



Searching for "Research Involving Human Subjects": What Is Examined? What Is Exempt?
What Is Exasperating?

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Searching for “Research Involving Human Subjects”

What Is Examined? What Is Exempt? What Is Exasperating?

BY IVOR A. PRITCHARD

Researchers, administrators, bureaucrats, and institutional review board (IRB) members sometimes disagree about when to apply the federal regulations requiring IRB review of proposed projects. The regulations, commonly called “the Common Rule,”¹ sometimes lack the capacity to promote common understanding. Despite the urging of regulatory officials who demand “plain English” in all government documents, the Common Rule still poses some complex logical and grammatical problems for even the most literate interpreters.

This essay aims to clarify what kinds of activities are covered by the Common Rule and must undergo IRB review. It suggests that the text of the Common Rule does not satisfactorily settle all of the issues raised, and that in these instances interpreters will have to look elsewhere to resolve their questions.

The thrust of the Common Rule is that IRBs should review plans for proposed activities before they get under way. The ostensible purpose of these reviews is to protect prospective participants in the proposed activities. The focus of the Common Rule is on *research involving human subjects*. Consequently, the two key terms identifying the intended scope of the regulations are *research* and *human subject*. The Common Rule provides definitions for these terms that bear the primary burden of determining whether a proposed activity falls with-

in its purview. In addition, however, the Common Rule exempts some research involving human subjects from its standard procedural review requirements, which complicates matters. Only after determining whether a project represents research involving human subjects, and determining whether it qualifies as exempt, do we know whether an IRB should review it.

Caveats, Qualifications, and Conditions

Several external factors have a bearing on whether the Common Rule applies. From an ethical standpoint, these factors may be irrelevant to the question of whether they should be beyond the reach of the Common Rule. Many experts have argued that participants in research outside the scope of the Common Rule’s authority deserve equal protection. From an administrative legal standpoint, however, these factors do influence the applicability of the Common Rule and must be taken into account.

Funding. First, the proposed activity must be funded or supported by the federal government; private sector research is not within the scope of the Common Rule. In fact, only research funded or supported by one of the federal agencies that has adopted the Common Rule must conform; neither other executive branch entities (e.g., the Department of Labor) nor any judicial or legislative branch entities (e.g., the General Accounting Office) must comply with the Common Rule. Research jointly funded with a Common Rule office may compel other federal entities to conform to

the rule; or entities may decide to conform voluntarily, but it is within their discretion not to.

Assurances. Second, a proposed activity may fall within the scope of the Common Rule due to the arrangements that an institution has with a Common Rule agency for IRB review. Some agencies, most notably the Department of Health and Human Services (DHHS), negotiate agreements with busy research institutions that cover not only the research activities at those institutions that are supported by the particular federal agency, but all of their research activities, regardless of the funding source. These agreements, called “multiple project assurances” (MPAs), set out the policies and procedures used by the institutions for reviewing research involving human subjects, and the institutions often—but not always—agree to apply the same policies and procedures to all their research activities. In this way, the Common Rule may be voluntarily extended beyond the minimal federal boundaries. Once the rule is voluntarily extended in this way, however, the institutions are obliged to conform to their agreements.

Agency Peculiarities. Third, for some federal agencies distinctive regulatory factors influence the scope of the Common Rule. Some agencies have adopted additional subparts to the Common Rule that provide further protections for certain vulnerable populations, one consequence of which is to alter the exemption status of research involving the vulnerable population. Also, the Common Rule exempts some research in which the

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confidentiality of the information collected is protected by legal statute, and such statutes may be specific to the activities of a federal agency or some part of that agency. Finally, the Common Rule reserves authority for the secretary or head of the specific federal agency or office to apply and interpret the Common Rule; consequently, designated agency officials from different agencies may apply the Common Rule differently. And the regulations give that same department or agency head the authority to apply the Common Rule to research activities even if they wouldn't otherwise be covered.

Other. Last, other policies beyond the Common Rule may have the effect of requiring IRB review. The regulations of the Food and Drug Administration (FDA), which are somewhat different from the Common Rule, extend IRB review to research involving human subjects under FDA authority that is not covered by the Common Rule. And research institutions may choose to implement IRB review policies and procedures on their own initiative, purely out of respect for the research participants, or for reasons related to protecting the interests of the institutions and their staffs. Whatever the source of their actions, the question then becomes, To which activities do institutions apply the Common Rule?

Definitions: *Research and Human Subject*

The Common Rule concerns “research involving human subjects.” These terms are defined within the regulation themselves.

First, consider the definition of *research*:

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (.102(d)).²

Various elements of the definition serve to narrow or widen the range of activities that qualify as research. Several terms are clearly relevant in this regard, and deserve attention.

“... *systematic* ...”

The definition requires that an investigation be *systematic* in order to qualify as research. People may ask questions in the course of an activity designed to find out something, but if the manner in which they are doing it is not sufficiently organized to call it a “systematic” process, then it does not count as “research.” For example, if in the course of using a federal grant to provide food to needy children the grantee will have a series of conversations with providers in which the grantee will try to find out whether the children are eating the food, this would only count as research if the grantee plans to go about it in an organized way, deliberately using a certain set of questions or observational strategies. Obviously, there will sometimes be questions about the scope of the relevant terms—in our example, when a process becomes organized enough to be called “systematic.” In any case, however, there must be some rationale for describing the knowledge-gathering activity as systematic in order for the Common Rule to apply.

“... *including* ...”

The definition specifically encompasses “research development, testing, and evaluation,” which means that an activity labeled with any of these three terms (or other similar terms) may also qualify as research. In some definitions “research” is distinguished from “development,” “testing,” or “evaluation,” implying that if a given activity is considered to fit one of these other three categories, it automatically cannot be labeled “research.” In the Common Rule that is not the case: The regulatory boundary of “research” clearly encompasses activities that may also be properly described as development, testing, or evaluation.

“... *designed to* ...”

The proposed activity must reflect the deliberate intention to have that activity “develop or contribute to generalizable knowledge.” The use of the term *designed* narrows the definition of research, in the sense that activities which do *in fact* develop or contribute to generalizable knowledge may still

not constitute research, if the activity generating the knowledge is not specifically intended to do so. For example, motor vehicle department driver records, or student records collected by schools, or patient medical records, are ordinarily not created for research purposes, even though researchers may subsequently seek to use them for research purposes. The original information collection is designed to identify individuals' driving characteristics, educational history, or medical conditions for purposes related to the specific individuals concerned. Some critics have complained about this term because it requires a judgment about the proposers' intentions, which are not directly observable. Presumably, however, the intentions that count are those that can be discerned in the activity's design, which the proposers must identify (see below).

“... *develop or contribute to* ...”

The definition of research is widened by the use of the phrase “develop or contribute to” because this includes activities that may not themselves produce generalizable knowledge, but are designed in such a way as to serve as a step toward that end. For example, a researcher might carry out a qualitative study in order to explore a particular phenomenon, with the idea of developing hypotheses suitable for testing in future large-scale studies. The preliminary study, even if it wasn't supposed to produce any knowledge at all, would still be considered research if the long-term objective were to create such knowledge.

“... *generalizable* ...”

The definition of research is narrowed by the stipulation that the kind of knowledge sought through the activity must be *generalizable*. Some knowledge is not, even if it is discovered through a process using scientific technology and methods. Using DNA testing techniques to identify the killer of a particular victim, for example, would not count as research under the Common Rule, even though it is an investigation designed to contribute to knowledge.

Similar comments are appropriate to the Common Rule's definition of a *human subject*:

Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or

(2) identifiable private information (.102(f)).

"... *living individual* ..."

The Common Rule only applies to research subjects who are living. The deceased do not count. For example, a research study designed to study the biological remains and personal records of Civil War veterans would not fall under the Common Rule.

"... *interaction* ..."

The Common Rule implies an extremely broad range of actions by the use of the term *interaction*, including data collection derived from any kind of activity, physical or nonphysical, engaged in with human beings. Any time the researcher does something to or with someone and collects data about that individual, or any time the researcher's action elicits a response from a person and that reaction is recorded, interaction with a human subject takes place. Asking people for directions, or standing in their paths, constitutes involvement of human subjects if data about their reactions are recorded. Only if one were to collect data without doing anything at all to or with the people involved might the researcher's observations fall outside the purview of the Common Rule.

"... *identifiable private* ..."

Even if no interaction takes place, the Common Rule also extends to certain kinds of information narrowed by the phrase "identifiable private." If data are recorded in such a way as to allow someone to identify the person, and the circumstances are such that the person concerned could reasonably assume that no recording was taking place, then the Common Rule applies. If the recording happens in public, however, or the information

does not allow identification of the people involved, the Common Rule does not apply. So, for example, videotaping people crossing the street, or recording only the gender and amount of time people spend in a doctor's office would not fall under the Common Rule. On the other hand, some kinds of activity constitute research involving human subjects even though no interaction takes place with the individual that the information is about. For example, using a hidden camera in someone's home, or obtaining information about particular people from a third party who has access to their medical, criminal, or personnel records, constitute research involving human subjects. Likewise, a survey or interview asking married people for private information about their spouses would be research involving human subjects even if the survey did not ask for any information about the respondents themselves, so long as the spouses were somehow personally identifiable.

The Exemptions: Tied Up in Nots

Even before the reader encounters the definitions of *research* and *human subject* in the regulations, the Common Rule provides exemptions for certain kinds of research involving human subjects. Exempt research does not have to undergo IRB review. Some institutions choose to review all research involving human subjects even if it may be exempt, because they believe that such ethical oversight is called for. Others choose to review it because figuring out whether a proposed research activity is exempt requires a complicated analysis of the exemption categories. Part of the trouble in this regard derives from the frequent use of negation in the Common Rule descriptions of exempt research. The term *exempt* itself expresses a negative relation, i.e., "not covered." Consider, for example, the use of negation in the following sentence, taken from the regulations in Subpart D:

The *exemption* in .101(b)(2) for research involving survey or interview procedures or obser-

vations of public behavior does *not* apply to research covered by this subpart, *except* for research involving observation of public behavior when the investigator or investigators do *not* participate in the activities being observed (.401(b)). [Italics added.]

The Common Rule lists six general categories of involvement of human subjects, prefaced by the following statement:

Unless otherwise required by Department or Agency heads, research activities in which the *only* involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(.101(b)). [Italics added.]

The use of the word *only* is crucial to the proper application of the exemption categories. To be exempt, all of the ways in which prospective human research subjects may be involved in a proposed research activity must fall within an exemption category. If part of a human subject's involvement squarely matches an exemption category, the reader cannot stop the analysis and conclude that the proposed activity is exempt. A research activity is still covered by the Common Rule if a research subject's involvement consists of more than one part, where some parts fit an exempt category and others do not.

For example, consider a research project in which the investigators are trying a new medical intervention that includes both a new surgical technique and teaching the patient how to carry out some of the post-operative care. The Common Rule's first exempt category, which concerns normal educational practices, may accurately describe the research activity's effort to teach patients to participate in their own care. The research activity is not exempt from the Common Rule, however, because it also involves the new surgical technique, and IRB review of the subjects' participation is certainly warranted. And, given that IRB review is required, the entire research project—not just the surgical technique—should be scrutinized. The

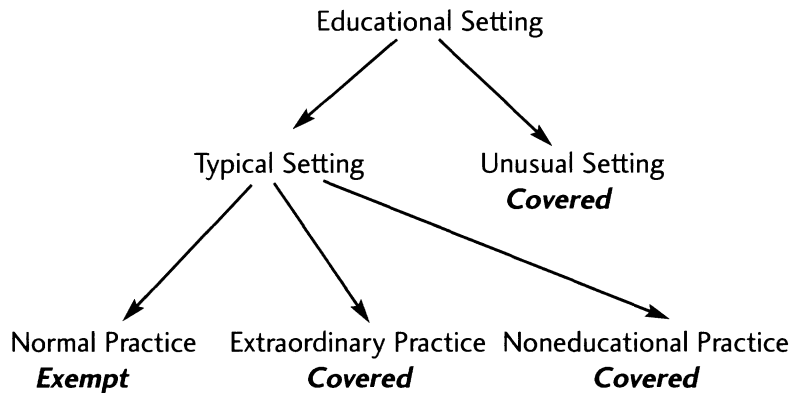


Figure 1: Diagram for Analyzing the Application of Exemption b(1).

evaluations of the surgical technique and of the educational element may be interrelated, and an assessment of the merits of the educational element is also desirable.

The exemption categories can be represented in diagram form to facilitate the analysis of compound research activities, that is, activities composed of several parts each of which may fall under different exemption categories.

Educational Practices. Consider the first exemption category, which the Common Rule describes as follows:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (101b(1))

Substituting some of the regulatory terms for the sake of convenience,³ this exemption can be diagrammed as in Figure 1.

Figure 1 represents an analytical approach to applying exemption b(1) to a given research activity, assuming that each part of that activity has to be traced out to the end of a branch of the diagram. (Think of this as fol-

lowing a flow chart.) To determine whether some part of a research activity fits an exempt category or a category of involvement of human subjects covered by the Common Rule, the reader begins at the top of the diagram, applying an element of the proposed research activity to the category options provided by the diagram. The reader continues this process to the end of a sequence of categories, following it down the series of arrows connecting the categories until the reader reaches a category identified as either "exempt" or "covered."

To conclude that a given activity is exempt under the Common Rule, all of the parts of the activity must fall within an exempt category. If any part of the activity falls within a covered category, then the activity must be considered covered, and go through IRB review.

Consider, for example, a proposed research activity about learning the Common Rule. If the proposed activity is to take place in a laboratory or a supermarket, this would not be considered an "established or commonly accepted educational setting" for this activity, and the research activity would be covered by the Common Rule. If, on the other hand, it is to take place in a conference facility or the classroom of a university bioethics course, this would represent a fairly typical educational setting for such learning and the analysis could go on

to the next level of the diagram.

Continuing the same example, if the instructional strategy to be used is a lecture followed by a question and answer period, this would be considered "normal practice" and the research activity would qualify as exempt in this regard. If, on the other hand, the proposed research activity involves teaching the Common Rule by setting it to music and playing it repeatedly to the research subjects, this would represent an extraordinary or unusual practice, meaning that it would be covered by the Common Rule. Alternatively, if the real purpose of the activity is not to study an educational practice at all, but rather to study the physiological and psychological symptoms of stress displayed by people asked to accomplish an impossible intellectual task(!), then the proposed research would be covered by the Common Rule. If the research activity is designed to investigate both questions, the Common Rule would apply to the whole activity, even though some of its elements fit the exemption category.

Information. The second, third, and fourth categories of exempt research are somewhat interrelated. They all concern some aspect of the process of creating, reviewing, analyzing, or disclosing data and other forms of information, or for presenting research findings based on data. Accordingly, Common Rule interpreters may wish to look at these exemption categories together in the process of applying them to proposed research activities. In other words, all of the data-handling elements of a research activity may be considered together, to see if those elements correspond to any of the exempt categories.

Here again, the reader compares each element of the proposed research activity to the relevant sequence of categories until the reader reaches a category designated "covered" or "exempt." If all of the elements of a research activity fit a category marked "exempt" then the activity is exempt; if not, the activity is covered by the Common Rule and requires IRB review. (In Figure 2 the wording of the categories has again been changed

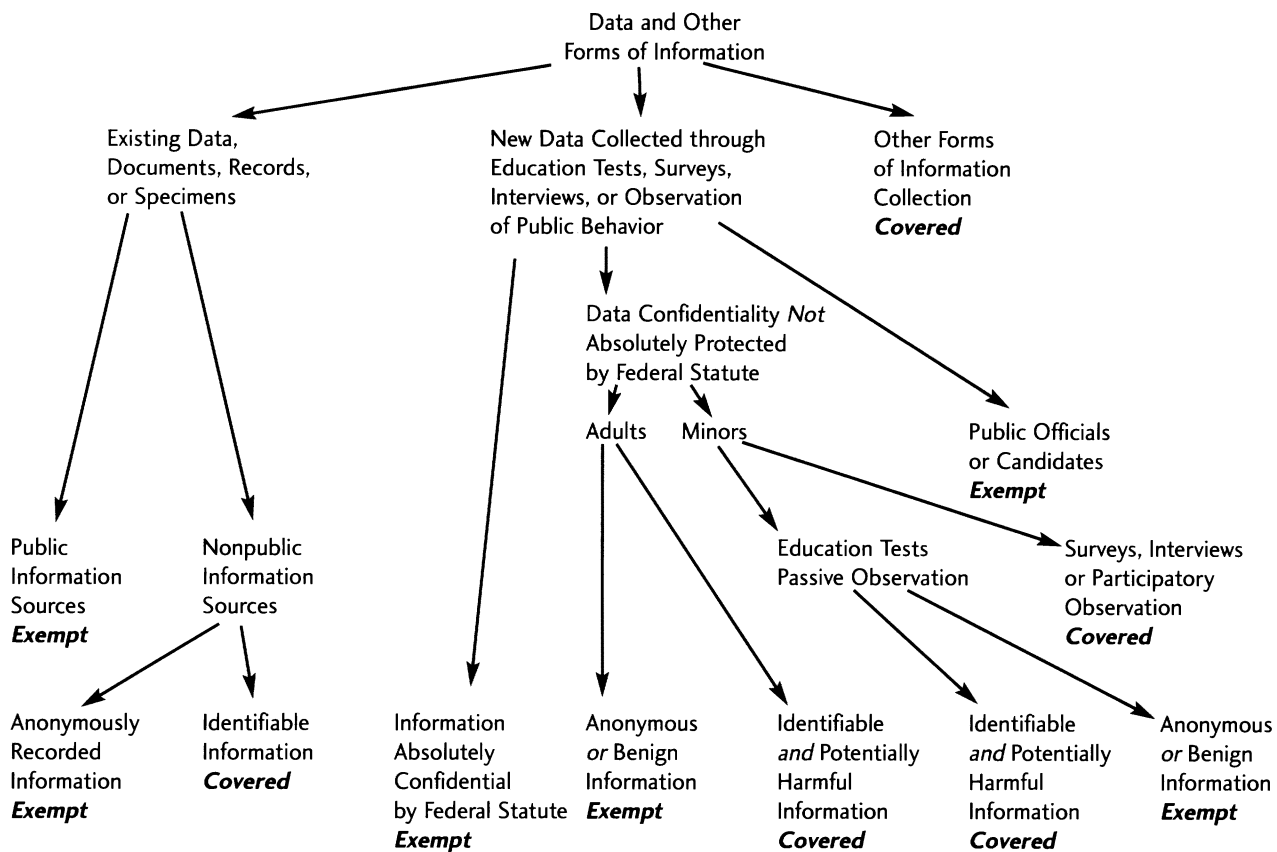


Figure 2: Diagram for Analyzing the Application of Exemptions b(2), (3), and (4).

somewhat to succinctly identify each category and make its meaning distinct from the others. The term *benign* is used as the contrary of the regulatory phrase “potentially harmful,”—that is, if information is not potentially harmful, it is benign.)

Two particular features of Figure 2 should be mentioned. First, note that the diagram refers to “other forms of data collection,” meaning forms of information that are neither (a) “existing data, documents, records, or specimens,” or (b) “new data collected through education tests, surveys, interviews or observation of public behavior.” The first of these categories refers to data, etc. that have already been collected at the time that the research is proposed. The second category refers to research data that are going to be collected, using identified methods. The diagram’s inclusion of “other forms of data collection” brings out the fact that the Common Rule covers other ways of collecting information in

addition to those explicitly distinguished in (a) and (b) from the exempt forms of data collections, e.g., surveys involving harmful information about identifiable individuals. The category of covered involvement of human subjects for “Other forms of data collection” includes:

- Documents, records, or specimens that will be collected in the future in nonresearch activities
- Psychological or medical tests that are not education tests (e.g., lie detector or tuberculosis tests)
- Observation of private behavior

Second, Figure 2 incorporates revisions of the exemptions that are mandated by Subpart D-Additional . . . Protections for Children Involved as Subjects in Research.⁴ Under these provisions, some research activities involving children are covered by the Common Rule that would be exempt if the research activity involved only adult research subjects. If the reader

were to review a research activity involving children supported by research institutions not bound by Subpart D, they would apply the same categories in Figure 2 that pertain to adults.

Public Benefit Programs. Exemption b (5) pertains to research concerning public benefit programs, and is diagrammed in Figure 3.

The historical basis for this exemption derives from efforts by DHHS to study various aspects of the Social Security system. The Department’s rationale for this exemption was that the kind of research involved was significantly different from biomedical and behavioral research with respect to the nature of the risks involved to human subjects, and that other review mechanisms in the department for such studies were more appropriate to protect the research subjects.⁵ The Common Rule does not provide a definition of “public benefit programs” that arguably could be construed as

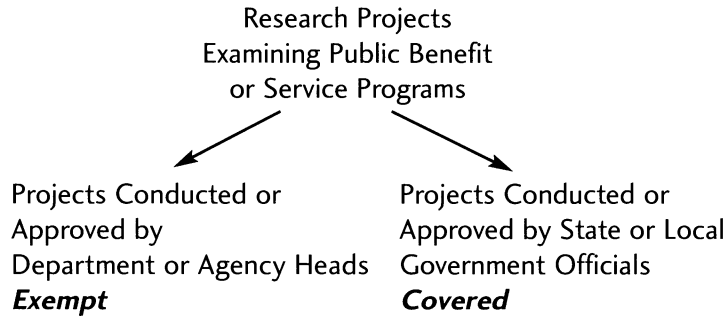


Figure 3: Diagram for Analyzing the Application of Exemption b(5).

including such large, federally funded activities as the entire federal law enforcement system or the system of public education. However, the DHHS rationale for the exemption clearly distinguished the exempt category from all biomedical and behavioral research, and federal officials have been hesitant to allow applicants to utilize this exemption for proposed research activities.

Food. Exemption b(6) concerns research involving human subjects and food or food ingredients. It also diagrams quite simply, as in Figure 4.

As with the other diagrams, an interpreter of the rule would compare the relevant element of a proposed research activity, tracing it from the top of the diagram down to a category

identified as either exempt or covered. If any element of the research activity is covered, the entire activity is covered.

For a compound research activity, more than one of the diagrams and exemption categories may be employed in the analysis. For example, a health and nutrition research study in a classroom health education course might involve educating research subjects about the value of a wholesome food, having them taste it, and then having them take a test about what they had learned in this process; in such a study, exemption categories at 101(b)1, 2, and 6 from the Common Rule would be relevant, as represented in Figures 1, 2, and 4 above.

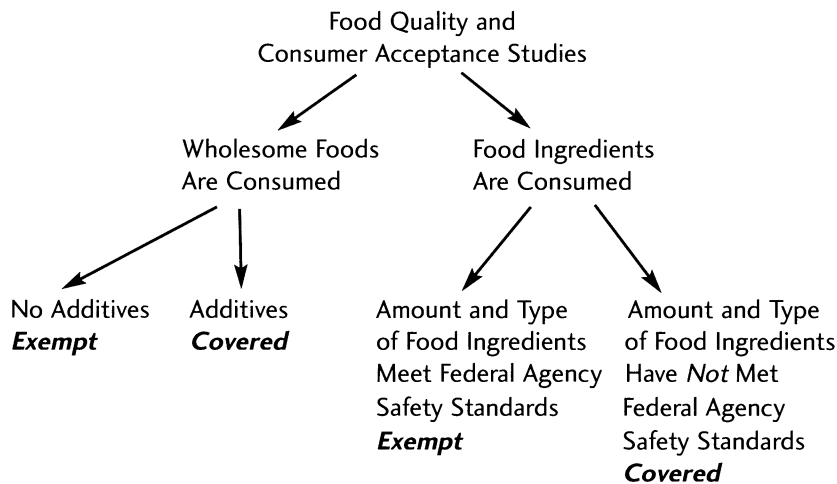


Figure 4: Diagram for Analyzing the Application of Exemption b(6).

Would such a study be exempt from the Common Rule? As noted earlier, all of the elements of a proposed research study must correspond to an exempt category if the research study is to qualify as exempt from the Common Rule. Unless there were another element to the proposed study, interpreters of the Common Rule would probably exempt such a study. The justification for such a decision, however, is not definitively grounded in the Common Rule, as the following discussion will show.

Exasperating Questions: Bending the Rule, or Bending the Mind?

The Common Rule implements policy in a complicated area of human activity influenced by numerous independent and often conflicting goals. It has to provide real protection for human research subjects while supporting the conduct of sound research. It must be flexible enough to accommodate the varieties of research methods, objectives, and conditions, yet still be sufficiently definitive to provide real guidance. It seeks to avoid impeding research; wasting time, energy, and resources; creating obstacles to policy objectives; or violating the dignity of any person. It represents a compromise among the interests of federal agencies and offices, research institutions, organizations, and communities. It is a hybrid creation of ethical principles drawn from rival ethical systems. Small wonder that the Common Rule does not fully achieve all of its aims.

To this point, I have sought to resolve a number of misunderstandings about the Common Rule by demonstrating that some interpretations are plainly inconsistent with the text of the Common Rule. Some difficulties, however, cannot be resolved so readily. One problem pertains to applying the exemptions, another pertains to the definition of a human subject, and a third pertains to the definition of research.

The Phantom List of Covered Research Categories. One of the Common Rule's flaws pertains to the issue of determining whether a

research activity is exempt based on whether “the only involvement of human subjects will be in one or more of the following categories,” with the emphasis on the “only,” as previously discussed. The question is, what other categories of involvement of human subjects besides the “following categories” are being referred to here? It is reasonable to assume that a category of involvement of human subjects that is explicitly distinguished from the categories of exempt research which follow this statement would be a member of the set referred to. (For example, research on an educational activity in an unusual setting is a category of involvement of human subjects clearly identified as covered.) But for the most part, the kinds of categories of involvement most likely to warrant covered status are never explicitly identified as such in the Common Rule. Since most of the set of covered categories is unnamed or only identified by oblique or indirect reference, the reader does not have a reliable basis for determining what other categories might pertain to a given activity that would then make a seemingly exempt activity covered. A complete set of the relevant categories of involvement of human subjects would have to be available in order to determine whether a given activity’s “only” involvement falls within an exempt category (or categories).

Consider a few illustrations of categories of involvement of human subjects whose relationships to the exempt categories in the Common Rule are undetermined at present, and that therefore call into question whether a given research activity involves human subjects “only” in an exempt category.

First, consider the category of “research involving IRB administrators.” The Common Rule does not provide a logical basis for dismissing this category of involvement of human subjects. So, logically speaking, one could claim that all research involving IRB administrators is covered, even if it also falls into one or more of the exempt categories identified in 101(b)(1)-(6). Common Rule

interpreters are likely to dismiss this category, though it is clearly defined, because it seems to be a spurious and arbitrary category of involvement of human subjects unconnected to risk or ethical indignity.

“Research involving a surgical intervention,” on the other hand, is certainly the kind of research that the Common Rule is meant to cover, but nowhere does the Common Rule explicitly list this category as covered. Yet logically, this category is related to the exempt categories in the same way as research involving IRB administrators.

The problem is that many other examples of categories of involvement of human subjects do not so easily divide themselves into those that common sense would suggest should be covered and those that should not. What about “classified research”? Or “research involving educationally disadvantaged people”? Or “research involving people in the District of Columbia or other U.S. territories”? These categories could arguably be associated with greater risks to subjects, and yet they are not commonly understood as representing a category of involvement of human subjects in the relevant sense of 101(b).

Logically speaking, the impact of this problem is to nullify any and all claims that research activities are exempt. Justifying an exemption claim requires knowing all of the classes of activity from which the exempt categories are drawn, so that one can classify the research activity as consisting of subjects’ involvement only among the set of exempt categories. Since the former set of classes of activity remains unspecified, the task of vindicating any exemption claim is logically impossible.

As a practical matter, interpreters of the Common Rule currently exempt research projects on a regular basis, blithely ignoring the logical mistake they are making as they do so. Presumably, these interpreters rely on a tacit set of categories of involvement of human subjects that they believe represent the categories that should be covered, and so long as an exemption

claim does not tread into one of those categories, they accept the claim. The discussion here suggests that consensus is unlikely among Common Rule interpreters as to the entire set of relevant categories which distinguish covered research and are separate from the exempt categories. Consequently, Common Rule interpreters are currently relying on their individual biases about what counts as a covered category whenever they consider an exemption claim.

About “... about ...”

The Common Rule’s definition of human subject includes the phrase “a living individual about whom an investigator ... obtains ... data” as one of the conditions for determining whether an activity constitutes research involving human subjects. Presumably, this means that the research project has to be gathering or studying data about people in order to represent research involving human subjects. While some research activities clearly include data about living individuals and some do not, it is also quite easy to construct examples that are not so clear. Consider the following:

- A researcher asks adolescents questions in a systematic way about what kind of person they want to be when they grow up. This constitutes research collecting data about living individuals (i.e., the adolescents).
- A researcher measures the physical dimensions of school buildings and classrooms. This activity doesn’t involve collecting data about living individuals.
- A researcher asks adolescents a series of identical questions about the qualities they admire in Venus Williams, Matt Damon, and other figures in popular culture. Even if the data collected do not include identifiable private information about Williams, Damon, etc. this is still research collecting data about living individuals, because the researcher is obtaining data about the adolescents being questioned, even though the questions ostensibly focus on the popular culture figures.
- A researcher uses a telephone

survey to ask school personnel about the physical dimensions of their school and its classrooms. In all probability, the purpose of the survey is to collect data unrelated to living individuals, i.e., data about the physical dimensions of schools. However, strictly speaking, such a survey does in fact collect data about living individuals, viz. *what school personnel believe* about school and classroom size. In such a case, however, Common Rule interpreters may well ignore this fact, and consider the research study not to involve human subjects.

- A researcher uses a telephone survey to ask school personnel what their school discipline policy is and how it is related to federal, state, or local law. In this case, the researchers may be interested in data about school policies, or they may be interested in data about individual school personnel's beliefs about their school's discipline policy and its origins.

- A researcher designs and creates an educational software program, asks students to try it out, and then asks questions about what the program's good and bad features are. Do students' responses constitute data *about* living individuals, or *about* the program, or both?

From these examples it should be clear that research studies might include the cooperation of people who are not necessarily human subjects in the sense of the Common Rule. They demonstrate that research studies may vary with respect to whether they are interested in data about people's responses to questions or in data exclusively concerned with the objective content provided in those responses. And they suggest that the actual content of the questions asked in a research study may not fully resolve whether the research study involves data about living individuals or not. Finally, there is no sharp and bright line distinguishing research involving *human subjects* from research that merely involves *people*.

In this, as in many other areas, there are true borderline cases. The Common Rule should not be faulted simply because of this; so long as the gray area of the boundary is not

unnecessarily wide, Common Rule interpreters must face the inevitable prospect of making some close calls. Presumably, in such cases interpreters of the Common Rule will look for whether the research activity involves potentially harmful or sensitive information about people's responses, and err on the side of using IRB review to protect them when such data are likely to be included. What is more troublesome is that a research activity may be clearly *designed* to develop or contribute to knowledge that is *not* about the living individuals, who nonetheless do participate in the research in some way and the data collected do in fact include potentially harmful information. In such circumstances, a research activity that *does* threaten people's welfare may miss IRB review.

Intentions [Primary] and Intentions [Secondary]. The Common Rule's definition of research stipulates not just that a research activity must develop or contribute to generalizable knowledge, but that it is *designed* to do so. As discussed previously, this notion of design or purpose narrows the scope of activities covered by the Common Rule. Some activities may in fact serve a research purpose, but unless they are undertaken with the intention of doing so, the Common Rule does not apply.

The question of whether an activity is being designed as research becomes more complicated with the realization that human activities may be designed to serve more than one objective: Workers may perform their duties both to fulfill their contractual obligations and to provide quality products to consumers, for example; adolescents may choose their wardrobe both to impress their friends and to challenge perceived authority figures; chief executive officers may contribute to charities both to support altruistic causes and to create personal tax benefits. And people may design an activity both to produce generalizable knowledge and to benefit the public. In cases of the last sort, does the Common Rule apply, or not?

The Common Rule does not directly address the question how to choose among more than one option when an activity reflects multiple designs,

although it does appear to recognize the possibility of multiple intentions. This is most obvious when the Common Rule refers to applied research, when the researchers have some reason to believe that their intervention will be therapeutic or beneficial to the subjects *and* that their activity also promises to provide important data. But while the Common Rule implies that some such activities with multiple purposes are within its purview, it does not explicitly provide a way to distinguish clearly which activities should count as research when the activities reflect multiple purposes, one of which is research oriented.

Some Common Rule interpreters have suggested that the way to resolve this issue is to draw a distinction between primary and secondary intention.⁶ On this view, the Common Rule applies only if the *primary intention* of the activity is to produce generalizable knowledge. Some activities that clearly include research-related considerations may still not count as research if their primary intention is something else, e.g., public health surveillance, emergency responses, or program evaluations to improve the quality of service delivered. Research objectives are included in these activities and are reflected in various aspects of their design, but they should not by virtue of this secondary intention be considered research covered by the Common Rule, interpreters argue.

The problem with this position is that it separates the intention to provide a public benefit from the intention to develop generalizable knowledge, and arbitrarily assigns priority to the former. This separation flies in the face of the reality that a considerable number of research activities derive their focus from the researchers' interest in solving some practical problem. Indeed, the argument has been made that the most successful research activities have been driven by a combination of scientific and public benefit interests.⁷ It makes no sense to try to disentangle the research and other intentions in such use-inspired basic research, and probably in other activities as well. The appeal to primary ver-

sus secondary intention does not tend to enlighten application of the Common Rule.

A better approach might be to adopt a more pragmatic perspective that also appeals to the ethical standpoint underlying the Common Rule. The Common Rule is designed to govern research activity, when research is understood to have a particular ethical status in society. In the United States today, research is taken to be a socially desirable activity, but not an imperative one. In other words, the public benefits of research are great enough to warrant public support for research, but the benefits are not such that society is willing to compel people's cooperation in it. The Common Rule is in fact designed to preserve and enhance the reputation of research, as well as to protect research subjects. (Indeed, it would be arbitrary to say that one or the other is the primary intention of procedures identified under the Common Rule.) The heart of the IRB review procedures reflects this ethical status: IRBs may approve or disapprove a project, meaning that it might be desirable but it is not ethically imperative that research take place. And individuals may consent or decline to participate, meaning that it might be desirable but it is not ethically imperative for anyone to participate in research.

If the Common Rule is designed to protect people participating in an activity that is socially desirable but not mandatory, then the issue of whether to view a particular activity as research should be approached with this in mind. If an activity is designed

in such a way as to develop or contribute to generalizable knowledge, and participation in it is voluntary, then the Common Rule should apply. If, on the other hand, society legitimately declares that an activity's public benefit is so compelling as to require participation—as in, for example, certain disease-reporting activities, or data collected under the U.S. Census, which are required in order to administer various legal rights and services—then the provisions of the Common Rule should not apply. It makes no sense to review an activity's plans for securing informed consent if refusing to participate is unacceptable.

This position is only defensible if society limits itself to compelling people to participate in activities when it has a legitimate basis for doing so. Examining where to draw that line is beyond the reach of the Common Rule, beyond the realm of human research activity, and beyond the scope of this essay.

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This essay is designed to promote the exchange of ideas among policymakers, researchers, and practitioners. The views expressed are those of the author and are not necessarily shared by the U.S. Department of Education. Your comments are welcome and can be addressed to Ivor Pritchard, OERI, 555 New Jersey Avenue, NW, Washington, D.C. 20208-5573 or Ivor_Pritchard@ed.gov.

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References

1. The name derives from the fact that the same regulations have been adopted by numerous federal agencies and offices, who are said to hold the rule *in common*.

2. Each of the Common Rule federal agencies codifies the Common Rule within its own regulations. The Common Rule is codified by the U.S. Department of Education at 34 CFR 97, for example. The Common Rule is often referred to by its DHHS regulatory location, at 45 CFR 46. For this essay Common Rule citations will be given using only the numerical reference after the decimal point, which is identical in all of the places where the Common Rule is found.

3. Here and in the later diagrams some of the terms and phrases of the actual regulations have been replaced in order to make the diagrams easier to read and to suggest more clearly the relationships among the category elements of the diagram. Of course, the actual text of the regulations is the ultimate authority for determining what that category covers, and so the reader may wish to refer to the actual text of the regulations when comparing an element of a research activity to an exempt category.

4. For those agencies that have adopted these protections (*viz.* the Department of Health and Human Services and the Department of Education), they are located under the same heading as the Common Rule, which constitutes Subpart A of the Protection of Human Subjects regulations.

5. Department of Health and Human Services. *Federal Register* 1983; 48 (March 4): 9266-70.

6. Snider, DE, Jr., Stroup, DR. Defining research when it comes to public health. *Public Health Reports* 1997; 112: 29-32.

7. Stokes, DE. *Pasteur's Quadrant: Basic Science and Technological Innovation*. Washington, D.C.: Brookings Institution Press, 1997.