Core Curriculum: Research Ethics for Radiology Residents

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Abstract

Rationale and Objectives:
Scholarly activity, which may include research, is now a required element of resident training. Additionally, residents are required to participate in a Systems-based Practice, or QI Project. Residency programs are expected to provide training for these endeavors, but may lack the necessary resources. This monograph is intended to provide a core curriculum in research ethics for radiology residents to help fulfill that need.

Materials and Methods:
The material was developed through discussion and collaboration of the authors, review of pertinent literature and consultation with experts in the field.

Results:
The paper includes a brief introduction to the topic, followed by cases designed to highlight the issues inherent in informed consent, privacy, disclosure of results, authorship, study subjects and health services research.

Conclusion:
Radiology residents are expected to learn about design, performance, reporting and critical evaluation of research, processes that raise ethical issues. Understanding the underlying ethical issues is critical for the future of radiology research.

Keywords: Research Ethics, Core Curriculum, Residents

Introduction

In order for research to provide useful results, it is critical to maintain strict adherence to a carefully designed research protocol, keep meticulous records and employ rigorous logic in drawing conclusions from the data. It is easy for researchers to become so deeply engaged in obtaining useful results that they allow ethical concerns to recede from their attention. The following is intended to introduce residents to principles of ethics as they pertain to the design, performance and reporting of radiology research.

In 1974, the National Research act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1). A charge of this commission was to identify the underlying ethical principles that should govern the treatment of research subjects, and to develop guidelines for researchers based on these principles. These principles were summarized in the report, issued in 1979, entitled "The Belmont Report, Ethical Principles and Guidelines for the Protection of Human subjects of Research". The three basic principles identified were respect for persons, beneficence and justice.

Respect for Persons

The principle of respect for persons requires that all persons who are asked to participate in a research project be given adequate information, be shown to be competent to understand this information, and not be subject to any pressure to participate in research. All three features are deemed essential for adequate informed consent.

There are disagreements about how much information counts as adequate information, but everyone agrees that participants should be given all the information that any rational person would want to know before agreeing to participate in the research. That is, potential research subjects should be told of the significant burdens and risks involved in participating. Whether they need to be told of trivial or very rare risks is a matter of dispute, but it is clear that the requirement for providing information about risks to research subjects is stronger than that requirement for patients. This is because, unlike patients, research subjects are not normally expected to receive any personal benefits from participating in research projects.

There are also disagreements about how competent a research subject should be, but again, because research subjects are not expected to receive any personal benefits from participating in research projects, the level of competence for research subjects should be quite high. For radiology research projects, investigators should strive to assure that subjects are competent enough to understand what they will be undergoing, why and that they are not participating for any direct benefit to themselves.

Patients are not regarded as having given informed (or valid) consent if they are subject to coercive pressure from anyone on the health care team. The standard in this regard, too, is higher for research subjects than for patients. For their consent to be valid, research subjects cannot be pressured to participate in a research project by anyone, either on the research project or independent of that project. Some believe that according to this

principle, physicians should never ask any of their patients to participate in a research project they are running, because of the pressure that most patients are likely to feel when being asked to participate by their own physician. However, although everyone agrees that a physician must be very careful when asking a patient to participate in his or her own research project; most experts in the area think that an absolute prohibition is too strict a limitation. In radiology, this is less likely to be an issue of concern, since radiologists do not serve as the patient's primary physician.

Beneficence

The principle of beneficence requires that the research project, if successful, provide sufficient benefit to warrant the risks involved for the research subjects. Thus the research project must be designed to involve as little risk as is consistent with the likelihood of obtaining reliable and useful results. It must also be designed so that it is clear what the benefits will be if the research project is successful.

Justice

The principle of justice requires that the selection of subjects be based on fair procedures, outcomes, and take into consideration the identification of "social, racial, sexual and cultural biases institutionalized in society" (1). There are examples of abuse of this principle, such as the Tuskegee Syphilis Study (2). From 1932 to 1972, 399 poor black men in Macon County, Alabama were deliberately deceived by the United States Public Health Service in order to study the natural history of untreated syphilis. Their true diagnosis was concealed from them, and treatment was withheld. The investigators made deliberate efforts to prevent them from receiving therapy from any other sources. In this case, racial and cultural bias influenced the researchers, allowing them to mistreat their subjects.

Specific Issues Addressed in this Monograph

Although they are not always aware of it, researchers make ethical decisions throughout the process of planning, conducting, evaluating and communicating about research. Many issues that researchers must consider involve ethical issues. For example, in planning, does the difficulty of obtaining informed consent in some populations mean they should be excluded from clinical trials that may demonstrate a response unique to them, or is obtaining informed consent the more important principle? In the course of conducting research, how should we reconcile the patient's expectation of best treatment with our responsibility to enroll subjects and assign therapies according to protocols, possibly through randomization? Is our responsibility to the patient within the physician/patient relationship always to the individual patient when we study populations?

Subject Privacy: It is the obligation of the researchers to protect the identity and privacy of their subjects, in addition to their safety. This is usually done through the deidentification or forms of "blinding" of the data. Determining the source of any outlying results requires breaking the code, which may compromise the generalizability of the results of the study.

When, if ever, is it morally acceptable to re-identify data so that it may be linked to subjects by name?

Early Disclosure of Trial Results: The early results of a study may be very compelling, either in a positive or a negative direction. The Principal Investigator and other members of a study team may feel obligated to divulge results, either to the patients in the trial or to the general public, possibly before the study monitoring board supports that decision. How should investigators make that decision, balancing their responsibility to the patient and to society with the demands of scientific research? There are many temptations to act in ways that may not be morally acceptable, e.g., there may be significant financial implications of the results of their study that are difficult to ignore as they relate to the release of information about the study.

Authorship: Although the Principal Investigator (PI) is held responsible for the oversight of all aspects of the research, it is very common for research to be multidisciplinary. To conduct research on a level that will advance medical care requires high levels of expertise in several disciplines, such as study design, statistical analysis, computer modeling, survey design and technology assessment. What responsibilities of the PI may be delegated to others?

Physicians and other researchers hope the success of their research will advance their careers, with future grants, lectures, publications and promotion all related to how the results are communicated. In many medical schools, the order of authorship is critical, yet the guidelines vary significantly regarding name placement on publications. Is the first author the person who wrote the article, the person who designed the research or the person who did most of the work? Which, if any, of those roles can be delegated or hired? Does the financial relationship affect authorship if you are paying a graduate student to do the research, or if you hired an editor to write the first draft?

Radiologists as Study Subjects: Sometimes radiologists are not just experimenters themselves but subjects in an experiment regarding reader variability and how that affects diagnostic accuracy. When must radiologists themselves give informed consent to participate in research studies as subjects?

Health Services Research: Quality improvement is a process physicians are expected to engage in, but research in this area occupies an as yet poorly defined position relative to medical research. Radiologists engaged in QI work, often find themselves in unfamiliar territory, and Institutional Review Boards (IRBs) differ in how they approach these efforts.

The expectation of the ethical conduct of research is implicit in the trust with which physicians and researchers have been regarded. Every time this trust is breached, it does irrevocable harm to our profession, and to our ability to help the people who need us. We all share the responsibility of protecting patients in all of our endeavors as physicians, but keeping the well being of the patient as our paramount concern is not enough, as you will see in some of the cases. This discussion is intended to help frame some of the issues you may face going forward.

Case 1: Informed Consent

Dr. Susan Smith, a breast imaging radiologist who is running a clinical trial of a new imaging technology versus mammography, is enrolling patients in her clinic into the trial. The technology is not yet approved for sale by the U.S. Food and Drug Administration. The study is funded by a leading equipment manufacturer that hopes to market the technology to radiologists as better than mammography for breast cancer screening.

Dr. Smith has hired a Research Associate (RA), Nancy Norfleet, who determines eligibility for the study of the patients who come to Dr. Smith's clinic by reviewing the patient records prior to their arrival, contacting the patients by phone in advance of their arrival if they seem to be eligible, and, if the patients express interest on the phone, asking them to arrive 30 minutes prior to their scheduled appointment to hear more about the study, have their questions answered and formally consent to participate.

All of these methods and the trial itself have been approved by Dr. Smith's Institutional Review Board (IRB). The review of the records that the RA performs is permissible to the IRB because all patients in Dr. Smith's practice sign a form allowing review of records by her employees for the purpose of research study eligibility and to assist in response to queries from insurers.

Sometimes Ms. Norfleet runs into difficulties with these procedures, including obtaining consent from patients. Here are some examples of these difficulties. How should Dr. Smith advise the RA on how to resolve these difficulties?

a) Nancy frequently reaches an answering machine or a family member when she tries to contact the patient. Is it okay to leave a message about the study on voicemail, on an answering machine or with a family member?

Messages left on answering machines may be heard by anyone with access to the machine, not just the potential study subject. So, it is better not to use this method for contacting potential subjects since subject confidentiality cannot be assured.

b) Nancy notices that one of the patients she wishes to contact does not have a signed consent form for review of her records. She assumes this was most likely due to an administrative oversight. Is it okay for Nancy to review the record anyway?

The only reason Nancy is permitted to review these records is the presence of the signed consent. If there is no consent, she cannot review the records.

c) A patient slurs her speech on the phone and asks repetitive and rambling questions. She seems somewhat confused by Nancy's responses, particularly regarding whether she herself might benefit directly from participating in the study, repeatedly noting that she always does whatever her doctor tells her to do. Should Nancy enroll this woman in the study?

The patient is obviously not able to give an informed consent. She does not appear capable of understanding the information she is hearing. Additionally, she, by her own admission, will do whatever her physician requests, and has no intention of participating in the informed consent process. She should not be enrolled in the study.

In fact, it is best to err on the side of NOT enrolling subjects than to enroll someone who may not understand the request to participate. If there is any doubt to the person responsible for obtaining informed consent about the potential subject's competence to consent, that person should not be enrolled.

d) After Nancy tells a potential subject that there is a chance that the new test might cause a "false positive" and that that result could lead to more testing for the patient, including possibly a breast biopsy, the patient indicates that she would be happy to participate if and only if she could refuse further testing if the experimental test is positive. How should Nancy respond to this proposal?

This patient should not be enrolled in the study since there is no way to know whether the positive result is real or not, and the expectation of her refusal to undergo further testing could result in a failure to diagnose and treat breast cancer. It is unethical to ignore the predictable, potentially negative consequences of this situation.

In addition, the patient has not really consented to participating in the study, but in only a subset of the study. She has not really agreed to what has been requested of her completely. While she is allowed to withdraw from the study at any time, she cannot decide to participate contingent on certain outcomes at the time of enrollment and truly have consented to participate in the study.

e) One day when a potential subject arrives for her appointment but before Nancy has had a chance to speak to her about the study, Nancy receives a call to go pick up her sick child. Anxious to recruit the woman to the study, Nancy hands her the consent form and tells the potential subject to read it, sign it and let the technologists know she is participating in the study. Did Nancy handle this situation appropriately?

This is not an acceptable way to obtain or manage consent. It does not allow the patient an opportunity to ask questions, nor does it make it clear to the patient that she can decline participation. The informed consent process should not be considered merely a hurdle to overcome, but should be understood as an important dialogue between the researcher and a subject that allows the potential subject to have all of her questions asked and answered and all potential risks and benefits explained explicitly.

f) Because of slow accrual of Hispanic patients, the National Study Coordinating Center provides a translation of the study's consent form in Spanish. No one who works in the office is fluent in Spanish, though one or two employees took Spanish in school and can speak a bit of Spanish. Should Nancy enroll Spanish-speaking patients in the study with the assistance of those who speak a bit of Spanish and the translated consent form?

Unless there are Spanish interpreters available, it is not possible for these patients to give truly informed consent. She could give them the form to read, and arrange for them to return when there is a Spanish translator available who can answer the potential subjects' questions. Otherwise, these patients cannot be enrolled.

g) There is a women's prison that sends inmates to Dr. Smith's practice for their screening mammograms. Should Nancy recruit these women as subjects in the study?

Most IRBs will not allow prisoners to enroll in research studies because they are presumed to be unduly pressured to participate by virtue of their status as captives of the state.

Some trials, particularly treatment trials of new (otherwise unavailable) therapies are open to prisoners. If a trial is open to prisoners, then care must be exercised in obtaining informed consent that the prisoner is clearly at liberty to decide to participate or not based on her own judgment of her best medical interests. The RA should ask questions of the prisoner to assure that she is not being pressured to participate by any party and should document in the study record the answers to these questions.

Case 2: Informed Consent

Dr. Smith develops a new breast magnetic imaging signal sequence that she thinks might work better for detection of breast cancer than the one currently available to her. She asks one of her employees, an office secretary, to undergo a breast MRI just to give her an idea how well it works. The secretary agrees to have the MRI. What do you think about Dr. Smith's request of her employee? Should she have requested IRB approval for this study before undertaking it?

Dr. Smith should not have asked her employee to test the new sequence because of the pressure that the employee is likely to feel to acquiesce to the request to participate. The employee may feel that her job is at risk if she refuses. In addition, in this case, there is no informed consent, nor has there been IRB review of the project. Dr. Smith should have requested IRB approval before employing the new tool on any human subject. Even if that were in place in this situation, however, the employee-employer relationship and differential power creates a situation of coercion, however subtle. Additionally, there is a very real possibility that an MRI may find something "incidental", which the radiologist may not be prepared to manage, having no clinical information about this subject, and no plan in place. Since there is no intention of making the images part of the medical record, it may be impossible to compare this incidental finding to future studies, which in addition might compromise this person's subsequent care.

Case 3: Conflict of Interest

Dr. Howard Braun is a prominent radiologist who is world-renowned for his work in the development of new molecular imaging techniques. He has led an NCI-funded multicenter clinical trial of a new PET agent, one that is widely expected to replace radiolabelled fluoro-deoxyglucose (FDG) in the diagnosis of metastatic disease for some cancers. The financial implications of the results to the companies that produce both agents are enormous.

a) Before the study started, he had extensive investments in several companies that make molecular imaging agents, including FDG and the new agent. Should he sell his stock?

The researcher must find a way to recuse himself from all decisions regarding his holdings in the companies that might profit from his research. This can be accomplished by selling his stock before the study begins or by placing his holdings into a blind trust managed by an independent person who has no knowledge of the results of his research.

If he does not handle his stock holdings in this manner, he opens himself to later accusations of insider trading. If he does not recuse himself from such decisions and eventually sells the stock that produces either agent, after he knows the results he has obtained and how they are likely to affect share prices, he has engaged in insider trading. In addition, his actions may trigger a reaction among other stock holders who will appropriately assume that his actions are based on his inside knowledge of the study results.

It is best for researchers who hold stock in companies whose products they investigate to remove themselves from decision-making about their holdings. In addition, all stock holdings must be revealed at the time of every publication and public presentation of results.

b) About a year before the study is completed, a Wall Street investment firm contacts Howard and invites him to join their "Medical Investment Advisory Board". He will be paid $5000 for his work on the Board for 2 days work per year. His university allows such activities with permission. Should Howard accept this request? If so, are there any limitations that Howard should make on his activities as part of the Board?

If his university allows such activities and he wants to participate, he should specify that he must recuse himself from participation in activities related to this study and its potential results. He should make it clear to the investment firm that he will not reveal the results of the studies he's running before the results are announced publicly. Under these terms, Howard should not be surprised if the investment firm loses interest in his employment on their advisory board.

c) Dr. Braun is invited to speak to a scientific group about the trial while it is in progress. What is he obligated to reveal to the groups he addresses about his financial relationships with the involved companies?

He is obligated to make full disclosure. The group may wonder about bias, which he will have to try to respond to with rigorous study protocols, and data. The lack of reporting of these sorts of biases is probably the most common error made by researchers in reporting their results. Listeners are entitled to complete disclosure of the real or perceived biases of all scientists. Such relationships that should be reported include paid consultancies and ownership of stocks.

d) Dr. Braun develops and patents a new agent during the course of the trial that could be useful for a different PET application, the detection of very small primary lung cancers. Is it okay for him to approach the companies involved in the study he is running for them to license this new agent?

There are no obstacles to the licensing of the new technology to one of the involved companies, as long as Dr. Braun discloses his relationship with the company when he speaks or writes about their products.

e) Dr. Braun has very good personal friendships with the local salesmen for both companies. They often provide lunch and small gifts to clinic staff, including residents and fellows, with whom he works on a weekly basis. What is your opinion about the propriety of the acceptance of these gifts and must they be disclosed when Dr. Braun presents his results or publishes his findings?

Although this has been standard practice for many years, it is no longer considered appropriate to accept such gifts, as they are considered inducements which influence medical decision inappropriately (3). Many institutions now have very specific policies about such practices (4). Many institutions will now accept only an unrestricted grant, to be used for educational purposes designated by the institution. If these gifts are accepted, they should be disclosed.

f) Dr. Braun is invited to serve on the Scientific Advisory Board of one of the companies that makes the new agent that his trial is testing. The company pays for a trip to Paris for him and his family so that he can attend a Board meeting. What is your opinion about the propriety of the acceptance of this trip and must this be disclosed when Dr. Braun presents his results or publishes his findings?

This is not acceptable. If it is necessary for Dr. Braun to attend this meeting in Paris, and attendance via conference call is not appropriate, it would be acceptable for the company to pay for him to fly to Paris only. There is no reason for them to pay for his family. This should be included with all of the other disclosures he makes when presenting his results.

A recent report from The Association of /American Medical Colleges and the Association of American Universities discusses this topic in greater detail (5).

Case 4: Deidentification of Study Records

Dr. Scott Harbrough is running a retrospective analysis of findings on liver MRI in patients with known hepatitis C. All subjects have had a liver biopsy. Scott's research dataset is deidentified so Scott does not know who the participating subjects are. As part of the study, an expert pathologist is re-reading their biopsy slides. Scott learns that for two subjects the expert's readings suggest that a hepatic malignancy is present in the biopsy sample that was not reported by the clinical pathologist who initially interpreted the samples. What should Scott do? Does he have an obligation to notify the subjects of this new information?

He has an obligation to report the results of this test, but not necessarily directly to the patient. In many cases, the original data would have been deidentified by an "honest broker", someone who is not involved in the project, who will link the investigators to the data and maintain the link. Through this person, the patient can be identified, but not to the investigator, and pertinent information can be given to the patient's physician.
Dr. Harbrough should contact his IRB and ask for guidance about how to proceed, and may also choose to contact the risk management office of his institution, although those are practical rather than ethical considerations. The physician who receives the information may also struggle with how to manage it, especially if significant time has passed since the biopsy was done, if the patient has died from this or from another cause or if the patient was diagnosed late and suffered as a consequence. On the other hand, if there would have been no change in the outcome from knowing the results earlier, one could question whether there was any obligation to inform the patient at all. The hospital Ethics Committee might be a helpful resource in managing this situation.

Case 5: Authorship
Dr. Elaine McNeil is writing several papers reporting research findings in several different studies.

a) Her boss tells Elaine that she expects to be listed as an author for all of the papers, even though she has not contributed to the work being described in the paper. The boss justifies her authorship request by saying "Without my help in giving you this position and covering clinic when you are doing research, you would not have been able to complete this work." How should Elaine respond to this demand?

This is a very difficult situation in that according to the usual authorship standards of most upstanding journals, Elaine should not list her boss as a co-author simply by virtue of hiring her. Handling this workplace issue will be very difficult, however. It is common practice now, for radiology journals to ask for attribution for specific tasks by each co-author. Elaine may be able to handle this problem by asking her boss which tasks she believes can be attributed to her efforts.

b) A college student who Elaine hired to enter data into an Access database asks to be included as a coauthor to help her make her *Curriculum Vitae (CV)* look more

attractive to the medical schools where she is applying. The student has not helped with study design, data collection or analysis, just data entry. How should Elaine respond to this request?

This student may have taken the job in hope of becoming a co-author, but in this case it should have been made clear at the time she was hired that she was not likely to achieve authorship status for her work in the lab. It is better to promise a strong letter of reference to someone who worked hard in one's lab than to misrepresent his or her contribution as worthy of co-authorship. It is also quite reasonable to acknowledge the student's contributions in the paper without giving the student undeserved co-authorship.

c) A colleague who works in the same field suggests to Elaine that they each add each other as coauthors on each other's papers, though they are not really working together, just working on the same general area of research. This will help both of them be promoted to Associate Professor faster than they would if each woman took credit only for her own work. What should Elaine say to this request?

What Elaine's colleague has proposed is dishonest, unless they have actually contributed to the research, analysis or writing of the paper.
Elaine should politely decline to participate in this sort of deception, even though it would help her career advancement.

d) An equipment manufacturer offers to ghost-write a paper for Elaine that will praise its product's efficacy based on an in-house study that the company's research scientists performed. She would be listed as the only author and she would be paid for her editing of the company's employee's writing and the use of her name as the author. How should Elaine respond to this request?

Elaine should decline this offer as it, too, is dishonest. Not only is she being paid and getting credit for work she has not done, she has had no input into the study and has no way of knowing whether the results are reliable or accurate. She would be allowing her name and reputation to be purchased.

Case 6: Radiologists as Study Subjects
Dr. Helen Pearce is interested in the topic of reader variability and its effect on diagnostic accuracy for the interpretation of Doppler sonography. Over the years, she has amassed an enormous number of interesting cases of various levels of difficulty, all with surgical proof of the imaging findings. She decides to run a study to see how variable "expert" radiologists are in their interpretation of the examinations. She asks her colleagues to participate in a study of the technology itself and promises them co-authorship of the subsequent paper that they will write together. She recruits 10 expert readers to interpret a subset of the sonograms. The readers complete the interpretations and when they are done, she informs them of the planned analysis of their performance as readers. Some of her colleagues are upset with her. Should they be?

She has enlisted these readers under false pretenses, and they are justified in being upset with her. Assuming that this study was IRB approved, as it should have been before it was undertaken given the involvement of human subjects, there must be informed consent by all participants. Although she may have felt informed consent would have compromised their objectivity and possibly influenced their performance as subjects, there is still an expectation of honesty between researchers and study subjects. If a researcher is not honest with subjects, even fellow doctors, it undermines the relationship of all scientists with human subjects and harms the research enterprise and the probability of potential subject's being willing to participate in future studies.

Case 7: Health Services Research

Dr. Craig Black is interested in the use of information technology to improve patient flow in the multidisciplinary breast cancer clinic. In this clinic, all new breast cancer patients are seen on the same day by radiologists, medical oncologists, surgeons, and radiation oncologists. He wants to replace the paper forms being used by physicians, technologists and nurses with hand held computers. These will allow the providers instantaneous access to information from other clinics, including the recommendations of the other doctors regarding their shared patients, and to the hospital's electronic medical record. These sorts of documents have long been shared across the clinic in the written format. The new wrinkle is that they are now electronic and therefore quickly available and easily monitored for quality purposes.

Dr. Black has worked very hard to assure electronic encryption of the forms so that they can only be accessed by through special de-encryption software to assure patient confidentiality. Dr. Black's hypothesis is that fewer errors will be made in patient care (for example, patients who do not receive biopsy of secondary findings when such biopsies are recommended) during the six months the electronic communication system is in place compared to a comparable 6 month control period when only a paper system was in place.

Should Dr. Black seek informed consent from all subjects in the clinic prior to implementing this study? Does he need IRB approval for his study?

What Dr. Black wants to do is really a Quality Improvement (QI) project, and this is a subject that has caused a lot of recent controversy. There is disagreement within IRBs about what constitutes QI, and how it should be handled. Although some IRBs say that if there is any intention to publish the results, it should be considered research and require IRB review, others say that it is an expectation that QI will be shared. There are journals devoted to this type of work. This type of project must be discussed with the IRB. In some cases it will trigger an expedited review, which involves less scrutiny than a full review. While some QI projects may get a letter of waiver from the IRB, it is unlikely that a study involving patients, with no consent, will require less than an expedited review.

In brief, consent is required when more than very minimal risk to participants is possible. This study presents no risk to these patients beyond the risk involved in

making any change in the way care is provided. This change could turn out to be less efficient and cause more errors in patient care, but because it is a change in operation of the clinic, it would not require informed consent if it were an unstudied change. The data being collected should not require informed consent; however, a signed consent from the patients, specifying that deidentified data from their visit might be reviewed for quality purposes, would be a good way to include this element. Recent reviews explain this topic in greater detail (6, 7).

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