Practical Tips for Working Effectively With Your Institutional Review Board

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The federal government regulates human research with a local institutional review board (IRB) at your institution. Your IRB's main responsibility is to protect the rights and welfare of human subjects recruited to participate in research. The IRB is responsible for reviewing and approving all research protocols that involve human subjects. The IRB evaluates your study design to ensure that it has the possibility of answering your research hypothesis. The IRB focuses on the risks and benefits of your research. The IRB wants to know that research subjects are recruited fairly and that the potential for benefit is distributed equitably. They also want to know how you plan to protect research subjects from the risks of research and how you will manage the data, especially protected health information. Though the Code of Federal Regulations is extensive, this article provides information to help you navigate your research protocol through the layers of regulations, including the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996. Whether conducting a simple chart review or participating in a multi-site randomized placebo-controlled trial, if you follow tried-and-true scientific methods and good clinical practice, you will be able to work effectively with your IRB. *Key words: human research, institutional review board, IRB, human subjects, study design, Code of Federal Regulations, Health Insurance Portability and Accountability Act of 1996, HIPAA.* [Respir Care 2008;53(10):1354–1361.

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Introduction

An institutional review board (IRB) is a group of scientists and nonscientists that convenes to review and approve biomedical and behavioral studies that involve human subjects. In the United States, IRBs are governed by Title 45, Part 46 of the Code of Federal Regulations.[1] These regulations are referred to as the Common Rule, because they were adopted by 17 different federal agencies. The Common Rule applies to all research activities that involve human subjects at institutions that receive funding, directly or indirectly, from the United States Department of Health and Human Services. Even though you may not be receiving funding from a federal agency, such as the National Institutes of Health, your institution might be, and everyone at your institution, including you, must follow the Common Rule. The Common Rule describes the ethical conduct of clinical research, the role and responsibilities of IRBs, their institutions, and clinical investigators, as well as detailing the process for protecting human subjects involved in research. The Office for Human Research Protections, within the Department of Health and Human Services, is charged with enforcing the Common Rule and monitoring the IRBs, institutions, and clinical investigators. The challenge for an IRB and its parent institution is that the Common Rule does not define how IRBs should carry out the regulations. Each individual IRB functions independently, and a research protocol may be rejected at one institution but approved at another, depending on how the Common Rule is interpreted locally. IRBs and clinical investigators may also be required to follow United States Food and Drug Administration regulations and state and local statutes and institutional requirements for the safe conduct of clinical research (Table 1).

Originally, IRBs were formed at academic institutions and medical facilities. Typically, medium-to-large institutions have 2 IRBs: one for biomedical clinical research that involves an intervention, such as a blood draw or a medication, and one for social, behavioral, and education research that involves human subjects. Today there are for-profit organizations, known as independent or commercial IRBs. Though not associated with an academic institution, independent IRBs are governed by the same federal regulations as the one at your institution.

Table 1. Regulating Human-Subjects Research on Many Levels

Organization or Term	Acronym	Description
United States Department of Health and Human Services	DHHS	The principal federal agency for protecting the health of Americans. Responsibilities include biomedical research, public health, Medicare, Medicaid, welfare, and many other services.
National Institutes of Health	NIH	A federal agency within DHHS, responsible for carrying out and supporting biomedical and behavioral research.
Office for Human Research Protections	OHRP	An office within the NIH, responsible for governing research that involves human subjects.
Code of Federal Regulations	CFR	The rules that all federal government departments and agencies must follow. Titles 45 (OHRP) and 21 (FDA) pertain to human research.
Food and Drug Administration	FDA	A federal agency within DHHS, responsible for monitoring the safety of drugs, medical devices, foods, cosmetics, veterinary medicine, and other products.
Investigational Device Exemption	IDE	A request by an investigator for the FDA to authorize the shipment of an investigational device for clinical research.
Investigational New Drug Application	IND	A request by an investigator for the FDA to authorize the use of an investigational drug in humans.
Institutional Review Board	IRB	A local committee established to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.
Health Insurance Portability and Accountability Act	HIPAA	This public law includes the national regulations on the use and disclosure of protected health information (known as the Privacy Rule).
Protected Health Information	PHI	Any information about a patient's health status, health care, or payment for health care.

Role of the IRB

The IRB has 2 competing moral responsibilities in clinical research. The primary responsibility of your IRB is to protect the rights and welfare of participants in research activities conducted at or on the behalf of your institution. This is accomplished by ensuring that research subjects make autonomous, voluntary decisions to participate; that investigators maintain subject privacy; that investigators treat subjects fairly and in accordance with the Good Clinical Practice guidelines;[2] and that, at all times, research risks are minimized. The IRB's secondary obligation is to promote the general welfare of society through the conduct of clinical research. Your IRB recognizes that to do clinical research, subjects have to bear some risks. The key is to ensure that the risks are reasonable in proportion to any anticipated benefits.

Your IRB is responsible for reviewing, approving, and continuingly monitoring all research projects that involve human subjects. Your IRB also functions independently of, but in coordination with, other institutional committees, such as the committees that ensure radiation safety, biosafety, and device safety, as well as your institutional pharmacy, cancer center, and the office that oversees contracts and grants between your institution (on your behalf) and a sponsor. Only your IRB can approve a clinical research protocol, and no other committee or local authority can override your IRB's decision to reject a research protocol. Your IRB might also serve as your institution's privacy board to comply with the Health Insurance Portability and Accountability Act (HIPAA).

The Process of Submitting a Protocol to the IRB

Respiratory therapists have the opportunity to conduct clinical research in a variety of medical settings, such as the intensive care unit, sleep laboratory, and out-patient pulmonary clinic. They may collaborate with other practitioners or initiate a protocol on their own. They may be asked to participate in a multi-center protocol sponsored by a large pharmaceutical company, or a cooperative group of clinical researchers such as the National Heart, Lung, Blood Institute's Acute Respiratory Distress Syndrome Network.

No matter if you are conducting a simple review of patients' medical records, a double-blinded placebo-controlled randomized trial, or any clinical investigation in between, a good clinical investigator employs the same basic principles of any scientist: the scientific method. First formulate a question; that is, develop your hypothesis (Table 2). Perhaps you question standard operating procedures and have a suggestion for a better process. Perhaps you see a trend in your clinical practice and want to explore the possibility that it is not a coincidence. Your next step is to do some background research, in order to see what other investigators have done to answer your question. Without a clear hypothesis, going any further in designing your research protocol is a waste of time. Your IRB wants to see hypothesis-driven protocols, and you must design your experiment to answer your question(s). An invalid research design is unethical because it exposes research subjects to risk without the possibility of conferring any benefit to the subject or to society.

Table 2. Conducting Clinical Research

Develop a hypothesis
Do background research on topic
Write research protocol
Submit protocol to institutional review board (IRB) for review and approval
Make required modifications to protocol
Recruit research subjects
Obtain informed consent from research subjects
Conduct trial with Good Clinical Practice
Collect and store data per the Health Insurance Portability and Accountability Act Privacy Rule
Analyze data
Reach conclusions
Share results at a scientific meeting and/or in a journal article

Your IRB may want you to provide some type of scientific review of your protocol. This may be a simple literature search, but could entail a review of your protocol by a senior member of your department or other local expert to ensure the scientific validity of your hypothesis and study design. If you are participating in a multi-center, sponsored study, the protocol and scientific review will be written and conducted outside of your institution, usually by a group of experts.

Once you have completed your written protocol and supporting documents, such as the informed-consent form, you will submit them to your IRB for initial administrative review. Your IRB staff will ensure that all necessary documents are present, and that any relevant, outside committees (such as radiation safety) have approved the protocol. The IRB must ensure that clinical investigators have completed any required training before the study can be approved. Any regulatory deficiencies will be communicated to you for correction before final review and approval.

In many situations your research protocol may involve no more than minimal risk to the research subjects (see below) and can be approved in an accelerated manner by the chair of the IRB, without going to the full IRB. This is called expedited review and approval. In situations where the investigational procedures involve interventions that have greater than minimal risk, your protocol must be reviewed and approved by the full IRB. An expedited review and approval is advantageous to you because it is usually done quicker than a full IRB review. In either case,

the IRB will communicate to you the modifications you must make to your protocol. In addition, the IRB may request that you change the wording of your consent form, change technical and medical terms into lay language, and simplify the overall reading level. It is essential that you address each item clearly and concisely when you communicate back with your IRB. Though some investigators feel this process can be discouraging and time-consuming, it is meant to help you develop an improved hypothesis-driven protocol, a well-written consent form, and to help minimize risks to your research subjects as much as possible.

After you have received IRB approval, you are then permitted to initiate your study. At all times you must comply with Food and Drug Administration mandated Good Clinical Practice (the ethical and scientific standards for conducting human research). You will recruit subjects in the IRB's approved manner. You will obtain subjects' consent, if required by the IRB. You will conduct the study as described in your protocol. The protocol is the blueprint of your experiment. Any deviations from the approved protocol need to be recorded and reported to your IRB. Basically, if it isn't written down in the approved protocol, don't do it. If in the course of conducting your study you want to make changes in the design of the protocol or consent form, you must submit a request to modify the protocol to your IRB. Only after the IRB approves the modification may you change the investigational procedures. As part of Good Clinical Practice, you need to monitor your research protocol for safety, record adverse events, and record data in a secure way. At the conclusion of your experiment, Good Clinical Practice dictates how you will analyze your data, draw any conclusions, and share the results with other practitioners.

In addition to its initial review and approval, your IRB is responsible for providing ongoing or continuing administrative and scientific review of your protocol. This process is as important as the initial review and approval. Your IRB wants to know if any subject has been seriously harmed and if there have been any unforeseen problems or accidents. If additional risks have arisen, you may be asked to modify your informed-consent form. In some situations you will be asked to undergo an internal audit, which may involve a review of your regulatory files, completed consent forms, and any data that you have collected. Audits are not meant to be punitive. Instead, they are an opportunity for you to improve your research activities. The audit findings are shared with the full IRB, who may require you to submit additional supporting documents, provide explanations for deviations from your protocol, and even for you to participate in educational activities if important deficiencies are identified. At any time the IRB can revoke its approval of your research protocol and halt your research. The best way to prevent this is to design your study well, obtain IRB approval, and follow the protocol exactly as it is written.

Risk and Benefit Analysis

During its review of your research protocol, your IRB will focus on the risks and benefits of your research protocol. They will analyze the risk/benefit ratio and will determine if the potential for benefit is proportional to the risks.

Risk

Risk is the probability of harm or injury, whether physical, psychological, social, or economic, that could occur as a result of participation in clinical research. When analyzing your investigational procedures, you and your IRB will need to tease out these risks from the risks a research subject would have from therapies he or she would undergo even if not participating in clinical research. You and your IRB are jointly responsible for ensuring that the risks of participating in your research protocol are minimized. Both the possibility and magnitude of possible harm may range from minimal to substantial, and there is difference between minimal and minimized risks.

The Common Rule only defines minimal risk.

> Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[3]

Unfortunately, that definition of minimal risk is ill defined and can lead to broad interpretation of what constitutes minimal risk by your IRB. For example, the risk of drawing a small amount of blood from a healthy adult for research purposes is no greater than the risk of doing so as part of routine physical examination. However, frequent blood draws may be considered greater than minimal risk by your IRB. Research protocols that involve medical-record review or questionnaires are usually considered minimal risk and may receive expedited review. Research that involves greater than minimal risk must be reviewed by the full IRB. Research that involves greater than minimal risk is restricted in certain vulnerable populations, such as pregnant women and children.

Benefit

Benefits are expressed as fact or state of affairs, though a more accurate assessment would be to consider the potential for benefit.

The benefits of research fall into 2 major categories: benefits directly to the research subject, and benefits indirectly to society through the advancement of general knowledge. In research that involves an intervention expected to directly benefit the subjects, a certain amount of risk may be justifiable. In a study of a therapy for a life-threatening illness, the risk of serious adverse effects and even death from the investigational procedure may be acceptable to the IRB, the research subject, and society. In research where there is no potential for direct therapeutic benefit to an individual research subject, the IRB must evaluate whether the risks are morally acceptable. There should be a limit to the risks society asks individuals to accept for the benefit of others.

In the final assessment, the investigator and the IRB must be certain that all risks have been minimized and must determine that the risks are reasonable in relation to the benefits to the subject and the importance of the knowledge to be gained.

Selection of Research Subjects

Defining the appropriate group of subjects for a research protocol involves a variety of factors: requirements of scientific design, susceptibility to risk, likelihood of benefit, practicality, and considerations of fairness. If your protocol design restricts the study population to a small group of people, it may not be possible to recruit the necessary number of subjects to test your hypothesis. Your IRB will probably reject a study design that has no chance of advancing general knowledge that would benefit society or the research subject.

Your IRB will want to know if the risks of research are distributed fairly. It is morally acceptable for the risks to fall on those most likely to benefit from the results of the research, though the study itself does not hold out the potential for direct benefit to the subject. For example, a pharmacokinetic/pharmocodynamic study of an investigational asthma medication may not directly benefit the asthmatic research subject, but this research subject may benefit indirectly from the advancement of general knowledge obtained by the study.

Your IRB will want to know if the potential benefits of participating in your study are distributed fairly. Have you overprotected potential subjects so that they are denied the opportunity to participate? There should be equitable inclusion of men and women, unless there are medical contraindications for exclusion. You should not age-restrict your subject selection, and children should be considered unless there are medical contraindications for exclusion.

Designing the Control Group

The scientific method may require that you have a control group of research subjects to control for other variables that may influence your results. Research subjects are usually assigned randomly to the control group or the study-treatment group. If your study involves normal healthy volunteers, it is appropriate to have a placebo or a sham procedure as your control group to test your hypothesis correctly. In studies that enroll patients as research subjects, your IRB will want to know if you are denying these patients beneficial treatment by enrolling them into a placebo control group. For instance, it may not be appropriate to deny asthmatic patients the usual care with inhaled bronchodilators to test an investigational bronchodilator. However, placebo could be used in a study where there is no known or available alternative therapy that can be tolerated by the patients.

In many situations it will be necessary to design a control group with an active treatment, usually the current standard of care or the current usual practice at your institution. In situations where there is a disagreement about the best treatment for a patient population, the ethical principle of equipoise allows you to design a control group and treatment group to compare 2 treatments.[4] Even if one clinician personally prefers one treatment over the other, randomization is still acceptable if there are other clinicians who disagree. In the landmark Acute Respiratory Distress Syndrome Network study of mechanical ventilation with low versus traditional tidal volume for acute lung injury and acute respiratory distress syndrome, some believed that the control group (traditional tidal volume) did not achieve clinical equipoise with the study-treatment group (low tidal volume), and hence questioned the validity of the investigators' conclusions.[5,6]

Managing Conflict of Interest

A conflict of interest is a situation in which someone in a position of trust, such as a clinical investigator, has competing professional or financial interests. When you recruit one of your patients into your study, you have competing duties to the individual, so there is the potential to have a conflict of interest. On the one hand, you have a duty to provide your patient with the best possible care that is customized to the patient's personal needs. On the other hand, as a clinical investigator you have a duty to follow your protocol, which may not be individualized to meet the patient's needs. Even though no improper actions may occur, you must recognize the potential conflict of interest. Your IRB wants to know how you are going to manage those conflicts of interest (Table 3). A simple technique is to separate yourself from the recruitment and informed-consent process, to help ensure that potential subjects make entirely voluntary decisions about whether to participate.

More serious are financial conflicts of interest. If you are the inventor of a new device, for instance, it is important that you recognize that you have a conflict of interest

Table 3. Ways to Manage, Reduce, or Eliminate Conflicts of Interest

Disclose conflicts of interest to potential research subjects in the informed-consent process and consent documents.
Have a non-conflicted member of the research team conduct all or part of the research.
Have a non-conflicted member of the research team obtain consent from research subjects.
Have independent reviewers monitor the conduct of the research, especially safety and efficacy data.
Publicly disclose conflicts of interest to journals to which you submit papers about the research and/or in public presentations of the research.
Sell financial interests that present conflicts of interest.
Resign position as officer, agent, or employee of a business entity that present a conflict of interest.

in doing clinical research with your device. You should separate yourself as much as possible from the conduct of the clinical investigation of the device. It may be necessary to go beyond removing yourself from the recruitment and informed-consent process. Your IRB may require you to have a neutral 3rd party manage your data, especially the recording of adverse events. The 3rd party can serve as a medical monitor or safety officer to decrease the appearance of a conflict of interest. Every institution has a conflict-of-interest policy. Often these policies center on financial conflicts, such as an invention or patent issues. You should become familiar with your institution's requirements and work closely with them when you have a potential financial conflict of interest.

Data Safety Monitoring Plan

All clinical research protocols that involve an intervention must include a written data safety monitoring plan (Table 4). The risks of participating in the study are outlined in your protocol. The safety plan outlines how you will assess these risks as the study progresses and how you will identify unexpected problems. Your safety plan should designate who will be recording these data, how often they will look for problems, and what problems they want to look for. For instance, if your patient population is patients in the intensive care unit, a safety plan that requires you to record every abnormal laboratory value until patient discharge would be unmanageable, and it would be difficult or impossible to ascertain the cause of the abnormality. Rather, your safety plan should focus on your intervention, especially if it is at only one point in time, to ensure the safety data you collect are meaningful for your evaluation. You will need to assess the severity of the event and whether you think that it was caused by your investigational procedures. In serious situations you will need to notify your IRB, and even federal agencies, in a timely manner.

Table 4. Data Safety Monitoring Plan Versus Data Safety Monitoring Board

Data safety monitoring plan	A prospective plan for identifying, monitoring, and reporting the safety information collected during a study. It describes the plan for reporting adverse events and protocol violations. The plan may include interim analysis of the risk/benefit ratio, stopping rules if the risk/benefit ratio becomes too high, and a formal data safety monitoring board.
Data safety monitoring board	A committee of scientists, physicians, and statisticians who independently collect and analyze safety and efficacy data during the study. The board monitors trends, such as an indication that one treatment is significantly better than another, and makes recommendations to the investigators about continuing or modifying the study.

Another aspect of your safety plan is self-monitoring the conduct of your protocol. It is an opportunity for you to review the accuracy of your data, your protocol compliance, and for you to report problems to your IRB as they occur.

Some IRBs have a template on which to base your safety plan. Be careful what you write, because if it is in your plan, you must do it as it is part of your protocol. Filling out such a template without reading it carefully could obligate you to collect safety data that you never intended to collect and that have no bearing on your safety analysis.

Data Safety Monitoring Board

A data safety monitoring board is an independent group of experts who advises the investigators, sponsor, and IRBs. Many cooperative groups, such as the National Institutes of Health and pharmaceutical companies, sponsor large multi-site randomized studies. Many randomized studies are double-blinded, which means that no one involved with the study knows which treatment was given to any individual research subject. The group sponsoring the trial, the clinical investigators, and the sponsor are blinded, so they cannot properly assess the safety of the study. Therefore, the sponsor must hire a group of experts, including a statistician, to review the data, subject safety, efficacy, and

compliance with the research protocol. A data safety monitoring board typically convenes every 3–6 months and reviews un-blinded results. The data safety monitoring board has the power to recommend terminating the study, based on their evaluation of these results. There are typically 3 reasons the committee would recommend termination of the study: safety concerns, outstanding benefit, and futility.

Informed Consent

The concept of informed consent is the heart of the ethics of protecting research subjects. Your IRB may require you to use an informed-consent form template with specific language. You may be asked to adapt a multicenter study's consent form into the local format with language approved by your institution's legal counsel and that meets federal, state, and/or local regulations. It is recommended that you comply with this request to help get your protocol approved in a timely manner.

The introduction should provide basic information and clearly identify that the consent is for "research" or an "experimental" drug or device. The introduction should include an explanation as to why the research is being conducted and what questions you are trying to answer. The expected duration of the subject's participation and the number of subjects involved in the study should be given. When describing the investigational procedures, the parts that are experimental should be clearly identified. The process of randomization, blinding, and the chances that the research subject will get the experimental drug or treatment must be described in simple-to-understand terms. You should describe the benefits, if any, or clearly state that there are no direct therapeutic benefits. A description of risks, including a statement that there may be unforeseen risks, is required. If your protocol involves greater than minimal risk, your IRB will need you to quantify the frequency and severity of these risks. In addition to ratios, fractions, or percentages, consider adding the phrases "common", "occasional", and "rarely" to help the lay person understand.

Some studies are financially unsupported and the subject may be responsible for the costs of the experiment, including tests and drugs. If a patient's insurance refuses to cover "experimental" treatment, there could be extensive economic risk involved.

Research subjects need to be informed that the investigator or sponsor may withdraw them at any time. Finally, research subjects must be informed that they have the right to refuse to participate and can withdraw at any time.

Incentives for Participating

In 1900 Walter Reed paid volunteers in his yellow fever studies $100 gold for their participation. If they contracted yellow fever, he paid them a $100 bonus.[7] Research subjects today continue to be paid, in various amounts, to participate in clinical research. Your IRB recognizes that it may be necessary to pay research subjects in order to enroll them and obtain the advancement of general knowledge that clinical research accomplishes.

There is no consensus on how to determine how much to pay research volunteers.[8,9] The compensation should be proportional to the time, effort, inconvenience, and unpleasantness of the investigational procedures. In addition, it is appropriate to reimburse subjects for any travel expenses, lost wages, and parking costs incurred. At a minimum, consider a meal card if your research visit exceeds 3–4 hours. Prorated compensation and a completion bonus may also be acceptable. Direct payment of subjects as an incentive or reward for participation, however, should not be considered a "benefit."

Too large a compensation may appear to unduly influence a subject's voluntariness in the decision to participate. Undue influence may occur through an offer of an excessive, inappropriate, or improper reward to obtain agreement with the research protocol. A research subject's age, health status, or financial status may also influence your IRB's reaction to the compensation offered. Inducements, such as free medical care, that would ordinarily be acceptable may appear to unduly influence a socioeconomically disadvantaged, uninsured, or underinsured person unfamiliar with the difference between medical care and clinical research.

Medical-Record Review, Registries, and Databases

Observational studies describe disease patterns and are often the first step in learning about the natural history of diseases and patient outcomes. Through the use of medical-record reviews, registries, and databases one can document the natural history of diseases and the benefits of treatment. Observational studies can describe patients at risk and the effectiveness of treatments. Though observational studies are limited in their ability to shed light on the causes of disease, they can help identify potential etiologies and provide important starting points for developing prospective randomized controlled trials. Chart review is a relatively easy, rapid, and inexpensive way to do clinical research. Data can be captured via review of medical records or previous research data. Whether you obtain the data directly from patients' medical records or from someone else's database, this is considered human research and must undergo IRB review. The IRB is focused primarily on data collection safety and maintenance of privacy, and must be involved whenever protected health information is used. Protected health information is any past, present, or future health information that can be identified as belonging to a particular individual, through the HIPAA "iden-

tifiers" (eg, address, birth date, social security number). Your IRB wants to know how you will guard protected health information from accidental disclosure. If your privacy plan meets the criteria of both the HIPAA Privacy Rule[10] and the Common Rule, your IRB may allow you to do the research without obtaining informed consent from the research subjects. This is called a waiver of consent, and is a determination made only by your IRB.

Privacy and Confidentiality

The major goal of the HIPAA Privacy Rule is to assure that individuals' protected health information and HIPAA identifiers are properly protected from accidental disclosure. Your IRB wants to know how you are going to use and disclose protected health information. Ideally, your IRB would like you to de-identify any health information you collect and store, whether on paper or in electronic form. There are no restrictions on the use or disclosure of de-identified health information, because the individual can no longer be linked to the health information, so HIPAA privacy regulations do not apply. Unfortunately, removing all identifiers and links back to the patient may impede your ability to conduct this type of research. Luckily, the Privacy Rule does allow a limited set of identifiers to remain with health information in order to conduct research. The regulations are complex, and you are encouraged to work closely with your IRB to ensure that your privacy plan will be acceptable to them.

At a minimum, your IRB will want you to keep protected health information and identifiers in a locked file in a limited-access room. Alternatively, electronic data should be kept in a password-protected file behind a firewall. Keeping protected health information and identifiers in a portable key drive or even a portable laptop computer has privacy risks. The recent loss of a hard drive from the Birmingham Veterans Affairs Medical Center contained identifying information from 535,000 patients and 1.3 million doctors being used in a nationwide study.[11] A data management strategy to protect privacy is to code patient identifiers and link them back to the health information, which exists in a separate, second file. By keeping 2 separate files in 2 separate locations, you can provide another layer of protection from unintended disclosure of protected health information. At a point in time when it is feasible for you to do so, you can destroy the link and forever de-identify the health information.

Summary

Risks to research subjects posed by participation in research should be justified by the anticipated benefits to the subjects or society. This requirement is clearly stated in all codes of research ethics, and is central to the federal regulations. One of the major responsibilities of the IRB, therefore, is to assess the risks and benefits of proposed research and to protect the rights and welfare of research subjects recruited to participate in research activities.

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