation to investigators for conducting clinical trial		Use of medical records for identifying/contacting potential subjects	Advertisement/ payment to subjects	news briefs	
				dual investigator-physician role				also defers to other guidance
American Academy of Allergy, Asthma and Immunology								
American Academy of Family Physicians	✪				✪			
American Academy of Neurology				✓				
American Academy of Ophthalmology		✪	✪					
American Academy of Orthopaedic Surgeons		✪	✓					AMA Code of Ethics
American Academy of Pediatrics			✓			✓		
American Academy of Physical Medicine and Rehabilitation	✪							Nuremberg laws
American Association of Neurological Surgeons					✪			

**APPENDIX A**

	Incentives			Dual Role	Confidential Records	Other Guidance		
	referral fees	disclosure to subjects of financial arrangements	Compensation to investigators for conducting clinical trial	dual investigator-physician role	Use of medical records for identifying/contacting potential subjects	Advertisement/ payment to subjects	news briefs	
American College of Emergency Physicians		✓						Declaration of Helsinki
American College of Obstetricians and Gynecologists		✱						
American College of Physicians	✓		✱	✓	✱		✓	
American College of Radiology		✱						
American College of Surgeons	✱	✱						
American Geriatrics Society								
American Medical Association	✓				✱		✓	
American Women’s Medical Association								
American Pharmaceutical Association								
American Psychiatric Association	✱	✓			✱			AMA Code of Ethics
American Society of Anesthesiologists					✱			AMA Code of Ethics
American Society of Plastic and Reconstructive Surgeons	✱	✱						
National Medical Association								

## Professional Medical Association Sources

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### 1. American Academy of Allergy, Asthma, & Immunology

*Code of Ethics*, adopted March 1998. [<http://www.aaaai.org/members/codeofethics.stm>, accessed December 1999].

And, Physician Reference Materials: Position Statement 14, “Unproven Procedures for Diagnosis and Treatment of Allergic and Immunologic Diseases, Reviewed,” 1992.

[<http://www.aaaai.org/professional/reference/positionstatements/ps14.stm>, accessed December 1999]

### 2. American Academy of Family Physicians

*Compendium of AAFP Positions on Selected Health Issues*, “Fees,” “Confidentiality,” and “Proprietary Practices.” [<http://www.aafp.org/policy>, accessed December 1999]

### 3. American Academy of Neurology

Ethics Subcommittee of the American Academy of Neurology, “Position Statement: Ethical Issues in Clinical Research in Neurology,” *Neurology*, March 1998; 50:592-595.

### 4. American Academy of Ophthalmology

*Code of Ethics*, Revised 1995, and *Advisory Opinion of the Code of Ethics*, “Disclosures of Professionally Related Commercial Interests,” approved June 1990, reaffirmed April 1998.

### 5. American Academy of Orthopaedic Surgeons

*Code of Ethics for Orthopaedic Surgeons*, adopted October 1988, amended December 1995.

### 6. American Academy of Pediatrics

“Policy Statement: Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations,” 1995; 95(2): 286-294.

### 7. American Academy of Physical Medicine and Rehabilitation

American Academy of Physical Medicine and Rehabilitation, *Code of Conduct*, November 1995.

### 8. American Association of Neurological Surgeons,

American Association of Neurological Surgeons, *Code of Ethics*.

### 9. American College of Emergency Physicians

“Policy Statement: Code of Ethics for Emergency Physicians,” June 1997, and “Policy Statement: Gifts to Emergency Physicians from the Biomedical Industry,” reaffirmed March 1997.

**10. American College of Obstetricians and Gynecologists**

*Code of Professional Ethics of the American College of Obstetricians and Gynecologists*, approved 1997.

**11. American College of Physicians**

*Annals of Internal Medicine Position Paper-- Ethics Manual*, 4<sup>th</sup> edition, April 1999.

[<http://www.acponline.org/journals/annals/01apr98/ethicman.html>, accessed December 1999]

**12. American College of Radiology**

*Code of Ethics*, approved Sept. 1998. [<http://www.acr.org/f-appcrit.html>, accessed December 1999]

**13. American College of Surgeons**

*Statements on Principles*, 1996-98. [[http://www.facs.org/fellows\\_info/statements/stonprin.html](http://www.facs.org/fellows_info/statements/stonprin.html), accessed December 1999]

**14. American Geriatrics Society**

Position Statement: “Research and Geriatric Medicine,” revised May 1999, and “Informed Consent on Human Subjects with Dementia,” approved May 1998.

**15. American Medical Association**

*Current Opinions of the Council on Ethical and Judicial Affairs*, A-99 Edition.

**16. American Medical Women’s Association**

*Principles of Ethical Conduct*, approved 1990.

[[http://www.amwa-doc.org/publications/Position\\_Papers/ethicalconduct.htm](http://www.amwa-doc.org/publications/Position_Papers/ethicalconduct.htm), accessed December 1999]

And, Resolution: “Research,” adopted 1990, 1995, 1997.

[<http://amwa-doc.org/publications/Resolutions/research.htm>, accessed December 1999]

**17. American Psychiatric Association**

*The Principles of Medical Ethics with Annotations Especially Applicable to Psychiatry (and Addendums)*, 1998 Edition.

“Guidelines for Assessing the Decisionmaking Capacities of Potential Research Subjects with Cognitive Impairment,” 1997.

**18. American Society of Anesthesiologists**

“Guidelines for the Ethical Practice of Anesthesiology,” amended October 1997.

[<http://www.asahq.org/standards>, accessed December 1999]

**19. American Society of Plastic and Reconstructive Surgeons**

*Code of Ethics for the American Society of Plastic and Reconstructive Surgeons*, 1998.

[<http://www.plasticsurgery.org/profinfo/resource>, accessed December 1999]

**20. National Medical Association**

*NMA Policy Database*, “Pharmacogenetics in Drug Development,” amended 1988, “Black Investigators in Clinical Trials,” approved 1990, “Pharmaceutical Research,” approved 1990, and “Revision of the Food and Drug Administration’s (FDA) Current Informed Consent Regulations,” 1995. [<http://nmanet.org/hq/reference/policies.asp>, accessed December 1999]

## Endnotes

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1. Department of Health and Human Services, Office of Inspector General, *Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Research*, OEI-01-97-00195, June 2000.

2. Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement--Ethical Conduct for Research Involving Humans*, Public Works and Government Services Canada, 1998.

The three Canadian councils that co-authored the Tri-Council Policy Statement are the three major Federal agencies responsible for funding Canadian medical research. Funding from these agencies is contingent upon recipients' compliance with the Policy.

3. The American Medical Association's Council on Ethical and Judicial Affairs focused on many of the issues discussed in this report in its most recent bi-annual discussion of emerging ethical issues in the medical profession. Specifically, it raised concerns about financial incentives given to investigators and about the dual doctor/investigator role. V. Foubister, "Clinical Trial Pay Troubling Topic at CEJA Forum," *AMA News*, 27 December 1999; 42(48): 8-9.

4. Pellegrino, E.D. and Relman, A.S., "Professional Medical Associations--Ethical and Practical Guidelines," *Journal of the American Medical Association*, 1999;282(10):984.

5. American College of Physician, "Research--Clinical investigation," *Annals of Internal Medicine Position Paper--Ethics Manual*, 4<sup>th</sup> edition.

[<http://www.acponline.org/journals/annals/01apr98/ethicman.html>, accessed September 1999]

6. University of Rochester Research Subjects Review Board, "Incentive Payments in Clinical Trial Agreements--ORPA Internal Policy and Practice."

7. St. Vincent Mercy Medical Center (Toledo, OH), "Position Statement Regarding Additional Payments for Ongoing Clinical Trials."

8. American Medical Association, "Fee Splitting: Referrals to Health Care Facilities," *Current Opinions of the Council on Ethical and Judicial Affairs*, E-6.03, A-99 Edition.

The AMA's prohibition of finder's fees in clinical research extends beyond its own membership, as many other entities require physicians to follow AMA's code of ethics in its entirety. For example, under Ohio state law, violation of the AMA Code of Ethics can be grounds for physicians losing their licensure. Ohio Revised Code Annotated: Occupations--Physicians; Limited Practitioners, ch. 4731, sec.22 (1998).

9. American College of Physicians, “Research--Clinical investigation,” *Annals of Internal Medicine Position Paper--Ethics Manual*, 4<sup>th</sup> edition.  
[http: www.acponline.org/journals/annals/01apr98/ethicman.html, accessed September 1999]
10. American Academy of Pediatrics, “Specific Aspects of Protocol Design: Recruitment,” *Policy Statement: Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations* 1995; 95(2).
11. Moore v. the Regents of the University of California, 51 Cal. 3d 120; P.2d 479. This case involved a patient (Moore) suing his physician for using his cell line, without his permission, to create a lucrative commercial product. The discussion from that case states:
- ...a physician who treats a patient in whom he also has a research interest has potentially conflicting loyalties. This is because medical treatment decisions are made on the basis of proportionality--weighing the benefits to the patient against the risks to the patient...A physician who adds his own research interests to this balance may be tempted to order a scientifically useful procedure or test that offers marginal, or no, benefits to the patient. The possibility that an interest extraneous to the patient’s health has affected the physicians judgment is something that a reasonable patient would want to know in deciding whether to consent to a proposed course of treatment. It is material to the patient’s decision and, thus, a prerequisite for informed consent.
12. Partners HealthCare System, Inc., “Incentives and Rewards for Recruitment of Patients and Referral to Clinical Investigators,” *Partners Human Research Committee Policies and Procedures: Recruitment of Research Subjects*, prepared April 7, 1999, p.3.
13. Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. “Conflict of Interest,” *Tri-Council Policy Statement--Ethical Conduct for Research Involving Humans*, Section 4, Public Works and Government Services Canada, 1998.
14. Memorandum from the University of California-Los Angeles Executive Vice Chancellor, “Disclosure of Possible Conflict of Interest to Human Research Subjects,” April 20, 1999.
15. Ethics Subcommittee of the American Academy of Neurology, “Position Statement: Ethical Issues in Clinical Research in Neurology,” *Neurology* 1998; 50:594.
16. Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. “Conflict of Interest,” *Tri-Council Policy Statement--Ethical Conduct for Research Involving Humans*, Section 4, Public Works and Government Services Canada, 1998, p.2.8.
17. Medical College of Ohio Research Office, “Study Subject Recruitment.”



18. University of California-Los Angeles, "Selection and Recruitment of Subjects," *Investigator's Manual for the Protection of Human Subjects* 1997, p.6-3.
19. American Academy of Family Physicians, "Confidentiality, Patient/Physician," *Compendium of AAFP Positions on Selected Health Issues*.  
[<http://www.aafp.org/policy/17.html>, accessed September 1999]
20. American Medical Association. "Disclosure of Records to Data Collection Companies," *Current Opinions of the Council on Ethical and Judicial Affairs*, Section E-5.075, A-99 Edition.