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by

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Experimentation on human subjects creates moral problems of some complexity. The great frequency of such experimentation, its importance, and its unavoidability press us to resolve these problems.

Thousands of medical experiments on humans are in progress at any given time; in most of these the risks to the subjects is slight, but in some it is substantial. Upon the outcomes of such experiments rest the hopes for advancement in medicine; the future well-being of very many human beings is affected, therefore, by presently imposed moral restraints upon experimentation. Experiments upon human subjects will not cease in any case. So long as there continue to be any advances in medical science, the results of research will be put to use on some human beings, somewhere, for the first time. Those will be experiments. The issue, therefore, is not whether we should permit such experiments -- they will certainly continue so long as medicine is not frozen in its tracks -- but what principles rightly guide such experiments, and what restraints are rightly placed upon them.

My aim in what follows is manifold. I shall explain some of these principles and constraints, in some cases defending, in some cases merely explicating, and in some cases exhibiting the tension between competing alternative views. The terrain I explore is extensive and boggy; I will achieve my principal purpose if I succeed in mapping its major features, giving a reasonably clear view of the whole, and identifying those sub-territories needing further reflective attention.

I shall be concerned chiefly with medical experiments; the testing of a new drug for a known disease may be taken as a paradigm case. But all that I shall say will bear, with appropriate adjustments, upon experiments pursued for any honorable purpose if the subjects are human beings. Whatever the sphere of experiment, the judgment of the justifiability of the risks run will require some technical knowledge of what is at foot. Yet the question of justifiability is not strictly a technical question at all. It lies in that special domain of moral issues that can be resolved--and indeed that can often be well formulated--only in empirical contexts well-understood. The task is essentially philosophical; yet without the cooperation of experimentalists any moral principles developed will have little concrete anchorage.

I divide my enterprise into four chapters. The first will be concerned with the foundations of the principle of consent. The second will undertake an explication of the principle of consent, and hence of the absolute protections to which potential experimental subjects are entitled. The third will be concerned with the task of determining whether (assuming consent obtained or obtainable) the experiment itself ought to be forbidden. The fourth will be concerned with three particularly delicate controversies that arise in connection with human subject use. I will conclude with a brief addendum on the problem of applying whatever principles emerge.

CHAPTER I: FOUNDATIONS OF THE PRINCIPLE OF CONSENT

It is now nearly universally agreed that the fully informed consent of every human subject is properly a precondition of all medical experiments in which such

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subjects are to be used. This principle has been proclaimed clearly in the Nuremberg Code, and adopted by the World Health Organization in the Declaration of Helsinki. What it entails I will examine below, but in a general sense everyone can understand and is likely to accept the principle. Human beings whom we seek to use as subjects ought to be asked first, and they ought not be so used if they do not give their consent freely. That seems a minimal demand of fairness.

But why? What larger moral convictions lie behind this principle? Since there is general agreement on the need for consent, this might be thought a needlessly theoretical question, if an interesting one. In fact, the answer becomes important when, as we shall soon see, the detailed content of "consent" becomes an issue. At that point the deeper grounds for the principle--if we can decide upon them--may help us to determine its content more precisely. What the concept means, operationally, depends in some degree on what the theories in which it is embedded seek to establish.

Three major alternative moral grounds for the principle of consent might be proposed. The first is strictly utilitarian. On this view it is simply the maximization of benefits to all--long-term and short-term-- that justifies the demand. If consent is not required it will often not be sought; if it is not sought, risks may at time be imposed upon subjects without their knowledge in ways that may subsequently cause great distress or controversy. The reports of such distress will make potential subjects, and many hospital patients, very suspicious of medical research, and may create a general atmosphere of distrust around medical investigation that will redound to the long-term disadvantage both of the research and of its potential beneficiaries. The need to obtain the consent of subjects will cause some researchers to refrain from undertaking unduly risky experiments which might have gone forward if that need had not been recognized. Moreover, the research itself benefits directly from the principle, since the assurance that consent has been given by subjects maximizes the likelihood of cooperation between subject and investigator, minimizes the likelihood of deliberate or negligent interference, by the subject, in the experimental process of which he is a participating element. In a host of ways, this argument concludes, the principle of consent is justified by purely utilitarian considerations.

Although appealing, this analysis leaves one unsatisfied. When the benefits to the subject are small or nil, but the risks run by them so great as to make their consent unlikely, it may yet be argued that a utilitarian analysis would justify the deceptive or forcible use of some subjects--if the long-term advantage to humanity were thought sufficiently great. Yet we all sense that such use--even if generally beneficial--would not be fair. Further, even if we were to agree that the calculation of benefits justifies the risks of the experimental procedure in a general way, the utilitarian approach may fail to distinguish the appropriate pool of subjects, or the appropriate distribution of risks among that pool. Not the calculation of benefits alone is before our minds when such matters are to be decided.

Of course utilitarian considerations may wisely enter in the application of the principle of consent, and will do so. But as its ground, two non-utilitarian moral approaches are more plausible. They are as follows.

Every potential subject may be viewed as having certain rights to the control and use of his or her own body. Using that body without the consent of the person whose body it is would be a violation of that person's right. The principle of consent insures that rights are not so violated. When the subject gives informed consent he waives, in effect, his right to exclude the researcher's invasion of his person. Because that waiver is an absolute prerequisite of the use of his person, the

principle that the consent of the subject must be obtained is an absolute one.

An alternative non-utilitarian account goes like this. Every human being, by virtue of his or her humanity, is an end, a locus of intrinsic personal value that cannot justly be treated as though it were not different from a dead tool. Human beings, Immanuel Kant taught, must never be treated as means merely, but always also as ends. This imperative is categorical; that is, it applies absolutely and universally whatever purpose we may have in view. It does not forbid the use of humans as means. It does forbid any use of them without their playing a role in the decision--a role to which they are entitled simply because they are human and are therefore members of the community of moral agents. Respect for this membership, when experimentation is the aim, requires the consent of the subject.

Between these two accounts I do not choose here. Both need to be spelled out in greater detail, and both have some difficulties. The categorical imperative, although very attractive, suffers notoriously from a formal quality that renders difficult the giving of empirical content to it in application. The supposition of rights possessed by each human over his person also encounters difficulties in application, and raises questions of moral epistemology that have perennially troubled philosophers. Recognizing these difficulties, it would still seem that on some such foundation (or both of these if the two prove consistent) the principles of consent is most solidly and most appropriately grounded.

CHAPTER II: EXPLICATION OF THE PRINCIPLE OF CONSENT

Assume the principle of consent granted, and grounded in some rational way. What does the principle entail? How shall it be cashed in practice?

I argue that the principle has, in fact, three component elements, each of which is absolutely essential. The first of these is information; the consent of the subject must be fully informed. The second is competence; the subject must be capable of giving consent in that situation. The third is voluntariness; the consent of the subject must be given freely, without duress or coercion. I look more closely at each of these elements.

(1) Informed consent. If one has not been told, or has been told falsely, what it is that may happen to him in a given experiment, he can hardly be said to have given consent to what does happen to him. So critical is this knowledge element that, in medical parlance, the principle in question has widely come to be called the principle of "informed consent." This phrase is infelicitous only because it emphasizes information so greatly as to obscure the role of the other two elements. If all three are to be attended to, the term "full consent" is preferable to "informed consent"--or better yet we may say, simply and rightly, "consent."

Whatever the term chosen, however, it must be clear that much more than a formality or a signature is involved. For his or her full consent the potential subject must indeed be informed. But of what? What must we tell him? What must he understand? It is obvious that his understanding of the experiment, its aim and its details, will inevitably be very far from complete. To require digested information at a level approaching that of the medical scientist himself is evidently absurd, but neither must we condescend. The general rule, easier to formulate than to apply, is this: we must give the potential subject information adequate, in content and form, for a reasonable person to make rationally the decision he is called upon to make: whether to participate as subject or not.

This general statement can be given a good deal more specificity. The subject

must be given the information any rational agent would need, information that would answer questions of the following kinds:

(a) What is the general purpose of the experiment? Full consent to participation supposes that the larger objectives of the enterprise are known. Those objectives can and must be clearly conveyed.

(b) What must the subject expect to happen to him, in the course of the experiment, as a result of his participation? What procedures will he be involved in, what drugs or injections will he be given, what tests made, etc.?

(c) What risks, if any, does the subject run? What adverse side-effects may be anticipated, or feared, and with what degree of probability? What discomforts or temporary disabilities are likely to ensue as a result of participation?

(d) What benefits, if any, may the subject anticipate, or hope for, with what degree of probability?

(e) Does participation in the experiment involve, for the patient who is sick, any changes from the normal treatment of his condition? If so, what are the differences in treatment being agreed to, and what are their likely consequences, to the best of present knowledge?

(f) Who is paying to support this research? What costs, if any, may be imposed upon the subject?

(g) May the subject withdraw from participation, or decline to participate in the first instance? All potential subjects have the right to withdraw or decline--a corollary of the principle of consent itself; their possession of that entitlement is something of which they must also be informed, lest it be inferred by them that some duress to give consent is being applied.

Because potential subjects are often patients themselves, and because their relations with doctors and other health care personnel are likely to be anxiety-creating, all needed information in the categories above should (save where the risks are utterly trivial) be conveyed in writing, so that the subject has an opportunity to make a deliberative choice. And the written account of the procedures, risks, benefits, and so on, must be in language clear enough for the ordinary subject to comprehend.

In sum, consent is informed when the potential subject is given full opportunity to know what an ordinary person would have to know to make a rational choice about whether to serve as subject or to refrain from doing so.

Informing the subject entails the clear and adequate provision of the facts. The subject should have opportunity to raise questions about the facts important to him, and is entitled to answers as full as accurate as the investigator's knowledge permits. Help in understanding what is needful is what is required. But informing the potential subject does not entail being certain that the person has, in fact, mastered the information provided, that he does remember and does comprehend all that has been provided. That some persons will not attend to or recall information essential for rational choice is a fact investigators may know, and may seek to overcome. The potential subject must be treated fairly; it is not part of that fairness that the subject's own steady rationality be guaranteed.

(2) Competent consent. The consent of the subject must be more than informed; it must issue from one who is capable of digesting the needed information and of directing his or her own conduct at a reasonably mature standard. If the potential subject is too young to appreciate the risks involved, or unable to understand the written account, or if the subject is too disordered in mind to make rational choices, consent will not be genuine even if it appears to issue from that incompetent person.

Here enter questions both of legal competence and of moral competence. They greatly overlap, of course, since the legally incompetent are distinguished, as a class, mainly in order that persons who are morally incompetent (by reason of age or other cause) be the better protected. I attend here and below not to the law, but to the principles that should govern the formulation of the laws.

(3) Voluntary consent. The consent of the subject must be more than informed and competent. It must be freely given. Of all the issues surrounding the principle of consent, this is perhaps the most tangled. Philosophers have been perennially concerned to underscore the importance of voluntariness in action, and perennially pained by the difficulties in drawing precisely the boundary line between the voluntary and the involuntary.

There are, obviously, degrees of duress. At one extreme I may do of my own will what I must do to avoid great hurt or loss immediately threatened. I choose to hand over my wallet when the armed robber presents me with his alternatives: "Your money or your life!" At the other extreme I may do without any determination of will whatever (inhale, cough) what I would do gladly and voluntarily on request without duress of any kind. A moment's reflection is sufficient to realize that it is not easy to say precisely what coercion is, or when the line between the voluntary and the involuntary has been crossed.

Yet we all have a pretty good feel for it. Potential subjects ought to have the power of choice protected insofar as circumstances permit. Whatever erodes or restricts that power and can be avoided ought to be avoided. Force or threats or pressure of any kind, designed to manipulate the subject's will, are to be scrupulously avoided.

In the concrete this means that the investigator seeking subjects for research must avoid all forms of manipulative behavior. He must not suggest that refusal to cooperate will be penalized in any way, nor must he, by the tone of his request, suggest that refusal is a selfish or otherwise immoral act. He must protect, so far as he is able, the potential subject's power of unmanipulated choice.

Problems remain. Manipulation takes many forms, some of which are coercive, in being ultimately reducible to some threat of bad consequences if consent not be given. Whatever the particular content of the threat (refusal to treat, or to admit, or whatever) coercion must be completely foresworn. Its target is the very freedom that genuine consent supposes. Some manipulation, however, is more accurately viewed as enticement than as coercion. Not all rewards for participation are enticing; many will be no more than bare recompense for inconvenience or discomfort. Paying volunteers, therefore, is not necessarily an undue enticement, nor are the other benefits that may accrue to the subject necessarily to be eliminated. Still, depending upon the circumstances of particular subjects, inducements may be so great as unfairly to manipulate the subjects' wills. Very large sums of money to inveigle indigent persons into the assumption of great risks, for example, may be improperly manipulative even when not coercive in the strict sense. The term "coercion" is often used to include the class of improper enticements, but is better restricted to manipulation grounded on threat. This terminological variation must not obscure the difference between the two classes, or their likeness. By threat, or by excessive inducement, the voluntariness of consent may be eroded. Fairness requires that both be avoided.

What cannot be avoided, however, are the differing circumstances of potential subjects. Some people are in circumstances in which participation as an experimental subject is attractive to a degree that it is not attractive to others. Sick people may be much more disposed to participate in an experiment—even a risky

one--aiming at a cure for their illness than those who do not suffer from that illness. Wealthy people may be less influenced by offers of small sums as compensation for inconvenience than are poor people. We cannot reasonably say that people--sick or poor or whatever--are coerced (or manipulated) by their conditions. All of us are in conditions making some choices more attractive and others less. If coercion be treated too loosely it swallows all conduct, whereupon voluntary consent becomes impossible for anyone--and the distinction between voluntary and involuntary consent for which we are seeking is unhappily obscured.

Although the ways in which conduct may be manipulated are various, not everything that influences conduct manipulates it. Circumstances affecting the subject's choice for which the investigator has no responsibility are not to be taken as coercive just because they are influential. On the other hand, the exploitation of persons in specially delicate circumstances may be unfair. When, if ever, is an offer in itself exploitative? I will return to this question, giving a partial answer, in Chapter IV, below.

These, then, are the three essential elements of full consent: information, competence, and voluntariness. By safeguarding them we apply the principle of consent in such a way as to give to potential subjects the protections they are universally entitled to.

CHAPTER III: FORBIDDING EXCESSIVELY RISKY EXPERIMENTS

The protection of human subjects must go beyond those absolute protections flowing from the principle of consent. Protections of another sort--"relative" or "institutional" might be the terms used to identify them--are also called for. To see that this is true we need only observe that not every proposed experiment involving human subjects ought to be undertaken. While the presumption of freedom of inquiry for the professional medical investigator is a weighty one, we are all likely to agree that, even where the consent of the subjects could be garnered, some experiments on humans should not be performed at all. Why not? Which experiments are rightly forbidden, and why?

Of all the terrain being charted in this paper, this is the portion least well explored to date. That there lies a duty on the part of those who would conduct research to constrain that conduct within certain moral bounds, to apply to any proposed research moral principles of general force, is universally agreed. But there is little agreement upon the content of such principles, or upon their grounds. In what follows I make an attempt to mark out general features of the constraints rightly applied.

Here, as in seeking the foundation of the principle of consent in Chapter I, the thrust is both utilitarian and deontological--looking to consequences and to antecedent right. But in this sphere differing principles resulting from the two foundations differ widely in content. They may conflict at times, but even when they do not they have very different targets.

On the utilitarian side the general aim is easy to formulate, but not always easy to achieve. It is to calculate the risks and the benefits of the experiment proposed, and to permit or restrict in the light of that calculation. Of course such calculations cannot, at the time of the research proposal, be made with precision, involving as they do judgments of merit and demerit that may be controversial, and depending as they do upon estimates of probabilities that are unavoidably crude. The resulting porous character of the concept of a "risk-benefit balance" ought not be forgotten,

but neither should it be overblown. Impossible though it may be to quantify the elements in such a calculation, it remains possible for reasonable persons to reach defensible utilitarian evaluations of particular experiments in the vast majority of cases. The evils of discomfort or minor risk for a few (always supposing their full consent) may be clearly outweighed by the good of the knowledge anticipated, and the weighing, in most cases, never even needs to be thought of in quantitative terms. Where the value of the expected goods declines, or their likelihood diminishes, while the magnitude of the risks required to seek it increases, or their likelihood increases, the tasks of calculation become more troubling. Sometimes our data are insufficient to make any reliable estimates of the probabilities of the several possible outcomes--whereupon the task of calculation becomes agonizing.

Yet that task must be performed if the moral judgment is to be made. And in fact we do perform it, individually or institutionally. We make the needed judgments as best we can, weighing good oranges against bad apples, and using subjective estimates of probabilities where the quantitative data are unobtainable. We cannot avoid making the requisite utilitarian calculations. If we propose to bypass them we do no more than allow the decision to ride upon other hidden consequentialist considerations--cost, convenience, personal preference of the investigators, or the like. At some point the moral agent whose conduct involves the well-being of others must ask himself or be asked whether the experiment is worth doing. Requiring that considerations of risk and benefit enter the resolution of that question is no more than a demand for a fully rational treatment of the issue, a demand that all relevant factors be considered. The experiment will be forbidden or it will not be. In coming to that decision we must do the best we can.

Because medical experimentation usually has an institutional setting--taking place in a hospital, a research center, etc.--the task of imposing any needed restraints normally falls to some institutional authority. The bodies that make such determinations presently--institutional review boards (IRB) is their generic name--make moral judgments that represent the institutions within which the experiments are proposed. Restricting the inquiry of its members is a distasteful, but occasionally an essential institutional task. A good deal of attention has recently been given to these institutional review boards, their makeup, procedures, and powers. The underlying principles upon which these reviewing bodies act, however, present a moral (as distinct from an administrative) problem. Even if there were no such institutional bodies (and only two decades ago there were virtually none) the same moral issues would be faced by individual researchers.

Two conceptual distinctions make the task of utilitarian calculation somewhat more manageable--or at least put its difficulties into clearer relief. The first, very commonly employed, is the distinction between what are called therapeutic and non-therapeutic experiments. The point of this distinction is easy to see, even if a given experiment may occasionally be hard to place with respect to it. The aim of a medical experiment is commonly to devise or improve means for the treatment of some known disease. To test the efficacy of the newly proposed drug (or instrument, or procedure, etc.) tests are often run among populations of subjects suffering from that disease. If the means experimented with are indeed more efficacious than previously used therapies, some of the subjects in that experiment may themselves benefit from the try. Such experimentation is called therapeutic. The same experiment may be using populations of healthy normal subjects as controls, and since no therapeutic advantage can be anticipated for them, it may, with respect to them, be viewed as non-therapeutic. Many experiments are entirely non-therapeutic. There are middling cases, too, as when the subject population is

suffering from a disease whose ultimate elimination is the object of the experiment, although the experiment itself cannot yield direct therapeutic benefit to any of its subjects. All this has to be sorted in practice. What needs recognition here is that the utilitarian calculations must weigh the possible therapeutic advantages to the subject, as well as the absence of such advantages where they are absent. Where placebo controls are used, in blind or double-blind experiments, it is the possibility of such therapeutic advantage for some that must be weighed.

The entry of therapeutic considerations can alter the appraisal of risk-benefit balance dramatically in some circumstances. When the subject population is very, very sick--near death or afflicted with terrible pain--the probabilities of success that will justify the use of drugs or procedures known to be risky will be proportionately lower; or, given the known likelihood of unpleasant by-product, the seriousness of that unpleasantness may be proportionately greater. The general form of the calculation is a balancing of the sum of the negative outcomes surmised, each multiplied by the estimated probability (objectively or subjectively determined) of its occurrence, against the sum of positive outcomes anticipated, similarly discounted. Where the subjects are in dire straights, and all other treatments of their illness have proved ineffective, even temporary remission of the disease may loom so large as a factor on the plus side that negative factors intolerable in experiments with other populations are in these cases outweighed.

A second distinction--also much used, but seldom well formulated--is that between two different kinds of obligation owed by the research investigators. We are seeking grounds for a moral judgment; the fulfillment of moral obligations by the investigators counts heavily in making the needed judgment. To whom are obligations owed by them, and with what weight? They are owed, I submit, to parties in at least two different kinds of circumstances. [I omit here consideration of obligations that may be owed to the funding agency, the home institution, etc., as being of lesser, although not trivial concern.] Obligations are owed to the actual human beings who serve as subjects in the experiment at hand. We know who they are, can (usually) have discourse with them, and can make a pretty accurate estimate of whether they are being treated fairly. Obligations are also owed--perhaps by all persons, but certainly by the physician-researcher--to those many persons who now suffer or will suffer from a disease that it is the researcher's profession to help cure. Persons in this category are (for the most part) not now identifiable. We may not be able to name them or speak to them; we are not sure how we will relate to them; yet they, too, must be treated fairly.

The contrast here is that between what Kant called "perfect" and "imperfect" duties. If I borrow a book from a friend promising to return it the next day, I have a perfect duty--a known and circumscribed obligation to perform a specific act (returning the book) with respect to a specific, known person (its owner). But I have duties also--imperfect ones--to protect the rights of my fellow citizens, to aid the injured and comfort the sick. To fulfill such duties I must act in ways that cannot be clearly specified in advance, and which therefore depend upon my circumstances and unknown future relations with other persons. Much of the tension in calculating the risk-benefit balance of a proposed experiment in close cases is the pull between perfect duties of a certain kind, owed to the known subjects, and imperfect duties of an uncertain kind, owed to unknown future patients. One who does not himself feel the duties taken on by the physician-researcher may more readily identify himself with the actual subject of the experiment, whose identity and circumstances are vividly known, and may come thereby to place too much emphasis upon the perfect duties of the

investigator, to the pain of distant others. The research scientist, driven professionally as well as personally to seek therapeutic means of general and long-term usefulness, may be tempted to place too much emphasis upon the imperfect duties of the investigator, to the pain of an immediate few.

There is no algorithm to resolve this conflict. Its unavoidability is a good reason to have the needed moral judgments reached through the deliberation of bodies on which both tendencies are represented. Recognizing the tension is far from enough to insure its wise resolution. But failing to recognize it is an invitation to utilitarian miscalculation.

Thus far I have been speaking (in connection with the moral judgments going beyond the matter of consent) only of the utilitarian calculations of risk and benefit by the researcher or the institution. Some constraints introduced, however, appeal not to consequences but to fairness or rightness.

These deontological constraints enter at a different level from those based on risk-benefit; they are likely to be thought of as boundary considerations marking out the area within which utilitarian calculations may go on. In this respect they are like the principle of consent discussed above. But unlike the consent principles, these must be formulated not with regard for the particular potential subject as the moral end or bearer of right, but with regard to justice in society at large. Even supposing consent, (we now ask) are there not proposed experiments that ought to be forbidden because their aims or procedures are not morally acceptable? Some such there will be, but it will not prove easy to state the principles on which such judgments must be made.

Two kinds of principles, I suggest, properly guide us in setting out the boundaries here. The first attends to the fairness with which the burden of risks is to be borne; the second concerns the rightness of the purpose of the enterprise. I will say a little about both.

(1) Equity. If the advance of medical science entails some risks to some subjects, it is a demand of fairness (possibly a demand whose satisfaction reduces utility somewhat) that those risks be distributed in such a way that no group or groups within society be singled out for the carrying of the burden. The risks cannot be spread with perfect evenness, of course, but the precarious circumstances of some groups (identifiable by class or employment) render them vulnerable to an excessive share of the load. Each subject in the group in question may indeed give full consent, yet the group may have been unjustly targeted. Examples of groups sometimes so exploited are students in and around a modern medical center, and the indigent sick in public institutions.

Some cautions are in order here. It should not be supposed that because a group does in fact bear a numerically disproportionate share of the experimental risks that it has, *ipso facto*, been unfairly treated. Reasons of a scientific sort may account for the distribution; or reasons of a practical sort may convince a reasonable person that no fairer distribution of essential risks could be achieved. Unfairness must be guarded against; numerical disproportions do not in themselves provide reliable evidence of unfairness. On the other side, it should not be supposed that a group is treated unfairly only if there had been a malicious intention to burden them while protecting others. That intention would be unconscionable, of course; but even without any malice whatever there may be unfairness springing from careless inattention to inequity. Fairness in the feasible distribution of risks must be thought of in material as well as formal terms. That is, we must consider the moral quality of the concrete result of any procedure for the selection of a subject pool, as well as of the moral quality of the intentions of those who propose and execute

it.

(2) **Purpose.** Wrongness of aim, as well as unfairness in risk distribution, is a proper consideration of the agent, whether individual or institution. Moral restrictions bearing upon purpose rarely ever occur to the individual medical investigator. Insofar as he pursues his inquiry in the spirit of his profession he has, understandably, little reason to be troubled by such matters. But institutions do have reason for concern because their members occasionally misbehave, sometimes acting with wrongful means. Experiments may be proposed whose larger purposes are inconsistent with the aim of the institution; or their ulterior motivation (usually financial) may be outweighing the central aims of the institution; or the object of the experiment may be intrinsically immoral. It is silly to exaggerate the frequency with which scientists are called upon to advance the development of instruments of destruction, or injury, or death--but neither can such circumstances be entirely ignored. It is not my purpose to formulate the rules determining what are and what are not permitted objectives or research, but some observations will help to delineate the tasks of judgment here.

First, some objectives may be defensible in large, yet indefensible in a specific institutional setting. National interests may conceivably justify the development of anti-personnel weapons; but even if such weapons are justifiable, experiments aimed at increasing their mutilatory capacity would be unjustifiable in a university hospital. Individuals have obligations partly as a consequence of their conscious institutional commitments. What a citizen may rightly do in one institutional context he may rightly be forbidden to do in another. Second, some objectives may be morally indefensible in every context. Within our lifetimes there have been national purposes, vigorously pursued, to which no person could contribute with moral honor. Governments, including our own, may sometimes be very wicked; individuals and institutions within them may--painfully--be morally obliged to refuse cooperation in advancing evil ends. The judgments required in such circumstances are far from simple; I only observe here that there are some moral boundaries within which utilitarian calculations properly transpire. The boundary judgments may have to be made by persons or committees different from those called upon to make the risk/benefit calculation--but that should not obscure the underlying need for moral judgments of both kinds.

CHAPTER IV: SPECIAL THEORETICAL DIFFICULTIES

Three moral controversies of particular delicacy are unavoidable where experimentation upon human subjects is regularly undertaken. One may better understand why these controversies must arise, and what the kinds of considerations are that properly weight in resolving them, by reflecting upon the conceptual map thus far drawn. The three essential components in the full consent of the human subject have been identified: information, competence, and voluntariness. The three unavoidable problems I now address are those which arise when, for honorable reasons, we seek to pursue experiments on human subjects whose consent, for reasons plausible on their face, is deficient with respect to one or more of these components. Sometimes subjects are deliberately not given all the information they might reasonably want or need: the problem of deception. Sometimes subjects are simply not able to consent, and others are called upon to make the decision for them: the problem of third-party consent for children and others. Sometimes subjects are so vulnerable to manipulation that the voluntariness

of their consent is brought into question: the problem of coercion of prisoners and others. Brief remarks--again without the aim of presenting solutions--on each of these three controversies are in order.

(1) Deception. Some moral philosophers have taught that one ought never lie, whatever the circumstances. If that be thought too extreme a position, it will at least be agreed that there is a very strong, prima facie obligation not to lie, or otherwise deliberately deceive another. Like the principle of consent discussed in Chapter I, this principle could be defended on utilitarian grounds: deception is often exposed; the distrust engendered by its exposure is likely to have adverse effects on all parties directly involved, as well as upon the parties who might have benefited from research which (as a consequence of that distrustful atmosphere) never is carried through, and so on. The argument has merit, as in the earlier case, but again it is doubtful whether, on such utilitarian grounds alone, the presumption against deception would be as strong as we commonly take it to be.

Indeed, the principle of consent itself seems to carry truthfulness in its train. If we are committed to the view that no one should be subject to an experiment without having given his consent, we may conclude that such consent is possible only when a true and complete account has been given to the subject of what he is asked to subject himself to. Else he cannot be said to have consented to that. Here, precisely, lies the tension between the principle of consent, on the one hand, and the need of some investigators to hide from the subjects the aim of their enterprise of some critical element within it. For some inquiries do require deception for their practical success. Are the results sought by these inquiries ever worth the deception needed to obtain them?

Degrees of deception should be distinguished. There is a moral difference between telling a potential subject an outright lie, and telling him or her less than the whole truth. All the facts cannot ever be related, so the decision as to which details (because they are inessential) may be left unreported must be a matter of judgment. But it is not hard to determine when that need for judgment approaches the point of deliberate deception. Without strong reasons to the contrary, we would insist that all be reported which, for an ordinary person, might reasonably be weighed in making the decision to serve or refrain from serving as subject. Although there are degrees of deception, we may (for present purposes) clump the deliberate refusal to reveal facts known to be critically relevant with outright lies; both would be morally wrong unless compelling moral reasons can be given in their support.

We supposed, a while back, that the obligation not to deceive was prima facie. If it were absolute, in the Kantian spirit, there would be no need for further discussion, and indeed no remaining moral issue. But we mean, by prima facie, that such obligations may be overridden by other obligations. Our moral situation, after all, is rarely so simple as to have but one component pressing in but one direction. If the components are several, the duty resulting from their integration and balancing may be to do what, in the abstract, we have a strong prima facie obligation not to do.

So it is here. May there be reasons to deceive strong enough to outweigh the obligation not to do so? There seems to be no way to reply to this question without weighing the object of the proposed inquiry, determining those whom it will serve, and how it will serve them, and what our obligations are to the beneficiaries of that deceit. Two comments may illuminate that weighing somewhat:

(a) The reasons supporting deceit--if the case is to be made successfully--must be moral reasons, as distinct from merely technical ones. It is undoubtedly true that, especially in some psychological investigations, the truthful telling to a subject of

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the nature of the results sought in experimenting on him renders it impossible to get those results. For some experiments, deceived subjects are essential because knowing the aim of the inquiry must distort the subjects' responses within it. By itself, however, this fact does not serve as justification for the deception entertained. For that justification (if there is one) we need to hear the reasons those results are wanted. The quest must have a substantial moral dimension.

What might serve? Consider the following hypothetical case. Suppose, to test the comparative efficacy of three pain relieving drugs, one of which is quite new, it is essential to deceive the experimental subjects, all of whom are told that, for their post-operative pain, they will receive "pain-killers"--but are not told that they are being used as subjects in which their reactions under the influence of the differing substances will be very carefully monitored and compared. Suppose that this deception is introduced only because it is essential to determine the true impact of the substances being tested, and because the slightest suspicion that one is an experimental subject is likely to distort his responses to pain. Suppose also that the greater efficacy of newly developed pain-relievers is truly sought in the interest of the comfort and healing of very many future patients. Is deception, in itself innocuous yet knowing and deliberate, justified in such a case? Any answer depends upon the resolution of the tension between obligations owed to the experimental subjects and obligations owed to future patients--duties perfect and imperfect.

(b) The need to weigh the obligation owed to the potential beneficiaries of the experiment points to a critical difference between deception in this context and deception in the normal therapeutic context, where the half-truth or the lie is used by the physician in what he honestly believes to be the good of the patient for which he, the therapist, is in part responsible. Treating reports as though they were a kind of medicine, he administers them in quantities, and at times, calculated to advance the patient's welfare. In such contexts also the component obligations may be multiple, but insofar as they all bear upon the well-being of the same moral claimant, the patient, those components may be the more readily integrated.

(2) Third-party consent. Complications in this sphere are many; I mention only some of them. If we begin with the premise that some experiments involving children and other persons incompetent to give consent are absolutely essential (because some experiments involving such subjects must be pursued for moral reasons--to make the better care of children possible) we are obliged to allow that, for some such persons, third-party consent will suffice. That only sets the problem, however. We cannot suppose that wherever subjects are used for whom third-party consent would be required, the fact of that requirement is itself the guarantor of the moral authority of the (most appropriate) third-party. What authority third parties have is a delicate question. Aside from all legal issues, we must consider two kinds of limitations that might restrict such moral authority.

The first kind flows from the moral role of the third parties. Do they serve as proxy for the incompetent? That is, do they properly make the decision (to participate or decline) as they suppose that incompetent would decide were he or she able to deal with the request made? Or do third parties serve as moral guardians, making the decision appropriate for one in the circumstances of that incompetent, without needing to determine what, in fact, that person's judgment would have been if it were feasible to obtain? The distinction here is important. For one who decides on behalf of an adult who is temporarily incompetent, it seems proper to do so within the limitation of inclinations or wishes expressed by that incompetent during earlier periods of competence. Here the role of proxy is supposed. When, however, the incompetent is a child of very tender years, the child's irrational fears

of very minor hurts may be properly overridden. Infants can hardly be said to have any clear inclinations in such matters. Here the role of moral guardian--making the judgment that one who is competent ought to make, all things considered--is supposed.

If we grant, arguendo, the role of moral guardian to third parties in at least some circumstances, we do not justify the inference that they therefore have absolute discretion in the affair. The corpus of that incompetent--infant or other--is not theirs to dispose of without principled restrictions. What restrictions? What constraints must third-party moral guardians act within? This philosophical thicket needs further exploration. To appreciate some of the difficulties, consider one constraining principle that has been proposed: that third parties may give consent for incompetents under their guardianship when the experiment in view is therapeutic (i.e., where there is potential benefit for the incompetent subject) and the possible benefit at least balances the risks incurred, but [this principle continues] consent may not be given for experiments upon the incompetent of a non-therapeutic kind. The argument in support of this principle goes like this: In non-therapeutic experiments the risks, however minor, cannot be balanced by benefits, and it is not within the moral authority of any third-party to be altruistic with the corpus of another human being, even his or her own child. Plausible though this principle (and its defense) may seem, it would in fact prove intolerably restrictive, rendering impossible the conduct of many vital experiments requiring the use of healthy normal children as controls. The proposed principle would have the effect, therefore, of putting children in general in an even more disadvantageous position that they now are with respect to the availability of promising pharmaceuticals and other new therapies. The proper constraints upon third-party moral guardians, I conclude, require a great deal more deliberation.

All this is with respect to limitations arising from the role of the third-party. A second kind of moral limitation arises from the expressed desires of potential subjects who, although incompetent, may yet be mature enough or sane enough to express clear preference. Eight-year-olds, twelve-year-olds, surely fifteen-year-olds, may have strong and rational views about their participation in some experiment--objecting to it perhaps, or favoring it strongly. How is that voice to be weighed? One plausible view is this: that the child's desire to participate (his "assent" as distinguished from "consent") not be permitted to override the moral guardian's veto, but that the child's refusal to give assent be weighed heavily, if not dispositively, should it conflict with the affirmative judgment of the guardian. How heavily that refusal should then weigh is not easy to say in general; we would need guidelines respecting age (say, that the participation of a subject fourteen years of age or over will not normally be allowed without the subject's assent, in addition to the moral guardian's consent); guidelines respecting the seriousness of risk (say, that the refusal of assent be weighed more heavily as the risks of the proposed experiment are the greater); and guidelines respecting the therapeutic potentiality of the experiment (say, that the refusal of assent be weighed the less seriously as the potential therapeutic benefits of the experiment are the greater). These are no more than exploratory suggestions, efforts to chart a territory so far largely uncharted. Such guidelines require moral substantiation, of course.

A final complication regarding the moral status of children as research subjects deserves remark. Some argue that in experimenting upon children the central ethical concerns are not the rights of the child, but the obligations of the parents. On this view the parents have heavy duties of care for the child which include the duty to see to its proper education and healthy growth of character. They are

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obliged, therefore, to protect the child, and also to introduce it to the world of participation in common and mutually supportive enterprise. What constrains the third parties, on this account, is not to be viewed as flowing from a putative claim of the incompetent, but as flowing from the assumption of parental duties, where the proper fulfillment of those duties requires the integration of conflicting demands.

(3) Coercion. Whenever prisoners or other precariously placed persons are the potential subjects, we may ask whether that precariousness renders genuine consent impossible. I have discussed the many complications in this region of our territory at substantial length elsewhere. [See, C. Cohen, "Medical Experimentation on Prisoners," Perspectives in Biology and Medicine, Vol. 21, No. 3, Spring, 1978.] It will therefore be sufficient to recapitulate, without entering the argument, the conclusions reached there.

Coercion is a concept philosophically complex; the word itself is often used loosely and with different senses, as I have shown in Chapter II, above. I contend that the sense in which prisoners (or servicemen on active military duty, or students in classes, or employees of drug companies, or indigent patients in public clinics) are unavoidably exposed to coercion is not the same sense of coercion in which, if it were present, their consent would be vitiated. In sum, the looser sense of the term—in which sense we are all "coerced" by our circumstances, by the perils or boredom of an uncooperative environment—is often unhappily confounded with the narrower, more critical sense, in which one is coerced when one is subjected to deliberate threat by others. Consent that is coerced in that narrower sense, or that is otherwise the product of manipulation by deceit or improper enticement, is not truly voluntary. To be sure, manipulation is easier when the pool of potential subjects is vulnerable as students or prisoners are. But it is simply a mistake (I refer my readers to the full defense of this conclusion in the essay mentioned above) to suppose that persons so precariously placed are incapable of giving voluntary consent. Prisoners, indigents, and others need special protection because of their vulnerability; they do not need to be patronized.

I contend, further, that to suppose such populations incapable of giving consent is not to protect them, but seriously to damage them by refusing them a measure of moral autonomy to which they are, as human beings, morally entitled. Moreover, the moral value of the results of experiments in which prisoners serve as ideal subjects (because of the possibility of the control of experimental conditions over prolonged periods) is exceedingly great. That value must also be weighed in determining the rightness of a rule that would forbid the use of prison (or other) populations. But all of this is territory that has been explored; I leave the reader to refer to those other (I think reliable) charts.

This completes what I shall say here about the special theoretical controversies arising in connection with consent—those pertaining to deception, incompetence, and coercion.

Whatever moral principles are proposed in this sphere, they must face difficulties in application and enforcement. These are chiefly administrative, not philosophical problems; but one practical addendum, promised at the outset, has a philosophical edge. It is this. The realities of medical investigations, the special moral relations between doctors and their patients and between researchers and their subjects, are such that no guiding principles can be expected to receive respect in practice unless their rightness wins the rational assent of at least a substantial majority of the scientists expected to act upon them. Efforts to police principles that cannot be effectively defended on moral grounds must fail in the long run, and will be likely

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to alienate many scientists, thereby seriously interfering with the appropriate introduction of moral concerns into the experimental enterprise. I conclude that our principles in this sphere must not only be right, but that our arguments in their behalf must be cogent and persuasive. Only with that foundation can the needed blend of technical judgment with moral sensitivity be harmoniously achieved.