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A Code of Ethics for Institutional Review Boards

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Institutional review boards (IRBs) focus on the ethical issues of people and organizations that conduct clinical research, as defined by applicable laws, regulations, guidelines, etc. However, the IRB itself, along with its individual members (and staff), have their own ethical challenges. A concise, common-sense statement of what constitutes ethical conduct by an IRB and its members — a code of ethics — could improve the quality of IRB reviews. Since IRBs are only one part, albeit a very important part, of a human subjects protection program, the code of ethics should be adapted accordingly.

The code of ethics proposed in Figure 1 focuses on *ethical conduct*, not the conflicts of interest (COIs) and other *potential causes* of unethical conduct, which constitute a separate, very complex topic. The proposed code of ethics assumes that IRBs have instituted COI policies and procedures.[1] Most of the individual items in the proposed code of ethics are probably followed widely, although perhaps not rigorously and universally.

Is an IRB code of ethics necessary? To the extent that an IRB's policies and procedures incorporate the contents of a code of ethics, a separate code of ethics is redundant. However, even in this case, a separate code of ethics can clarify the ethical responsibilities of the IRB and its members.

This article is not meant to be the last word on the topic of an IRB code of ethics. Rather, it is intended to stimulate discussion about what constitutes ethical conduct by IRBs, lead to the adoption of codes of ethics superior to the one proposed here, and promote ethical conduct by IRBs and their members.

Ethical Conduct

IRBs, also known as "ethics committees," are charged with the responsibility of protecting the safety and welfare of participants in clinical studies and other human research projects in accordance with the applicable laws, regulations, guidelines, guidances, and institutional policies and procedures that define "ethical" research conduct.

IRBs must ensure that the research they approve is ethical. They must also review research in a proper manner, defined largely by 45 CFR 46 and 21 CFR 56: Institutional Review Boards. An *improper* review is also *unethical* if it results in an incorrect review decision, and might be unethical for other reasons as well, e.g., unfairness to the investigator. If one believes that any deviation from the law is unethical, such deviations would constitute unethical conduct as well.

Compliance with a code of ethics requires the elements of a quality management system: policies, procedures, training, inspections/auditing, reporting, corrective action, and a person (e.g., the Director of Human Subjects Protection) with sufficient standing, authority and independence to manage this system.

It is not entirely clear what constitutes ethical conduct by an IRB and its members. The relevant laws and regulations certainly set a minimum standard, but to what extent should an instititution or IRB establish higher standards? Regulatory guidelines and guidances offer "safe harbors" (conduct deemed not to violate a law), but they do not have the force of law, so might be ignored when circumstances dictate. To the extent that documents like the Belmont Report and Declaration of Helsinki relate to *IRB conduct*, what weight should be

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given to them? While relevant institutional policies and procedures should be followed, to what extent should an institution allow its IRB to make exceptions?

Jury members must take an oath to apply the law according to the judge's instructions, despite any disagreements they might have with that law or those instructions. If an IRB member's ethical beliefs are more stringent — or just different — than the relevant laws, guidances, policies, etc., should he or she vote according to those beliefs? For example, if an IRB member believes that community consent is unethical, should he or she disregard the institution's policy to the contrary? To resolve such questions, the institution should make clear what ethical authority it delegates to the IRB and its members, and the IRB should have policies and procedures for addressing such issues.

Figure 1. Proposed IRB Code of Ethics

We follow this Code of Ethics when reviewing human research applications.

Values

a. The safety and welfare of human research subjects must be protected.

b. The Board must comply with the laws, regulations and other applicable rules.

c. Reviews must be performed independently, in a competent manner, and undistorted by conflicts of interest.

Board

1. The Board protects the safety and welfare of human research subjects as its first priority.
2. The Board protects the independence of its decisions.
3. The Board complies with all applicable laws, regulations and guidelines, as well as institutional policies and procedures that govern legal and ethical conduct.
4. The Board has and follows policies and procedures for avoiding, disclosing and managing conflicts of interest.
5. The Board has and follows policies and procedures for protecting the privacy and confidentiality of study participants, study sponsors, investigators and others to whom it owes duties of privacy and confidentiality.
6. The Board does not approve or disapprove any application until it has devoted adequate time, attention and expertise to the review.
7. The Board is subject to the authority of an official with sufficient standing, authority and independence to ensure compliance with this Code of Ethics.
8. The Board has and enforces written policies and procedures to ensure compliance with this Code of Ethics.
9. The Board has a structure and process to prevent, elicit, record and address reports of noncompliance with this Code.
10. The Board publishes this Code of Ethics, measures its compliance with the Code, and attempts to improve compliance over time.

Members

11. Members comply with the Board items above.

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12. Members avoid conflicts of interest and disclose to the appropriate authority any conflict of interest prior to participating in an application review.
13. Members recuse themselves from, or limit their participation in, the review of any application in which they have a financial or other conflict of interest.
14. Members limit their participation to matters for which they are competent and prepared to review, with appropriate reliance on experts.
15. Members maintain independent judgment, support due deliberation, and do not vote with the majority simply to maintain collegiality.
16. Members report to the appropriate authority any attempt by an institutional authority or other outside party to improperly influence a Board decision.
17. Members report to the appropriate authority any perceived ethical lapses by other members.
18. Members demonstrate that they understand and apply this Code of Ethics.

Disclaimer

This Code of Ethics is a statement of good-faith intentions. It does not constitute any contractual or legal obligation beyond that required by applicable laws and regulations.

AAHRPP Accreditation Standards

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) has published the following relevant documents:

- Accreditation Standards (http://www.aahrpp.org/apply/process-overview/standards)
- Evaluation Instrument for Accreditation (http://humansubjects.stanford.edu/research/documents/AAHRPP_Evaluation_Instrument_2011.pdf)
- IRB Evaluation Checklist (http://www.aahrpp.org/apply/resources/evaluation-instrument-for-accreditation)

Figure 2 presents the AAHRPP standards and their elements that are most relevant to an IRB code of ethics. The Evaluation Instrument for Accreditation supplements each element with commentary, regulatory and guidance references, required written materials, common types of materials that may be used to meet the element, and outcomes. Figure 3 presents relevant extracts from AAHRPP's Evaluation Checklist.

The proposed code of ethics differs from the AAHRPP standards, although implementation of the AAHRPP standards might address the differences.

Figure 2. Proposed IRB Code of Ethics vs. AAHRPP Standards

Code of Ethics	AAHRPP Standards & Elements	Notes
1. The Board's primary concern is for the safety and welfare of human research subjects.	**Standard III-1:** In addition to following applicable laws and regulations, Researchers and Research Staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Researchers and Research Staff have the protection of the rights and welfare of research participants as a primary concern.	This AAHRPP standard states that protection of subjects is *a* primary concern, not *the* primary concern.

2. The Board protects the independence of its decisions related to human subjects protection.	**Element I.1.B.** The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program. **Element I.1.C.** The Organization has and follows written policies and procedures that allow the Institutional Review Board or Ethics Committee to function independently of other organizational entities in protecting research participants.	
3. The Board complies with all applicable laws, regulations and guidelines, as well as institutional policies and procedures that govern legal and ethical conduct.	**Standard II-3:** The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidance.	This AAHRPP standard does not reference institutional policies and procedures.
4. The Board has and follows policies and procedures for avoiding, disclosing and managing conflicts of interest.	**Element I.6.A.** The Organization has and follows written policies and procedures to identify, manage, and minimize or eliminate financial conflicts of interest of the Organization that could influence the conduct of the research or the integrity of the Human Research Protection Program. **Element I.6.B.** The Organization has and follows written policies and procedures to identify, manage, and minimize or eliminate individual financial conflicts of interest of Researchers and Research Staff that could influence the conduct of the research or the integrity of the Human Research Protection Program. The Organization works with the Institutional Review Board or Ethics Committee in ensuring that financial conflicts of interest are managed and minimized or eliminated, when appropriate. **Element II.1.C.** The Organization has and follows written policies and procedures to separate competing business interests from ethics review functions. *(Checklist Area 3)*	Financial COIs are not the only COIs.
5. The Board has and follows policies and procedures for protecting the privacy and confidentiality of study participants, study sponsors, investigators and others to whom it owes duties of privacy and confidentiality.	**Element II.3.D.** The IRB or EC has and follows written policies and procedures to evaluate the proposed arrangements for protecting the privacy interests of research participants, when appropriate, during their involvement in the research. **Element II.3.E.** The IRB or EC has and follows written policies and procedures to evaluate proposed arrangements for maintaining the confidentiality of identifiable data, when appropriate, preliminary to the research, during the research, and after the conclusion of the research. *(Checklist Areas 14, 15, 16)*	AAHRPP standards address only study participant privacy and confidentiality.
6. The Board does not approve or disapprove any application until it has devoted adequate time, attention and expertise to the review.		AAHRPP standards do not explicitly address this issue.

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7. The Board is subject to the authority of an official with sufficient standing, authority and independence to ensure compliance with this Code of Ethics.	**Element I.1.B.** The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority and independence to ensure implementation and maintenance of the program.	AHHRPP standards have a broader scope.
8. The Board has written policies and procedures to ensure compliance with this Code of Ethics.	**Element I.1.D.** The Organization has and follows written policies and procedures setting forth the ethical standards and practices of the Human Research Protection Program. Relevant policies and procedures are made available to Sponsors, Researchers, Research Staff, research participants, and the Institutional Review Board or Ethics Committee, as appropriate.	These AAHRPP standards do not specifically address IRB-member conflicts, and focus on *financial* conflicts.
9. The Board has a structure and process to prevent, elicit, record and address reports of noncompliance with this Code.	**Element I.5.C.** The Organization has and follows written policies and procedures so that Researchers and Research Staff may bring forward to the Organization concerns or suggestions regarding the Human Research Protection Program, including the ethics review process.	
10. The Board publishes this Code of Ethics, measures its compliance with the Code, and attempts to improve compliance over time.	**Standard I-5:** The Organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes and guidance. The Organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.	
11. Members comply with the Board items above.		
12. Members avoid conflicts of interest and disclose to the appropriate authority any conflict of interest prior to participating in an application review.	**Element III.1.B.** Researchers and Research Staff identify and disclose financial interests according to organizational policies and regulatory requirements and, with the Organization, manage, minimize or eliminate financial conflicts of interest.	This AAHRPP standard does not address IRB member conflicts.
13. Members recuse themselves from, or limit their participation in, the review of any application in which they have a financial or other conflict of interest	**Element II.1.D.** The IRB or EC has and follows written policies and procedures so that members and consultants do not participate in the review of research protocols or plans in which they have a conflict of interest, except to provide information requested by the IRB or EC. *(Checklist Areas 4, 21)*	Circumstances might require various degrees of participation.
14. Members limit their participation to matters for which they are competent and prepared to review, with appropriate reliance on experts.	**Element II.1.E.** The IRB or EC has and follows written policies and procedures requiring research protocols or plans to be reviewed by individuals with appropriate scientific or scholarly expertise and other expertise or knowledge as required to review the research protocol or plan. *(Checklist Area 5)*	This AAHRPP standard requires participation by qualified IRB members, not limits to participation of unqualified or unprepared members.
15. Members maintain independent judgment, support due deliberation, and do not vote with the majority simply to maintain collegiality.		AAHRPP standards do not explicitly address issues of group dynamics.

16. Members report to the appropriate authority any attempt by an institutional authority or other outside party to improperly influence a Board decision.	**Element I.5.C.** The Organization has and follows written policies and procedures so that Researchers and Research Staff may bring forward to the Organization concerns or suggestions regarding the Human Research Protection Program, including the ethics review process.	This AAHRPP standard does not require reporting by IRB members.
17. Members report to the appropriate authority any perceived ethical lapses by other members.	**Element I.5.C.** The Organization has and follows written policies and procedures so that Researchers and Research Staff may bring forward to the Organization concerns or suggestions regarding the Human Research Protection Program, including the ethics review process.	This AAHRPP standard does not require reporting by IRB members.
18. Members demonstrate that they understand and apply this Code of Ethics.	**Element I.1.E.** The Organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.	This AAHRPP standard focuses on training rather than end result.

Figure 3. Extracts from AAHRPP Evaluation Checklist

Area 3: Separation of Business and Review Functions (Element II.1.C.)

Policies and procedures prohibit individuals who are responsible for business development from:

- Serving as members or ex-officio members on the IRB.
- Carrying out day-to-day operations of the review process.
- Policies and procedures prohibit IRB members from owning equity in the Organization.

Area 4: IRB Member and Consultant Conflicts of Interest (Element II.1.D.)

Policies and procedures define when an IRB member or consultant is considered to have a conflict of interest. The definition considers:

- Non-financial interests, including:
    - Involvement in the design, conduct, or reporting of the research.
    - Involvement of immediate family in the design, conduct, or reporting of the research.
- Financial interests, including:
    - Financial interests of IRB members and consultants.
    - Financial interests of immediate family members of investigators.
    - Financial interests related to the research.

The IRB defines immediate family members as one's spouse and independent children.

Policies and procedures describe the process to identify IRB members with a conflict of interest for:

- Review by a convened IRB.
- Review using the expedited procedure.

IRB members with a conflict of interest:

- Are excluded from discussion except to provide information requested by the IRB.
- Are excluded from voting.
- Leave the meeting room for discussion and voting.
- Are not counted towards quorum.
- There is a process to identify consultants with a conflict of interest.
- Consultants with conflict of interest do not provide information to the IRB or consultants with conflict of interests are disclosed to the IRB with the information provided by the consultant.

AREA 5: Delegation of IRB Review (Element II.1.E.)

Policies and procedures describe:

- Someone is responsible to evaluate each protocol and determine that at least one IRB member with appropriate scientific expertise will conduct an in-depth review of the protocol.
- When the IRB reviews research that involves participants likely to be vulnerable, someone is responsible to evaluate each protocol and ensure that at least one IRB member knowledgeable about or experienced in working with such participants will be present at the meeting.
- The IRB defers to another meeting or obtains consultation if there is not at least one person on the IRB with appropriate scientific or scholarly expertise to conduct an in-depth review of the protocol.

Area 14: Protection of Privacy Interests (Element II.3.D.)

Policies and procedures state that, in order to approve research, the IRB determines that the research plan makes adequate provisions to protect the privacy interests of participants.

Applications include a description of provisions to protect the privacy interests of participants.

Area 15: Protection of Confidentiality of Data (Element II.3.E.)

Policies and procedures state that, in order to approve research, the IRB determines that the research plan makes adequate provisions to maintain the confidentiality of data.

Applications include a description of provisions to maintain the confidentiality of data.

Area 16: The Consent Process and Documentation of the Consent Process (Element II.3.F.)

Policies and procedures state that the IRB must determine that the following information will be provided to each participant in the consent document:…

- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained…

Policies and procedures have the IRB follow the following issues regarding data retention when participants withdraw from a clinical trial:…

- A researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant must…address the maintenance of confidentiality of the participant's information…
- If a participant withdraws from the interventional portion of a stud y and does not consent to continued follow-up of associated clinical outcome information, the researcher must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. However, a researcher may review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status…

Area 21: IRB Minutes (Element II.5.B.)

Policies and procedures state that IRB minutes must document the following:…

- The names of IRB members who left the meeting because of a conflict of interest along with the fact that a conflict of interest was the reason for the absence…

Conclusion

IRBs should hold themselves to a gold standard of ethical conduct. However, not even the most dedicated bioethicist can fully understand all the numerous laws, regulations, guidelines, guidances, commentaries, etc., that define or discuss ethical conduct in clinical research. Leading bioethicists disagree about many ethical principles — that’s part of their job — to say nothing of their application to specific circumstances.

A concise, commonsense IRB code of ethics that focuses on conduct, not potential causes, could promote ethical conduct by IRBs and their members.

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This article is intended to stimulate a discussion that clarifies the ethical responsibilities of IRBs and their members, and promotes conduct that consistently meets or exceeds these standards.

Reference

1. "Twenty Questions for an IRB to Ask When Assessing its Members' Conflicts of Interest," Dennis J. Mazur and Norman M. Goldfarb, Journal of Clinical Research Best Practices, March 2015.

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