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Incidental Findings and Ancillary-Care Obligations

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This paper explores the convergence of two recent and growing streams of bioethical work and concern. Each has originated independently, but each arises from the fact that the Common Rule that has shaped medical research ethics,¹ as institutionalized in the United States and also abroad, is largely silent about what needs to be done in response to researchers' positive obligations. One stream concerns what to do about the sometimes vast range of findings that may arise incidentally to performing research procedures. The other asks whether medical researchers owe their study participants any "ancillary care" — that is, medical care that their study participants need but that goes beyond what is required to do the science safely.

The first of these streams has arisen in leading universities and research hospitals, at the high-tech heart of modern medicine. Contemporary magnetic resonance imaging (MRI), computed tomography (CT) scans, and genetic assays collect such a vast amount of information that latent in these procedures are various "incidental findings" about those who undergo them. This is an issue, of course, for clinicians, but a more troubling one for researchers, who may not be used to dealing with diagnoses and may not even be physicians. Here the emblematic case has been that of structural brain MRIs. A number of studies now show that brain MRIs of asymptomatic, normal volunteers will reveal anomalies requiring prompt clinical follow-up in a non-trivial percentage of cases.² A serious issue raised by these cases is the rate of false positives to be expected among any tentative diagnoses so generated; in part because the technology is quite new, the "unidentified bright objects" and other anomalies seen on a brain scan can be very hard to interpret.³ Do researchers who employ such scans have a duty to read their scans diagnostically (or to have an appropriate expert such as a neuroradiologist do so) or, to cut down on the rate of false positives, to have a clinical-grade scan done and then read for each normal volunteer? The question of what to do about incidental findings remains an agonizing conundrum in research ethics.

The second of these streams has arisen, instead, principally amidst the deprived and primitive conditions of the world's poorest nations, ravaged as they are by oppression, malnutrition, and diseases, in particular the HIV-AIDS epidemic. Although there is always an element of arbitrariness in tracing a stream back to a single origin, HIV-vaccine trials are perhaps the source of this stream. As the world's medical-research community struggles to develop potential

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HIV-vaccines effective against the clades of the virus prevalent in Africa, HIV-vaccine trials have gotten under way there. These trials raise a kind of research-ethics question that the crafters of the Common Rule apparently did not contemplate and that its provisions do not begin to adequately address, namely: do the researchers or their sponsors have any obligation to help secure post-trial antiretroviral treatment (ART) for trial participants who become HIV-positive during the course of the trial? Although the design of a vaccine trial depends upon a certain background rate of HIV seroconversion in the population under study, the trial vaccine itself — which is now never a live vaccine and is often merely a genetically engineered fragment of viral coating — may be presumed not to have caused these individuals' HIV. If we also assume that adequate counseling was in place for all participants, then any responsibility that the researchers bear for any false sense of security that participation in the trial may have induced will be highly attenuated. Many commentators feel that the researchers do have some positive obligation to help those unfortunate trial participants who seroconvert during a trial.⁴ But what sound ethical argument, if any, generates this conclusion? In many parts of Africa, ART provision is unfortunately still not standard care for HIV sufferers. Further, although there are now internationally well-established guidelines pertaining to the “standard of care” in research studies,⁵ these do not comfortably apply to the post-trial period. The bare idea of beneficence is too vague and undifferentiated to do the work. Some have instead reached for the idea of justice, hoping to build from the fact that many injustices lurk behind the vast disparities of income and wealth between the research-sponsoring nations and the poor, former colonies in Africa.⁶ The impartiality built into the idea of justice, however, does not fit well with the claim that these vaccine researchers have a special obligation to see to it that these trial participants get ART; indeed, it is in considerable tension with this claim.⁷ The issue remains a serious puzzle in medical research ethics, especially insofar as that subject takes its bearings from the Common Rule.⁸

My principal message is that these two streams come together. Looked at with adequate breadth — abstracting from the reality that the ancillary-care problem is based in poverty and deprivation and the incidental findings problem is a product of multi-million-dollar modern machinery — each is but a different facet of the same fundamental issue. This claim is a substantive one, and depends upon a particular view about the nature of the obligations that arise in each context. I will lay out and briefly defend that view after first taking a little more time to compare the two issues of incidental findings and ancillary care. Since ancillary care is the issue on which I have previously worked, I close by noting some implications for incidental findings that arise from seeing the two issues as different sides of the same coin. As I head into this joint discussion of these two pervasive issues of medical research ethics, each quite neglected until very recently, I want to emphasize the seriousness of the metaphors I have been using. I have no adequate name, yet, for the river that is formed by the confluence of these two issues, nor for the coin whose two sides they describe. Accordingly, I am *not* claiming that all issues about incidental findings are, at bottom, ancillary-care issues. What I argue, instead, is that these two issues are so intimately related that a proper understanding of the nature and basis of medical researchers' ancillary-care obligations will have important implications for our understanding of their duties with regard to incidental findings.

Comparing the Two Topics

The topics of incidental findings and ancillary care each require more careful definition than I have provided thus far; doing so is a necessary preliminary to comparing the issues.

I take my working definition of incidental findings from Susan M. Wolf and colleagues: “An incidental finding is a finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research but is beyond the aims of the study.”⁹ To begin with a point that is obvious yet helpful to orienting

our comparison with ancillary care, incidental findings are elements of belief. They are not mere items of information: information that lies latent within a blood sample, DNA sample, or gene assay is not yet “found.” To “find” something, in the relevant sense, does not imply that one is necessarily the first person to have found it, let alone the only one; but it does imply that one has become aware of it or (accounting for the possibility that one is mistaken) has come to believe that one is aware of it. In particular, what the researchers incidentally find may (as far as this definition goes) have been already known to the individual research participant concerned. More interestingly, I would like to highlight and discuss two additional features of this definition.

The first is its stipulation that to count as an incidental finding, a finding must have been “discovered in the course of conducting research.” The core meaning of this phrase is clear enough: if the design of a study calls for researchers to carry out certain procedures and if, by carrying out the procedures, they discover some information pertinent to the health of the study participants (or of their offspring, existent or potential),¹⁰ then that counts as a pretty clear case of a finding that arises in the course of conducting research. Even here, there is room for a philosopher to worry the definition — a tendency I will briefly indulge, as it helps flag a point useful for my upcoming comparison. Suppose that the study calls for the use of intravenous (IV) medication and that, in carrying out the order to place an IV, one of the study nurses discovers that the research participant is an IV-drug abuser. I would read the definition quoted above as indicating that this would count as an incidental finding. I am not sure, however, that the authors of the definition intend this kind of breadth. Certainly, the research procedures they mainly discuss are not interventions such as placing an IV but rather information-gathering procedures such as doing MRIs or CT colonography or running analyses of gene arrays. Since the broader range of cases covered by this definition fits better with my understanding of ancillary-care obligations, however, I will leave the definition unaltered.¹¹

In addition to the relatively unproblematic breadth just noted, the phrase, “in the course of conducting research” contains an ambiguity that needs to be resolved. This phrase might simply mean “during the time in which the research is ongoing,” or it might mean “by carrying out research procedures.” As an example of what might fall under the former, broader interpretation, we may think about what highly trained individuals may “find” on their way to work. One relatively well-studied example of this, which has been discussed under the rubric of “unsolicited medical advice,” is the case of what looks to a trained person to be a melanoma on the back of someone’s neck.¹² The typical setting of this story in the literature so far is the bus stop. Let us change that. Suppose that, while escorting a research participant down the hall to the MRI machine, the researcher, who did a dermatology rotation in medical school, notices what looks to be a melanoma on the back of the participant’s neck. Does that count as an “incidental finding” in the intended sense? For reasons I will explain below — which have to do not simply with relating the ancillary-care topic to the incidental-findings topic, but more substantively with the nature of the underlying obligations as I see them — I will assume that this does *not* count as an incidental finding. I will assume that “in the course of conducting research” is to be understood as meaning “by carrying out study procedures.” Thus, walking the participant down the hall is not a study procedure.¹³

The second aspect of the definition I want to comment on is the notion of being “beyond the aims of the study.” This idea seems both clear and apt to me, though of course, marginal cases will arise. I take it that we should interpret it in a way that makes room for the fact that scientific studies can, and frequently do, surprise or disappoint their designers. Certainly, the definition should include findings that pertain to side effects of any drug or intervention under study. To choose an actual example, you might find out in the course of doing a study of a proposed heart medication that it enhances the erectile function of some of the participants. Although you had not aimed to find out anything about erectile dysfunction specifically, tracking the side effects

of the medication was clearly within the study's aims. (While we now tend to think of this newly discovered effect of the drug as beneficial for those who choose it, it could easily count as adverse for those who neither desire nor expect it.) Hence, this was not an incidental finding, but a finding pertinent to the study's aims.

Let me turn now to ancillary care. The definition given in my articles with Leah Belsky says that "ancillary care" is "care not required by sound science, safe trial conduct, morally optional promises, or redressing subject injury."¹⁴ As the context for our analysis suggests, we are talking about medical care that research participants need (or seem to need). However, instead of defining "ancillary care" directly by reference to the aims or purposes of the research, as does the above definition of "incidental findings," we defined it negatively by relation to the other leading reasons for thinking that medical researchers might be morally required to provide medical care to their research participants. We were seeking above all to understand a certain kind of obligation. The design of a sound study will often include providing some medical care, both because it is instrumentally necessary (say, because one has to stabilize a patient before administering a trial intervention in a way that yields clear data) and because validly addressing a worthwhile scientific question (itself an ethical requirement¹⁵) requires comparing the "standard of care" for the disease or condition under study. Researchers' responsibility to conduct their trials safely will also often mean that they need to provide medical care to help minimize adverse reactions. Researchers may further need to promise various sorts of medical care in order to recruit subjects. And if participation in research has harmed a participant's health in some way, then researchers may well have some obligation to see to it that they get adequate follow-up care. But what about care that the participants need, but that is not covered by any of these rationales? These further cases are what raise the issue of ancillary care. The case of post-trial ART provision to HIV-vaccine trial participants who become HIV-positive during the trial, but not as a result of it, is one case in point. Here is another example, from a real case. Researchers in Benin studying vaginal microbicides discovered in one of the trial participants an ectopic pregnancy that did not result from the microbicides and that urgently called for surgery not available at the trial location. They agonized about what to do about it, ultimately deciding to pay for the woman's surgery at another clinic.¹⁶

Ancillary-care issues and incidental-findings issues, defined in these ways, importantly intersect, but do not perfectly overlap. I will mention a couple of reasons for non-overlap that are artifacts of the particular definitions before turning to a question that is more central to how we should understand incidental findings. The rubric of ancillary care is in one way narrower than that of incidental findings because care for the disease or condition revealed by some incidental findings may well be covered by one of the other grounds of obligation that our definition of ancillary care excludes. Most simply, the researchers might explicitly have promised their study participants that they would provide or organize care that responded to any incidental finding uncovered by the research. From the point of view of our analysis of ancillary-care obligations, this possibility is not very interesting, for two reasons. First, that these researchers have promissory obligations to provide care dealing with incidental findings is compatible with their also having ancillary-care obligations covering the same care, in the sense that *they would have had* ancillary-care obligations to provide this care even if they had not promised to do so. Second, since it is important to address ancillary-care obligations when protocols are undergoing ethical review, these ancillary-care obligations might well have implied that these researchers *should have promised* to provide this care.¹⁷ A more interesting instance of this first sort of non-overlap, then, would be if trial safety requires providing care that follows up on an incidental finding. Suppose, for instance, a research scan done to assess the effectiveness of a new breast-cancer drug reveals a heart anomaly that increases the risk that the drug will trigger a heart attack. Responding to this incidental finding would be covered by the safety rationale, and hence would not count as a case of ancillary care.

In the opposite direction, the field of incidental findings is in one way narrower than that of ancillary care because of the former's exclusion of items of information contributory to the study's aims. For instance, the information that triggers the question about post-trial ART provision to participants in HIV-vaccine trials is hardly an incidental finding: rather, the fact that an individual has become HIV-positive during the course of the trial is the crucial study endpoint, the basis on which the effectiveness of the vaccine is assessed. Providing the follow-up ancillary *care* makes no contribution to the scientific aims of the study, but tracking the *finding* about individuals' HIV status is central to the study. Accordingly, the ancillary-care framework we have defined will embrace this case as an issue to be addressed, while an incidental-findings framework rightly would not.

These complementary areas of non-overlap just mentioned are, as I say, relatively "technical" implications of the precise definitions put forward on either side — definitions that attempt, each in their way, to capture a concrete set of concerns that seem to flow together to form an important stream. In comparing the two issues, let us now look at those concrete concerns more directly, without paying so much attention to the details of the respective definitions. On the ancillary-care side, I have emphasized that much of the discussion has been about cases arising in developing countries, where medical resources are very scarce. In working on ancillary-care obligations, however, Belsky and I set out to address the issues more inclusively than that, and in fact, included a brain-MRI example in our original article. Ancillary-care questions are, as a practical matter, generally less difficult in developed-world settings, as it often suffices to refer the participant to an appropriate specialist. However, even in the United States, there are people without health insurance, and difficult questions on whether to have research scans diagnostically read still go unanswered. Since the issue of ancillary care had been so totally neglected, we set out, in taking a first cut at it, to try to frame principles that would be applicable to the whole range of medical-research contexts. Approaching things this way meant that we were unable to be very

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concrete in interpreting "obligation to provide care" in our framework. For a given ancillary medical problem, an appropriate moral response in rural Africa and an appropriate moral response in a tertiary-care U.S. hospital might look quite different. In either context, though, if the researchers have an ancillary-care obligation with respect to a given medical need of one of their participants, then they will have an obligation to see to it that the person receives adequate care addressing that need.

Whereas our initial efforts at theorizing about ancillary care attempted to generalize beyond the concrete contexts that most often and most dramatically raise ancillary-care issues, discussion of incidental findings has remained primarily focused on the difficult-to-interpret high-tech results that have given rise to the issue.¹⁸ Indeed, at least one bioethicist grappling with the issue has *defined* "incidental findings" as having the kind of uncertain practical import that is common with the output of the new, high-tech procedures.¹⁹ The definition I quoted and discussed above, however, has no such limitation — and, for reasons I will set out more fully in the next section, I think quite appropriately not. I can make a quick case for this sort of inclusiveness here. To begin with, even the new technology can generate incidental findings for which the appropriate follow-up is quite clear. For instance, a "virtual colonoscopy" using CT technology might incidentally and unmistakably reveal an operable aortic aneurysm.²⁰ Further, difficulty of interpretation and lack of clarity about appropriate follow-up is hardly a monopoly of the new technology. For example, a physical exam of a study participant at the enrollment stage of a diabetes-drug trial may reveal, not an obvious melanoma, but what may

or may not be an incipient melanoma. While the latter possibility raises many of the concerns about false positives around which the debate on incidental findings has swirled, an obvious melanoma revealed by a physical exam should also be counted as an incidental finding.²¹ It certainly fits the definition of “incidental findings” discussed above, duly narrowed in the ways I suggested so as to focus on what arises from conducting trial procedures.

In an important way, then, the incidental-findings current naturally broadens to include most of what is of concern to those of us interested in ancillary-care obligations. In proceeding, therefore, I will largely ignore the ways in which, as a result of the precise definitions developed on each side, the two topics fail perfectly to coincide, and instead concentrate on the large area of overlap. My next task will be to summarize my account of researchers’ ancillary-care obligations so that I may then go on, in the final section of the paper, to see what implications it has for the issue of incidental findings. This is a natural way of proceeding. The concept of incidental findings refers to a range of *problems*. Since ancillary-care obligations, by contrast, are defined as covering a residual moral space between other, familiar obligations, any interpretation of ancillary-care obligations already points, at least by elimination, toward an *answer*. More particularly, my central substantive claim is that the best way to interpret ancillary-care obligations is to center them on incidental findings. If this is right, then an understanding of ancillary-care obligations provides a good moral basis for tackling the issue of incidental findings.

The Basis and Limits of Ancillary-Care Obligations

At the outset, I described both the ancillary-care and incidental-findings issues as raising questions about the positive obligations of medical researchers. It seems that if there are obligations under either rubric, they are, like beneficence obligations more generally, positive ones (i.e., obligations to do something helpful, not merely obligations to refrain from harming). They are obligations specially incumbent on medical researchers, by which I mean that researchers bear these obligations because of some feature (to be explained) of the distinctive professional relationship that researchers have to their study participants.²² To assert the existence of such special, positive obligations is not to deny the existence of more general ones; indeed, in our original ancillary-care articles, Belsky and I made a point of stressing our assumption that there is a general duty of rescue, incumbent on all persons, that comes into play when the need is dire and the needed intervention is comparatively easy to provide and risk-free.²³ We see the ancillary-care obligations as additional obligations, specially owed by researchers to their trial participants, over and above any more general positive obligations.

To exhibit the intuitive appeal of this analytic structure, it will help to consider a marginal sort of case in which the general duty to rescue does not apply. Different people, operating intuitively, will locate this boundary differently. Some physicians I have spoken to submit that the case of spotting a melanoma on the back of someone’s neck at a bus stop may invoke a duty of rescue (incumbent on anyone with the ability to diagnose it), whereas other cases cross the line into “unsolicited medical advice” that is not morally required but actually morally prohibited. For instance, while a neurologist at a bus stop might, from closely observing the person next to her, confidently reach the judgment that there is a good chance that the person has a brain tumor, say, or incipient Parkinson’s, many would balk at saying that she has a moral obligation to say something to this stranger.²⁴ Indeed, some would say that it would be an abuse of her power as a physician to intervene — or, that if she were to mask her expertise by saying, “Hey, you’re blinking kinda funny. Did you ever ask your doc about that?” she would not only be abusing her power but also would be acting duplicitously. While it will be controversial where to draw the line between cases imposing a general duty to rescue and those not imposing that duty, it seems clear that there is a line to be drawn.²⁵ Take, then, a case in which you think it is certainly not morally required, and perhaps even morally problematic,

for a physician to intervene with a stranger. Perhaps you think that one of my cases of a neurologist observing symptoms at the bus stop (either the brain tumor variant or the Parkinson's variant) is one in which it would be problematic for the neurologist to say anything. Now take that case and place it in the research setting. That is, suppose that the neurologist notices the relevant symptoms, not at a bus stop, but during an examination that is part of a research study. I suspect you will find that this change in context makes an important moral difference, and that the neurologist has an obligation in the research setting that was missing at the bus stop. If so, then you will have recognized what I am referring to as an obligation specially incumbent on the neurologist in her capacity as a researcher and, specifically, in her capacity as part of *this individual's* research team.

In considering the topic of medical researchers' ancillary-care obligations, then, we are contemplating special obligations incumbent on certain individuals in virtue of their professional role and, specifically, in virtue of their standing in a professional relationship with their research participants. There are several reasons why this is both a difficult topic and one that has not yet been adequately addressed by research-ethics guidelines. One reason is that ancillary-care obligations are positive obligations — that is, obligations to do certain things for people, as opposed to negative obligations, obligations not to do certain things to people. I have already alluded to how little the Common Rule expresses positive obligations — except derivatively, as means of ensuring that researchers' negative obligations are not violated. For instance, in response to scandals and abuses, the Common Rule imposed the positive duty to obtain informed consent in order to establish a procedural check that would help prevent researchers from manipulating their subjects or exposing them to undue risks. Here, the positive duty created by the regulations is in service of the underlying, negative duties. Positive obligations are generally less well understood than negative ones, and are less well reflected in the Common Rule.

An additional reason for the unsettled character of the ethical issues surrounding incidental findings and ancillary care is that the profession of medical research sits uneasily at the intersection of two older and better-understood professions: science and medicine. Rhetorically, there are many different ways of getting at this distinctive feature of medical research. In our original ancillary-care article, Belsky and I contrasted two “polar views” about ancillary care: one analogizes medical researchers to personal physicians, and hence sees researchers' ancillary-care obligations as extending very broadly to all aspects of their study participants' health; the other analogizes medical researchers to “pure scientists,” and hence denies that researchers have any ancillary-care obligations.²⁶ Here, however, to vary the rhetoric and to engage with an important recent article by Franklin G. Miller and Donald L. Rosenstein on the professional obligations of medical researchers, I will present things differently.

Miller and Rosenstein, writing generally about “The Therapeutic Orientation to Clinical Trials,” decry the confusions that flow from conflating clinical research with medical care. “To avoid exploitation and misplaced trust,” they argue, “an investigator approaching a patient about enrollment in a study should describe his or her own role as primarily that of a scientist in pursuit of knowledge aimed at improving medical

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care for future patients, rather than as that of a personal physician dedicated to promoting the individual patient's health.” More generally, they suggest, ethical progress would be made over the current “therapeutic orientation” by seeing research on healthy volunteers, in most of which “the vantage point...is solely scientific,” as being paradigmatic.²⁷

Although the rhetoric here differs quite markedly from our own dialectical use of the figure of the “pure scientist,” I actually have no quarrel with these claims of Miller and Rosenstein. I agree that medical researchers occupy a very different role than that of primary-care physicians and other clinicians, and that this difference hinges on the fact that medical researchers aim primarily to contribute to general knowledge. In my papers with Belsky, however, the “pure scientist” had an additional defining characteristic, namely the tendency to assert that *because* medical researchers are scientists first and foremost, they have no ancillary-care obligations. In arguing against the model of the pure scientist in our articles, therefore, Belsky and I were not disagreeing with Miller and Rosenstein’s sort of characterization of medical research, but instead were targeting the claim that medical researchers have no ancillary-care obligations. That medical researchers lack ancillary-care obligations simply does not follow from the fact that they are scientists, first and foremost. After all, they are scientists involving human subjects in their research.

Miller and Rosenstein concede that the analogy to research with healthy volunteers only takes one so far: “Just as it is inaccurate to conceive of clinical trials as a form of medical care, it is unrealistic to think of research involving patients as the same as research involving healthy volunteers. Unlike healthy volunteers, patient-subjects do need treatment and care.”²⁸ This is fair enough as far as it goes, but the issues of incidental findings and ancillary care show that it does not go far enough. These issues reveal that the idea of a “healthy volunteer” is a misleading abstraction. A non-trivial percentage of the supposedly healthy and indeed asymptomatic volunteers who sign up for brain MRI studies, as we have seen, will be harboring, unbeknownst to anyone, potentially dangerous brain anomalies. A “healthy volunteer” for a study on CT colonography may turn out to have a dangerous aortic aneurysm. Yes, theoretical individuals who are stipulated to be, in a pure and abstract sense, “healthy” will not need treatment or care, but the flesh-and-blood “healthy volunteers” that research medicine actually enrolls may, in fact, not be fully healthy after all, despite the best efforts of the study’s pre-enrollment screening team. When the research discloses their lack of perfect health, we have an incidental finding and a potential claim for ancillary care.

Our argument against the polar view that assimilates ancillary-care obligations to a clinician’s obligations to his patients was essentially the same as Miller and Rosenstein’s central argument against the “therapeutic orientation”: this polar view clashes with the organizing purpose of the research enterprise. The attempt to maintain it in the face of contrary reality thus leads to all sorts of “ethical distortion.”²⁹ But what are the arguments against seeing medical researchers as scientists who, given their primary allegiance to science, have no ancillary-care obligations? This is an issue on which Miller and Rosenstein leave matters open. I see two principal ways of arguing this latter point, one more direct and intuitive and the other working more indirectly, by analogy to other spheres. It was the latter, indirect mode of argument that led Belsky and me to our specific proposal about the content of researchers’ ancillary-care obligations. Before I come to that line of argument, though, let me briefly describe the more direct line.

The more direct line of argument takes off, in effect, from the way in which, as we have just seen, Miller and Rosenstein’s concession needs to be revised. It is not merely that medical research deals with “patients” as well as with “healthy volunteers.” The point, more generally, is that the medical research we are talking about enrolls human beings, on whom it experiments. When one does that with another human being, one naturally comes under particularly close scrutiny by reference to a moral principle that constrains all of our actions, namely the Kantian principle that we ought not treat persons as mere means. Although the general meaning of this principle is notoriously elusive, the context of medical experimentation on human subjects exemplifies the dangers of treating persons as mere means. To treat someone as a mere means to gathering proteins or genes or to observing the interaction between T-cells and viruses is to

treat them as a mere means, period. What it takes, in this context, to treat them also “as an end” thus becomes the question. If research participants had full information about their condition and have attained a full understanding of the nature and the risks of the procedures involved in the research, securing their informed consent to participation would probably suffice. Indeed, under those idealized suppositions, interfering with their ability unconstrainedly to enter into researcher-participant relations — say by institutionally imposing an ancillary-care obligation, a level of enforcement the present essay does not reach — would seem to be an objectionable form of paternalism. Equally clearly, however, these idealizations falsify. Research participants generally lack this full understanding. Further, as the case of incidental findings again shows, they enter studies lacking full knowledge about their own medical conditions. Hence, any paternalism here is “soft” because interference is justifiable by reference to what the individuals would choose if they had full information and ideal understanding.³⁰ Given the lack of full information and given the huge average asymmetry in knowledge and understanding between the researchers on the one side and research participants on the other, we should conclude that the procedural safeguard of informed consent does not ensure that research participants are treated “also as ends.”

Concretely, we may confirm this conclusion by imagining a confrontation in which a researcher denies ancillary care to a research participant who otherwise would be unable to get it. Suppose that, in a variant of the Benin microbicide example mentioned above, microbicide researchers discover a dangerous ectopic pregnancy in one of their participants, someone who otherwise would lack any access to surgical care; but suppose that, unlike in the real case, the research team includes a surgeon and has an operating room in its local clinic. Suppose further that they could do the operation needed to save the woman’s life, though with some considerable strain and some diversion of study resources.³¹ Refusing to do the surgery on the ground that the team is there to do research and not to provide clinical care would be, it seems to me, to treat this woman as a mere source of data about the effectiveness (or whatever) of microbicides, and not also at the same time as an end.

This direct argument, insofar as it is successful, helps explain why there would be ancillary-care obligations that constrain the arrangements otherwise freely arrived at between researchers and study participants, but it does little to help us figure out the specific contours of these obligations. For that purpose, and to confirm the conclusion that these obligations exist, it is useful to consider some analogous situations. There are many potentially illuminating analogies to draw on. Here, to vary and supplement the approach taken in our original articles, I offer one drawn from general beneficence and one drawn from legal ethics.

As I have noted, we all have general duties of beneficence that include at least some limited duty of rescue. Within the context of these general duties, something interesting occurs once one has started helping someone else. As Barbara Herman observes:³²

Normally, in providing aid, we take on new responsibilities. You have a headache; I offer aspirin, but by mistake give you antacid. Even if it is now harder to give you the aspirin you need than it would have been, because I started helping I now have to do more. If the aspirin I give you makes you suddenly ill, I am at the front of the line of those who should get you help.

My intuitions align with Herman’s here; but if she and I are right, the question is, why is this so? At the most elementary level, it is obviously relevant that by starting to help a stranger, one enters into a relationship where previously there had been none. If the existence even of this informal and praiseworthy sort of relationship begins to heighten one’s responsibility for helping another, so, too, may the existence of a researcher-participant relationship.

To begin to work out how to understand the idea of “relationship,” here, and for a type of case considerably closer to that of medical research, consider the moral position of a litigation attorney, Marvin, in the following two scenarios:³³

Strangers on the Plane

Marvin’s seat mate on the long trip has been chatty. Immediately upon finding out that Marvin is a litigator, the seat mate launches into a complex description of a lawsuit he is intending to file. From the description, Marvin can tell that unless the seat mate files suit within three days, the claim will evaporate. Nonetheless, Marvin is tired, and instead of mentioning this fact, which would require some explanation, he cuts off his seat mate’s conversation as soon as he can, and goes to sleep.

A Stranger in the Office

As soon as the new potential client, who is sitting in Marvin’s office, has finished explaining the matter he wants litigated, Marvin can tell two things: first, that he has no intention of taking on the case himself, and, second, that unless the person files suit within three days, the claim will evaporate. Nonetheless, instead of mentioning the latter fact, which would require some explanation, Marvin cuts off his visitor’s conversation as soon as he can, saying that he is too busy to take on the case, and proceeds to his next appointment.

While these two scenarios are similar, Marvin has a special obligation in the second case that he lacks in the first.³⁴ I gather that this is so as a matter of accepted canons of legal ethics, and it also seems an intuitively clear difference to me; but this differentiation cries out for explanation.

Making explicit the moral difference between these two cases, as I see it, will bring me to the positive proposal Belsky and I have made about researchers’ ancillary-care obligations, our “partial-entrustment model.” In both cases, the stranger offers Marvin information that would otherwise be covered by a right of privacy — that would be privileged, for instance, had the stranger already communicated it to another attorney. Only in the office case, however, has Marvin consented, even implicitly, to be the recipient of such private information. Once having agreed, as a legal professional, to be the recipient of this otherwise private information that he is relatively expert in processing, Marvin may be presumed effectively to have become entrusted with this information. To say this is not to make any claim about the state of mind either of Marvin or of the person in his office. The point, rather, is that in these circumstances, as described without any reference to the parties’ beliefs about entrustment one way or another, Marvin may appropriately, as a moral matter, be *deemed* to have accepted this information in trust. His having done so gives him some special responsibility to respond to it in a professionally competent manner on this erstwhile stranger’s behalf, whether or not he ends up taking the case. This special responsibility by no means extends to the visitor’s whole welfare, but is delimited by what would count as responding appropriately to this information.

As I now understand our partial-entrustment model of medical researchers’ ancillary-care responsibilities, they are precisely analogous to these special obligations that arise in the office case. To explain this in detail, I need to invite the reader to consider informed consent from a non-standard angle. The Common Rule, with its preoccupation with preventing another Tuskegee, casts informed consent as playing the roles — naturally enough — of adequately informing research participants (as the Tuskegee participants were not) and of securing their voluntary consent. Informed consent thus serves as a substantive ban on duping research participants and as a procedural device to help prevent them from being abused or exploited. In addition to these roles for informed consent, however, there is a third role, one that is, in a way, morally more primitive. Researchers need their participants’ informed consent because

they need their participants' permission to do all sorts of things that would otherwise be impermissible: to touch the participants in certain ways, to collect and study samples of their tissues and bodily fluids, and more generally to collect confidential medical information about them.³⁵ Although permission may be needed for various reasons in each of these cases, a common thread runs through them all: each of these types of action for which medical researchers need special permission is saliently, from the researchers' point of view, a mode of gathering information from this particular individual information that would otherwise be covered by a right of privacy. By soliciting these permissions, the researchers have implicitly consented to being the recipients of this private information. Accordingly, just as in the office case, medical researchers, via the informed-consent process, become entrusted with special responsibilities pertaining to the information thus gathered. Again, to say this is to make no claim about whether either party believes that any entrustment has occurred or whether either party trusts the other. Rather, it is to make the moral claim that it is appropriate to *deem* the researchers to have implicitly accepted an entrustment-style responsibility to respond appropriately and professionally to the information thus gleaned. This special responsibility is the core of their ancillary-care obligations.

Because this talk of waivers of the right to privacy may seem rather highfalutin', it may help to go back to Herman's observation about what happens when one starts to help a stranger. From the point of view of this notion of partial entrustment, we can see that, once one offers a stranger an aspirin, one willingly enters into aspects of the stranger's life that would otherwise have been none of one's business. Once one starts finding out intimate details about someone's headaches — or tumors, or aneurysms — by a process that (unlike in "Strangers on the Plane") one has voluntarily accepted, one starts to accrue special responsibilities to deal with the follow-up.

Every incidental finding thus falls within the scope of the ancillary-care obligation and therefore counts as giving rise to a potential ancillary-care claim, unless a stricter basis of obligation, such as the requirement to conduct studies safely or the requirement to fulfill one's promises, already covers it.

I have just said that this idea of partial entrustment captures and explains the "core" of medical researchers' ancillary-care obligations. I do not believe, however, that it is the whole story. Medical research is a tremendously varied enterprise, and studies differ radically one from another. Many of the differences of study design, conduct, and context play some role in shaping the specific ancillary-care obligations that apply to a given study. In order to mark these two aspects, our original articles labeled the core concern a matter of the "scope" of the ancillary-care obligation, provisionally lumping the remaining factors together under a test of the obligation's "strength." A given aspect of a participant's health is rightly deemed to have been entrusted to the researchers' care — and so to be within the scope of the special ancillary-care obligation, only if the researchers needed permission to collect information pertaining to it in order to proceed permissibly with their study.³⁶ The factors affecting the ancillary-care obligation's strength in the context of a given potential claim (within the scope of the obligation, as just defined) and a given study include the following: (1) how much difference getting care would make to the welfare of the individual ("vulnerability"); (2) how dependent such an individual is on the research team for getting that care ("dependence"); (3) how intense and long-lived the relationship expectably is between researcher and participant ("engagement" — recall the case of starting to help a stranger); (4) whether the researchers owe the participants any debt of gratitude for their willingness to undergo procedures that may be risky, painful, or inconvenient ("gratitude"); and (5), countervailingly, the cost to the research enterprise of providing any ancillary care.³⁷ For a given claim to ancillary care to succeed, it must pass both tests, scope and strength.

On this analysis, all of the factors that shape medical researchers' ancillary-care obligations can be assessed at the stage of initial protocol review, on the basis of the study's general design, though of course there may always be some surprise needs for ancillary care. One might not be able to predict an ectopic pregnancy, but one would be able to say in advance that if a researcher conducting physical exams as part of a vaginal microbicide trial discovered an ectopic pregnancy, dealing with that would fall within the scope of the research team's ancillary-care obligation. In this case, the difficult question will be whether the ancillary-care claim passes the test of strength. In the actual case in Benin, where the closest surgical facility capable of doing the needed surgery was in the capital of a neighboring country, the cost to the research enterprise of diverting resources to the necessary evacuation would probably have justified omitting to ensure that this woman receive the operation she needed, tragic as that outcome would be. Judging by his inspiring commitment to the poor in Haiti, Dr. Paul Farmer would have insisted on finding some way to get her there, and in so doing would have taught the world a lesson about the injustice of a world in which this predicament arises; but it seems to me doubtful that these researchers had a moral obligation to take such a step. We should not forget, however, that in many cases the test of strength will be easily met. If, for example, infectious-disease researchers find worms in the African children they are studying, they have, over and above any duty of rescue, an ancillary-care obligation to provide them with de-worming pills, which are cheap and effective. And very many cases will fall in between the Benin case and the de-worming case.

Implications of the Partial-Entrustment Model for Incidental Findings

I am now in a position to develop my earlier remark about the idea of incidental findings posing a question to which an understanding of ancillary-care obligations provides an answer. If we accept the interpretation of "in the course of conducting research" for which I argued in Section 2, which includes any incidental finding arising from carrying out a study procedure, then every incidental finding falls within the scope of what has been entrusted to the researchers' care, according to the partial-entrustment model. Every incidental finding thus falls within the scope of the ancillary-care obligation and therefore counts as giving rise to a potential ancillary-care claim, unless a stricter basis of obligation, such as the requirement to conduct studies safely or the requirement to fulfill one's promises, already covers it. Accordingly, because the test of scope is automatically satisfied by incidental findings so interpreted, the significant moral question from the point of view of the partial-entrustment model is always whether a given type or instance of incidental finding satisfies the test of strength. If it does, then the researchers who generated it have some obligation to see to it that the research participant gets appropriate care. Again, what it means to "see to" this will vary radically, depending on whether the researcher is in rural Benin or in a tertiary-care hospital in Boston.

Related to this variability in the economic and institutional context of research is variability in the composition of research teams. In speaking of "researchers'" ancillary-care obligations, I have proceeded as if a study were the work of one, lone primary investigator who is a physician. In reality, of course, this is rarely the case. Research teams are often large and variegated, and researchers often work hand-in-hand with sponsors, host governments and institutions, individuals' personal physicians, and others. How ancillary-care obligations ought to be parceled out among all of the various partners to modern medical research is a difficult question.³⁸ Specific cases of this kind of question are whether researchers have a duty to seek the advice of an outside consultant about a scan that looks suspicious and whether, if a reasonably high rate of suspicious scans is expectable, the research team ought to include a radiologist or other diagnostician from the beginning. I will return to these cases below.

In recent discussions of the issue of incidental findings, the question has been raised as to whether researchers have any obligation to hunt for incidental findings. The partial-entrustment

model answers this question with an unqualified “no.” To explain why, I need to remind you of the precise grounding for the partial-entrustment model set out in the last section. A different sort of partial-entrustment model, which I reject, might generate another answer — for example, a partial-entrustment model according to which “aspects” of a person’s health, thought of as being almost a kind of “thing,” are entrusted to the researchers’ care. For instance, one might think that participants in an emphysema study entrust the health of their *lungs* to the researchers’ care (or is it their respiratory system more generally?). For someone proceeding down this route, the tendency would be to let the boundaries of the entrustment be set either by the boundaries of major organ systems or else by the conventional boundaries of medical specialties. On the latter basis, a participant in an ear-infection study might be thought to entrust to the researchers the care of his ear, nose, and throat. This crudely reified and body-based idea of the scope of entrustment is not the one that our partial-entrustment model endorses.³⁹ Instead, our account of the scope of entrustment is keyed to the *procedures* — understood broadly so as to include taking medical histories, doing physical exams, running scans, administering drugs, and otherwise intervening — that the research protocol involves. To summarize the relevant part of the last section’s argument, the thought is this: doing such procedures will elicit information about the participants that, in the absence of the permissions collected in the informed-consent process, would be covered by the participants’ rights to informational privacy. Having gotten the participants to waive these privacy rights, the researchers correspondingly come to have duties of care with regard to the pieces of information — and in particular the incidental findings — that fall in their hands by doing the research procedures. On this understanding, a participant’s claim to ancillary care is a kind of remedial claim: it is a kind of remedy for the relaxation of privacy rights dictated by the study. Information that sits latently in a computer’s digital encoding of an MRI image or other kind of scan, recall, has not yet been “found” and so is not yet an incidental finding. Now, to go hunting for *additional* incidental findings is, in the first instance, to exacerbate the blow to privacy for which the ancillary-care obligations function as a kind of remedial compensation. The emphatic nature of the “no” issuing from the partial-entrustment model to this question about hunting for incidental findings, then, expresses the conclusion that such hunting is not morally required on ancillary-care grounds and, indeed, is morally problematic.

Strictly speaking, in fact, hunting for incidental findings is conceptually *impossible*. What people seem to mean by “hunting” for them is to widen the scope of one’s information-gathering beyond what would be dictated by the research design so as — either by oneself or with the help of a consultant — to seek a broader range of findings of potential diagnostic significance. But the definition of “incidental findings” that I am using here, especially given the interpretation of “in the course of research” for which I have argued, implies that these further findings would not count as incidental findings. Because they would not be arrived at in the course of research — that is, not by carrying out study procedures but by engaging in some further hunting expedition — they would not be incidental findings.

So the partial-entrustment model of ancillary-care obligations issues no call for researchers to go hunting for incidental findings; but what if there is a mismatch between the procedures done and the permissions obtained? Cases of this kind are likely to occur, for instance, with research utilizing CT colonography. As the name of this technique indicates, it is a way of using CT scans to obtain a detailed image of the colon. As it happens, however, the scans done for this purpose often end up collecting imaging data not only about the colon but also about the whole lower torso. Accordingly, research on the effectiveness of this procedure in detecting colonic abnormalities turns out to generate numerous incidental findings outside the participant’s colon.⁴⁰ But now what would be interesting to know is whether the informed-consent forms for these studies ask the participants’ permission to collect information about that whole lower torso, or whether the forms instead simply ask permission to

Stepping back to take a broader view of the territory I have covered, what I hope above all to have established is that the streams of concern exhibited in the heretofore independently discussed issues of ancillary care and incidental findings do, in fact, flow together.

collect information about their colons. In studies in which CT colonography researchers collect only the latter, narrower permission, we would have the kind of mismatch I have in mind between the permissions given and the range of the likely incidental findings. What does the partial-entrustment model say about this?

My perhaps simple-minded response is to remind the reader that the partial-entrustment model holds that the scope of entrustment is fixed, not by the permissions that the researchers happen to have collected, but by the permissions that they needed to have collected in order to proceed permissibly with the study. My guess is that, across the full range of medical research, the permissions actually collected are most commonly far more inclusive than they need to be to cover the procedures that the research will actu-

With regard to incidental findings and ancillary care, at least, we can gain considerable clarity by stepping back far enough to see how these issues join to form a mighty river.

ally involve. Whether because lawyers get involved in drafting informed-consent documents or for some other reason, there seems to be a tendency to gather very broad permissions, just in case they end up being needed. In the case of a CT colonography mismatch, however, we have an opposite kind of example, in which the researchers did not collect a broad enough permission to cover what they have actually done. If the extra-colonic information remained merely latent in the computer, then this would not be the case; but if the information is converted into a readily interpretable image on the screen, then it has been exposed to the view of the member of the research team (or the expert to whom they have, in effect, subcontracted) who reads the scan. If there is a large, extra-colonic tumor in the lower abdomen, this person will have no choice but to see it. Studies that involve reading scans covering the whole lower torso should obtain permission for so doing.

In response, researchers might wish to redesign their CT colonography scan software so that the only digital information converted to an image on the screen is information about the colon. If they are able to do that, then the permission they require would not be as broad and the corresponding ancillary-care obligations would shrink accordingly. I have no problem with that outcome in the abstract. What I *would* find morally troubling would be a case in which researchers pursued this sort of technological innovation *solely* for the purpose of evading the ancillary-care responsibilities that they would otherwise have. That would be like getting drunk at the beach, not for the enjoyment of it, but solely for the purpose of evading any obligation to rescue anyone who begins to drown. So to proceed, in either context, would be to display the vice of pusillanimity or mean spiritedness. I can well imagine, however, that modifying the software supporting virtual colonoscopies so that only the colon is displayed might well enhance this tool as a means of detecting anomalies in the colon, for this modification would get rid of a lot of potentially distracting images and let the viewer concentrate on what they are supposed to be looking for.

What about having an image such as a brain scan read by a diagnostician instead of simply by the researcher, as the researcher's training might be in psychology (or, nowadays, in philosophy), and not in medicine? Or, alternatively, what about doing a clinical-grade brain scan in addition to the cruder research-grade brain scan? Neither of these ways of adding to the diagnostic power and accuracy of a study's procedures is directly called for by the partial-entrustment model. The first, the optional diagnostic read, looks like a case of hunting for additional diagnostic findings. The second, the diagnostically tuned scan, could also be entered

into in this spirit; but it is more likely to have a different purpose, one that may also apply to the first option. Each of these additions to brain-imaging studies could be justified by the following blend of pragmatic and ethical argument:

Research scans always have the potential of hitting even the medically untrained reader in the face with an obvious anatomical anomaly. When this happens, the scan will have generated a concern that falls within the scope of the researchers' ancillary-care obligations. Researchers without diagnostic training, however, or researchers working from scans not appropriately tuned for diagnostic purposes, will have a much higher tendency to reach false-positive conclusions about participants' health, potentially wreaking havoc with their lives. In order to reduce this danger that the researchers' attempts conscientiously to fulfill their ancillary-care obligations will have negative, and even disastrous, unintended results, it is better to import some techniques of clinical medicine into the study.

This strikes me as a fully reasonable argument, but one requiring much fuller exploration of the many questions it raises. The sort of blending of research and clinical approaches it proposes, for instance, flies in the face of the clear separation of these enterprises for which Miller and Rosenstein argue. I cannot purport to offer closure here on these difficult issues about false positives and incidental findings; I hope only to have made clear what the partial-entrustment model of ancillary-care obligations implies about the issue.

Stepping back to take a broader view of the territory I have covered, what I hope above all to have established is that the streams of concern exhibited in the heretofore independently discussed issues of ancillary care and incidental findings do, in fact, flow together. They come together because a sound understanding of researchers' ancillary-care obligations will key them to what count, strictly speaking, as incidental findings. Incidental findings in the formal sense — the sense secured by Section 2's work with the slight, residual ambiguities in the definition from Wolf and her colleagues — are findings that arise from carrying out study procedures. It is precisely those findings that, according to the partial-entrustment model of researchers' ancillary-care obligations, give rise to a potential claim for ancillary care. Whether researchers actually have a duty to provide ancillary care of a given sort depends also on the additional factors I have lumped together under the heading of "strength." For instance, among the factors on which the strength of ancillary-care obligations depends is the one we called "vulnerability": how much difference would it make to a subject's health for the ancillary care to be provided? The more ambiguous the clinical import of a given incidental finding, the weaker the subject's claim to ancillary care. But there are also many other, situationally variable factors that affect the strength of subjects' claims to ancillary care. In ethical theorizing such as this, we can never afford to forget the tremendous concrete diversity of the cases from which our concerns spring. However, with regard to incidental findings and ancillary care, at least, we can gain considerable clarity by stepping back far enough to see how these issues join to form a mighty river.⁴¹

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2. One early such study is Katzman GL, et al. Incidental Findings on Brain Magnetic Resonance Imaging from 1000 Asymptomatic Volunteers. *JAMA* 1999;282(1):36–39. [PubMed: 10404909]
3. On this issue of false positives in this connection, see Illes J, et al. Ethics: Incidental Findings in Brain Imaging Research. *Science* 2006;311(5762):783–784. [PubMed: 16469905]
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5. World Medical Association Declaration of Helsinki (rev. 2004), at para. 29, available at 2008 <http://www.wma.net/e/policy/b3.htm> (last visited February 26,
6. Shapiro K, Benatar SR. HIV Prevention Research and Global Inequality: Steps towards Improved Standards of Care. *Journal of Medical Ethics* 2005;31(1):39–47. [PubMed: 15634752] See, e.g., Tucker T, Slack C. Not If, But How? Caring for HIV-1 Vaccine Trial Participants in South Africa. *The Lancet* 2004;362(9388):995.
7. One aspect of this tension, as it arises in a closely allied context, is thoughtfully explored in Merritt M, Grady C. Reciprocity and Post-trial Access for Participants in Antiretroviral Therapy Trials. *AIDS* 2006;20(14):1791–1794. [PubMed: 16954719]
8. This issue is addressed in Report from a WHO/UNAIDS Consultation, *supra* note 4 and Tarantola D, et al. Ethical Considerations Related to the Provision of Care and Treatment in Vaccine Trials. *Vaccine* 2007;25(26):4863–4874. [PubMed: 17466418] For an application to this issue of the approach to ancillary-care obligations that I developed with Leah Belsky and will here be summarizing and elaborating, see Richardson HS. Gradations of Ancillary-Care Responsibility for HIV/AIDS in Developing Countries. *American Journal of Public Health* 2007;97(11):1956–1961. [PubMed: 17901449]
9. Wolf SM, et al. Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations. *Journal of Law, Medicine & Ethics* 2008;36(2):219–248.
10. This parenthesis glosses what I take to be the intended import of “reproductive importance,” since the research participant’s own reproductive capacities fall within his or her health. Strictly speaking, of course, concerns about the health of already existent children do not fit under the rubric of “reproductive importance.” Still, incidental findings in genetic studies, in particular, can certainly arise that are highly relevant to the future health of already existent children.
11. To narrow the definition to rule out the IV/drug-abuser case, it would suffice to replace the phrase “in the course of conducting research” with “via the information-gathering means used in conducting research.”
12. Ratzen RM. Unsolicited Medical Opinion. *Journal of Medicine & Philosophy* 1985;10(2):147–162. [PubMed: 4009080] with a reply by Moseley R. Excuse Me, But You Have a Melanoma on Your Neck! Unsolicited Medical Opinions. 163170
13. Why not? The answer that will be supported by the substantive view I lay out below is that it is because no permission was needed from the participant in order to walk down the hall with them. For readers in doubt about this, however, I could change the case in the text back to the bus-stop context in order to bring out the ambiguity in question: “In the course of ” a study — that is, while it is still ongoing — a researcher might run into one of the participants at a bus stop and while there, notice what looks to be a melanoma on his or her neck.
14. Richardson HS, Belsky L. The Ancillary-Care Responsibilities of Medical Researchers: An Ethical Framework for Thinking about the Clinical Care that Researchers Owe Their Subjects. *Hastings Center Report* 2004;34(1):25–33. [PubMed: 15098404], at 26cf., Belsky L, Richardson HS. Medical Researchers’ Ancillary Clinical Care Responsibilities. *BMJ* 2004;328(7454):1494–1496. [PubMed: 15205296], at 1494.
15. See the discussion of the ethical requirement of “scientific validity” in Emanuel EJ, et al. What Makes Clinical Research Ethical? *JAMA* 2000;283(20):2701–2711. [PubMed: 10819955]
16. The Ethics of Research Related to Healthcare in Developing Countries: A Follow-up Discussion Paper. London: 2005. Nuffield Council on Bioethics; p. 33

17. For such reasons, and not merely reasons of limited space, we dropped mention of promises made for recruitment purposes from the definition we give in BelskyRichardson, *supra* note 14.
18. For example, although Wolf, *supra* note 9, note that incidental findings may arise more broadly, that consensus paper concentrates on high-tech imaging and gene assay cases.
19. Moira Keane's thoughtful presentation at the Minnesota conference suggested this.
20. Hellström M, et al. Extracolonic and Incidental Findings on CT Colonography (Virtual Colonoscopy). *American Journal of Roentgenology* 2004;182(3):631–638. [PubMed: 14975961]
21. On the basis of the analysis of ancillary-care obligations to be put forward in the next section, my position would be that noticing a melanoma during an enrollment physical on some part of the participant's body that is normally covered with clothing, brings it within the scope of the researchers' ancillary-care obligations, although spotting a melanoma on the back of a participant's neck while he or she is walking down the hall does not. While this differentiation may seem counter-intuitive, I explain the basis for the distinction in privacy concerns below.
22. I do not mean to assert that this professional obligation of medical researchers lacks analogues in other professions; indeed, I affirm that it does, and describe some analogues below in the text. Even so, this obligation of medical researchers, as I will explain it, seems to me to be self-standing in the sense that even if there were no other professions in which a like responsibility arose, this one would still exist. I am grateful to Franklin Miller for discussion of this point.
23. See RichardsonBelsky, *supra* note 14, at 26BelskyRichardson, *supra* note 14, at 1494
24. In a survey in the late 1990s of European adults about the case of a doctor who sees a black spot that he is almost certain is a melanoma on the face of a woman at a bus stop, only a minority of lay people (34 percent) thought the doctor should say something, while even fewer of the doctors surveyed (23 percent) thought so. Zwitter M, et al. Professional and Public Attitudes towards Unsolicited Medical Intervention. *British Medical Journal* 1999;318(7197):251–253. [PubMed: 9915739] In the text, I have described the example as involving a spot on the back of a person's neck in order to make it seem more likely that the person might not have noticed it.
25. In saying that there is this line to be drawn, I do not mean to be disagreeing with Sarah Buss's point that, in U.S. culture, the idea of minding one's own business has too much sway, leading us unduly to constrict our interpretation of our general obligations of beneficence. Buss S. Appearing Respectful: The Moral Significance of Manners. *Ethics* 1999;109(4):795–826.
26. See RichardsonBelsky, *supra* note 14, at 2627
27. Miller FG, Rosenstein DL. The Therapeutic Orientation to Clinical Trials. *New England Journal of Medicine* 2003;348(14):1383–1386. [PubMed: 12672867], at 1385.
- 28.
29. *Id.*, at 1386
30. Because the paternalism involve in constraining medical research with regard to ancillary care and incidental findings would be "soft" in this way, it would avoid the main brunt of the critical argument in Miller FG, Wertheimer A. Facing Up to Paternalism in Research Ethics. *Hastings Center Report* 2007;37(3):24–34. [PubMed: 17649900]
31. The point of this further stipulation is to put this surgery beyond the reach of the general duty of rescue, which is generally thought of as being limited to relatively easy interventions. If the case still seems to you to fall within the scope of the duty of rescue, please vary the hypothetical facts accordingly.
32. Herman B. The Scope of Moral Requirement. *Philosophy & Public Affairs* 2001;30(3):227–256., at 231.
33. My thanks to Aaron Marcu for the example, which I take verbatim from my unpublished essay, "Special Obligations of Beneficence: The Case of Medical Researchers' Ancillary-Care Obligations."
34. Some readers will deny that there is a moral difference between the cases because they hold that, in effect, that Marvin has a duty-to-rescue sort of duty to warn in both cases. To restore the difference between the cases, I would ask these readers please to adjust downward the urgency and stakes of the warning. I do agree that, when the stakes are high enough and the urgency extreme, the duty to rescue will supersede the difference that the two scenarios are designed to highlight.

35. At the Minnesota conference, Ellen Wright Clayton asked me what I would say about research that is done on the basis of tissues in tissue banks without collecting any permissions. That is an interesting question. If the tissue samples are not fully anonymized, then permissions should have been collected, if not by the researchers using the tissue bank, then at least by the researchers who collected the tissue in the first place. If those latter permissions included permission to do future research using the tissues, then perhaps the research participants should be taken to have waived any further privacy claims that pertain to the tissues. I gather that federal statutes would encourage this reading. If we understand things that way, then the researchers doing the research using the tissue bank may not be the same people as the researchers who agreed to be the recipients of otherwise private information. If that is so, there would be no partial-entrustment relationship of the kind on which my analysis focuses between the tissue-bank researchers and the initial tissue donors.
36. A principal reason for this rather cumbersome wording is that the permissions that researchers in fact collect from their study participants are often far more sweeping and inclusive than they need to be, whereas our analysis attempts to keep things focused on (1) what actions called for by the study protocol bump up against the participants' bodily and informational privacy rights and (2) what permissions the study design therefore requires the researchers to collect in order to proceed without violating those privacy rights. I come to an additional, complementary reason for this wording in my section in the text on the "Implications of the Partial-Entrustment Model for Incidental Findings."
37. For a much more detailed analysis of some of these "strength" factors in a particularly challenging context, see Richardson, *supra* note 8.
38. This is a question on which Participants in the 2006 Georgetown University Workshop on the Ancillary-Care Obligations of Medical Researchers Working in Developing Countries, "The Ancillary-Care Obligations of Medical Researchers Working in Developing Countries," *PLoS Medicine*, forthcoming 2008, makes a start.
39. Our analogy to the old common-law idea of bailment in RichardsonBelsky, *supra* note 14, at 28, has the disadvantage that it may suggest this reified interpretation of the scope of entrustment, since bailment is the limited entrustment of some valuable *thing*, such as an automobile. Our intention, however, was simply to use this analogy to introduce the idea of a limited and partial entrustment. I continue to think the analogy to bailment useful, as it illustrates how obligations can arise from voluntary transactions in a non-promissory way. See my Special Obligations of Beneficence. *supra* note 33.
40. See Hellström, *supra* note 20.
41. "The big muddy," the unsympathetic reader will nickname it. I cannot claim to have attained ideal clarity about these complex issues. I can only invite this reader to further improve our understanding of how these issues interrelate.