INTRODUCTION: TWO MODELS OF INFORMED CONSENT

In Chapter 1 we argued that current thinking about informed consent, its justification, scope and standards, is problematic in a number of ways. We suggested that it would be profitable to 'rethink' informed consent. In Chapters 2 and 3 we explored two distinct models of information and communication. These models, in turn, support distinct approaches to informed consent. We shall argue in this chapter that although each model supports an account of the justification, the scope and the standards for informed consent, the conceptions of informed consent that emerge from these models differ in important ways. These differences have powerful implications for biomedical practice. By making explicit two different conceptions of informed consent, we pave the way for 'rethinking' informed consent in this chapter. In the chapters to follow we then shift from general and abstract theorising about communication and consent to a number of specific and concrete issues where informed consent is of key ethical importance.

The 'standard' way of thinking and talking about information and communication is, we suggested, the conduit/container model. When information is discussed in terms of the conduit/container model, it is thought of in abstraction from agents and from the speech acts by which they communicate. When we rely on this model, we think of information as 'flowing' or being 'transferred' between agents, who are thought of quite abstractly as 'originating' or 'receiving' messages. The message or content is highlighted, but the act of communicating is hidden.

By contrast, when we view informing or communicating in terms of the agency model, we focus not only on content, but also on the speech acts by which agents communicate proposals, understand others' proposals and respond to them. The agency model takes account both of what is said (the speech content) and of what is done (the speech act). It provides a framework for recognising the transactional or interactive character of successful communication.

These two models of communication support different conceptions of informed consent. As we saw in previous chapters, the conduit/container model of information fits well with a view of informed consent that focuses on disclosure for decision-making. A disclosure-based account of informed consent requires those who seek consent to ensure that the relevant information flows to — is disclosed to — those who have to decide or choose whether to consent. This selective emphasis on disclosure for decision-making highlights some aspects of consent requirements, but also hides much that is essential to giving and refusing consent. By contrast, an agency model of communication locates informed consent in communicative transactions between agents. It provides a framework for a transactional model of informed consent, which emphasises what is said and what is done both by those who request consent, and by those who respond by giving or refusing their consent.

A transactional account of informed consent, we shall argue, has a number of advantages. It provides a basis for deeper and more plausible justifications of informed consent than the autonomy-based justifications typically used to support accounts of informed consent that centre on disclosure-for-decision-making. A transactional account of informed consent also provides the basis for a convincing account of the scope of informed consent requirements, and for a plausible and differentiated account of the standards they must meet. In the following sections we shall first rethink the justification for consent requirements, and then reconsider their scope, and finally rethink the standards that they must meet.

WHY CONSENT TRANSACTIONS MATTER: BEYOND AUTONOMY

We begin our rethinking of informed consent requirements by returning to questions of justification. It has become conventional
to justify informed consent as a way of ensuring that information is disclosed to those who have to make decisions, thereby (it is hoped) allowing them to exercise their individual autonomy. However, as we argued in Chapter 1 under 'Improving Justifications: The Quest for Autonomy', autonomy-based justifications of consent requirements are problematic. Which conception of autonomy is to be protected and secured? How must consent requirements be structured if they are to ensure respect for individual autonomy (variously conceived)? Why should respect for the individual autonomy of patients and research subjects trump other ethical considerations?

These questions are particularly acute for minimalist conceptions of individual autonomy that identify it with mere, sheer choice. Why should all choices — even those not based on an adequate grasp of others' proposals — be protected at all costs? Is it of no importance that choices may be good or bad, right or wrong, kind or callous, prudent or risky, informed or ignorant? Or that choices may be based on misleading views of others' proposals, or of the realities, risks and benefits of consenting to — or refusing — those proposals? Does it not matter that individuals may accept proposals for action that are likely to injure them, may 'go along' with manipulative proposals, or may succumb to 'offers they can't refuse'? Respect for mere choice has been widely, and in our view plausibly, viewed as a shaky and questionable justification for invasive treatment.

The favoured alternative to justifying informed consent as securing such minimal autonomy seeks to justify it as securing (some conception of) rational autonomy, such as informed, or reasonable, or reflective (rather than mere) choice. Informed consent is seen as justifying invasive interventions by ensuring that patients or research subjects not merely choose or decide whether to accept such interventions, but make informed, reasonable or reflective choices to do so: only then can their choices be seen as reflecting their rational autonomy. This line of thought risks justifying both too much and too little.

Appeals to conceptions of rational autonomy may justify too much where individuals choose dire alternatives in the appropriate way: would consensual cannibalism, consensual torture or consensual killing be acceptable, provided victims choose them in the appropriate way? Even if the victim's consent cannot justify these sorts of illegal action, can it justify interventions that are within the law but more risky than available alternatives, provided they are chosen in the appropriate way? Or will such cases not arise because clinicians and researchers (not to mention research ethics committees) will not propose or sanction unnecessarily risky treatment? But if that is the situation, then can we still claim that rational autonomy, operationalised by informed consent procedures, is a fundamental principle of medical and research ethics? Or would this move concede that other standards, in which consent plays no part, are of equal importance?

In other cases appeals to rational autonomy may justify too little: they have nothing to say about the treatment of non-competent patients, or about interventions whose complexity overwhelms the cognitive capacities of (otherwise) competent patients and research participants. Yet if we require patients and research subjects to exercise demanding conceptions of rational autonomy, failure of competence will more often be overtaxed, and the number of cases in which consent cannot be given will rise.

These realities are often obscured in discussions of medical and research ethics by a range of tacit assumptions. It is assumed that clinicians and researchers will not intend to injure their patients, and that they will not propose interventions that they think useless, unprofessional, too risky or illegal. Rather, they will propose only interventions that they take to be lawful and professionally acceptable, reasonably likely to benefit (the patient or others with the same condition) and unlikely to injure. These assumptions tacitly limit the choices patients and research subjects are offered to 'approved' options. Reliance on these assumptions is in great tension with the thought that informed consent procedures are fundamental to clinical and research ethics because they ensure respect for individual autonomy. If individual autonomy presupposes a large number of normative constraints that are not open to choice, those other normative standards will do a lot of the ethical work, and respect for individual autonomy will not be the sole, nor perhaps the main, basis for justifying medical and research practice. More provocatively, one
might say, the standard model of informed consent is based on disclosures that inform individual decision-making, and paradoxically sees patient autonomy and the autonomy of research subjects as merely responsive. Patients are typically asked to choose—or refuse—from a very limited menu (often a menu of one item); research subjects to choose—or refuse—to participate in a single project. Do appeals to autonomy in biomedical practice perhaps presuppose and rely on a residual paternalism that frames and protects the supposed exercise of individual autonomy?

**JUSTIFYING CONSENT TRANSACTIONS: CONSENT AS WAIVER**

If, on the other hand, we think of informed consent as embedded in communicative transactions, we can take a broader and (we believe) more convincing view of its justification. In this section we set out an alternative approach to the justification of informed consent, on the assumption that it is a distinctive type of communicative transaction. Informed consent transactions are typically used to waive important ethical, legal and other requirements in limited ways in particular contexts. Where informed consent is important or required, it has to meet a range of standards, which we discuss in the later sections of this chapter. We shall deal with questions of justification first, because arguments for the scope of consent transactions, and for the standards they must meet, cannot easily be set out without a clear understanding of the justification of informed consent.

The use of consent transactions to waive ethical or legal requirements is well understood in everyday life. In consenting we waive certain requirements on others not to treat us in certain ways (sometimes this will include waiving rights), or we set aside certain expectations, or license action that would otherwise be ethically or legally unacceptable. Informed consent has a role only where activity is already subject to ethical, legal or other requirements. We do not have to seek others’ consent to action that we have every right to do, or to meet others’ legitimate expectations. I do not have to request others’ consent to cross the road, or to arrive at work on time. (The absurdity of such requirements is even more evident if we ask whose consent would be required.) Consent is relevant only where there are already legal, ethical or other requirements and the question of setting them aside arises. For example, I may have to request consent if I want to picnic in somebody else’s field, or to take the morning off work.

Using consent to waive prohibitions on action that would otherwise wrong us, or frustrate our legitimate expectations, is an everyday matter. Where an act would otherwise wrong an individual or disrupt their legitimate expectations, that individual’s consent can waive their right, or modify their expectations in particular cases, and so justify an act that would otherwise be unacceptable. If Jane takes her family for a picnic in Roger’s garden she will be trespassing—unless he has waived his right to exclude them. His consent to their picnic justifies action that would otherwise be trespass. If Tony picks Sue’s plum trees bare, he will be stealing—unless she has waived her right to exclude him from doing so. Her consent to his fruit-picking justifies action that would otherwise be theft. If Ann goes to the head of a queue, she will be disrupting legitimate expectations—unless those in the queue have agreed to let her go ahead of them. Their consent justifies what would otherwise be queue-jumping.

Waiving prohibitions on wrongful action and waiving legitimate expectations is a daily practice by which we permit certain others to act in ways that would otherwise be unacceptable, and thereby justify their action.¹

Any justification of informed consent has therefore to start from a recognition of the underlying legal and ethical claims and legitimate expectations that are selectively waived by consent transactions, and of the reasons individuals may have for waiving them in particular cases. We do not propose in this book to argue for a definitive list of

¹ Cf. ‘When individuals consent to undergo medical operations, to engage in sexual intercourse, to open their homes to police searches, or to testify against themselves in court, they convert what otherwise would be an invasion of their person or their rights into a harmless or justified activity.’ George P. Fletcher, Basic Concepts of Legal Thought (Oxford: Oxford University Press, 1996), p. 109.
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legal and ethical requirements or norms (let alone of legitimate expectations, which will of course vary with cases). We propose, rather, to rely on the fact that certain ethical norms or standards are very widely accepted and endorsed by an overlapping consensus among those with an extremely wide range of ethical, social and religious outlooks. Still less do we propose to offer a list of significant legal requirements. Instead we will rely on the fact that certain types of action will be prohibited in most jurisdictions. We assume, for example, that nearly all ethical outlooks, and nearly all legal systems, will converge in prohibiting action such as injury, torture, poisoning or killing. Further, nearly all legal systems will prohibit the use of force, fraud, duress and coercion, deception and manipulation, and nearly all ethical outlooks will condemn such action as wrong. The convergence is likely to be very extensive, although lists, definitions and drafting will vary.

Yet what, we might ask, can justify waiving such significant and deeply entrenched and important ethical or legal requirements? If these requirements are important, they should surely be respected in all circumstances, and there can be no case for waiving them. However, in specific circumstances refusal to waive an important ethical or legal requirement for a specific purpose may itself lead to pain, injury, damage, distress and even to death. Nowhere is this more evident than in biomedicine. Patients and research subjects can have sufficient, indeed urgent, reason to consent to interventions that would otherwise wrong them in significant ways and violate legitimate expectations. They may consent to treatment or to participate in research, thereby sanctioning action which, if inflicted without consent, would be ethically and legally unacceptable. Here too consent is not ethically fundamental: rather it is a way of justifying action that would otherwise violate important norms, standards or expectations.

Consent is important in clinical and research practice because physicians and researchers often cannot help patients, or develop better treatments, without invading bodily integrity in ways that may hurt or harm, and at the limit damage, health, life and limb. Invasive and potentially damaging action is generally prohibited: it may cause pain, injure, poison and even kill. However, in medical and research practice there may be good reasons for consenting to specific invasive interventions. They may benefit individual patients, or establish how to benefit patients with a certain disease. Even when potentially beneficial invasive interventions go well, they may cause discomfort, pain, anxiety and harmful ‘side’ effects; and where things go badly, they may lead to complications, serious injury, even death. If invasive and risky action were undertaken without consent, it would normally violate very significant ethical and legal norms. Medical treatment, let alone surgery, done without consent might constitute assault or injury. Administering powerful drugs without consent might amount to poisoning. Conducting clinical trials without consent might treat others as guinea pigs. Informed consent requirements provide effective ways of waiving requirements and expectations in limited and defined ways in some cases, while insisting that these requirements and expectations nevertheless be respected whenever they are not specifically waived. Although the centrality of consent in discussions of clinical and research ethics has

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3 The *locus classicus* for this argument is Immanuel Kant's *Metaphysic of Morals*, 6230–31; see Immanuel Kant, *Practical Philosophy*, tr. Mary Gregor (Cambridge University Press, 1996). Kant is an aberrant social contract theorist, in that he grounds the legitimacy of government not on the consent of the governed but on the argument that while coercion is generally wrong, it is rational to waive rights not to be coerced in favour of the exercise of state power when this is needed to prevent more extensive coercion. For details see Onora O’Neill, ‘Kant and the Social Contract Tradition’, in François Duchesneau, Guy Lafrance and Claude Piché, eds., *Kant Actuel: Hommage à Pierre Laberge* (Montréal: Bellarmin, 2000), pp. 183–200.

3 Cf. Roger Brownsword ‘it is a mistake to view consent as a free-standing or detached principle (on the same level as privacy, confidentiality and non-discrimination); rather, consent is implicated in the right to privacy, the right to confidentiality, and the right against discrimination – in each instance, the right-holder may consent to waive the benefit of the right in question’. ‘The Cult of Consent: Fixation and Fallacy’, *King’s College Law Journal*, Vol. 15 (2004), 223–51 (p. 225). We would add that consent can be used to waive a far wider range of basic norms.
grown massively in recent decades, these realities have been recognised for far longer.\(^4\)

Anybody who inflicts medical treatment without consent, or conducts research on others without their consent, is likely to violate important ethical norms and legal requirements. Those who intervene against the will of a patient or research subject are likely to breach ethical norms and laws that prohibit the use of force, duress or coercion. Those who do not intervene against the will of a patient or research subject, but nevertheless act without consent, are likely to breach ethical norms (and possibly laws) that prohibit deception, manipulation or fraud. In some cases, action without consent breaches norms of both types. Invasive investigations, treatment and experiments undertaken without informed consent normally violate significant ethical norms and legal requirements, and are likely to violate fundamental rights of the person, as well as to flout or neglect a range of legitimate expectations.

Consent requirements offer a routine way of obtaining a limited waiver of requirements that are generally inviolable. They confer a special right—a permission—on certain medical practitioners or researchers to act in ways that would otherwise be prohibited. Consent may not be sufficient to waive such norms in all cases\(^5\) but it functions reliably as an everyday way of permitting action that would otherwise violate important norms and standards. So, far from providing the fundamental ethical standard for biomedical practice, informed consent justifies action only against the background of other important ethical and legal norms, and is used to give limited permission to act and intervene in ways that would otherwise do wrong to others, or otherwise fail to meet legitimate expectations.\(^6\) It provides a way by which individuals who would otherwise be wronged, or whose legitimate expectations would otherwise be denied, can waive those requirements on others in limited ways in a particular context, or agree to adjust legitimate expectations in limited ways in a particular situation.

**Scope and Standards**

We do not doubt that the consent of patients and research subjects to invasive procedures can be of high importance. There have been notorious cases in which medical treatment or research undertaken without consent inflicted injury, even serious or fatal injury. The atrocities perpetrated in the name of medical research under the Nazi regime provide incontrovertible evidence of the importance of consent.\(^7\) So do some of the most widely discussed examples of medical malpractice elsewhere.\(^8\) Had consent requirements been honoured in these cases, consent would have been refused, and grave injuries would not have been inflicted.

Nor do we doubt that lesser asymmetries of power and information, which are commonplace in clinical and research practice, can expose patients and research subjects to serious mistreatment if they make it easier to breach consent requirements. However, the


\(^5\) For example, consensual cannibalism and consensual torture may be prohibited in some jurisdictions. But this is not invariably the case. For examples of legal uncertainty consider the 2004 trial of the German cannibal, Armin Meiwes, who claimed in his defence that his victim consented, where the court reached a verdict of manslaughter, and the appeal court a verdict of murder; or consider *R. v. Brown* [1993] 2 All ER 75 (HL), in which the lower court finding that certain sadomasochistic practices were lawful if consensual was overruled on appeal to the House of Lords.

\(^6\) In developing this account of the justification of informed consent we have learned a great deal from Roger Brownsword’s far reaching criticisms of tendencies to drift towards treating consent as a free-standing ethic. See Brownsword ‘The Cult of Consent’.


importance of consent in many circumstances does not show that where consent is needed it must be sought and given in a uniform way or to a uniform standard.

In this section we move on from rethinking the justification of informed consent to rethinking its scope and the standards it must meet. When does consent matter in medical and research practice? Where it matters, what standards should consenting meet? As we have seen, consent requirements far from being ethically fundamental, presuppose other more basic ethical and legal standards. In this section we shall argue that procedures for consenting and the specificity of consent sought and obtained must both take account of the underlying norms that are to be waived in particular cases. Consequently differing clinical and research interventions are likely to require varying rather than uniform standards for consent. We shall then move on to explore the issues that are relevant in setting standards for consent in a given type of case in the following two sections of this chapter.

Consent transactions, we suggested in the first two sections of this chapter, can be used to justify action that would otherwise wrong others, by failing to meet adequate ethical or legal standards, or by disregarding legitimate expectations. This suggests immediately that consent is not required for all 'other-regarding' action, which may affect others, and merely self-regarding action which does not. It is basic to his well-known arguments for individual liberty.

Clinicians need not seek consent from patients to chat with them about non-medical matters, to ask them how they are feeling, to sympathise with them or to close an office window. Researchers need not seek consent from research subjects to talk about the work they are trying to do, or about its interest or importance. These and countless other permissible aspects of clinical and research practice violate no norms, and require no consent.

Informed consent is important in medical or research practice only when a proposed intervention would violate important norms if done without consent, or disrupt a legitimate expectation. Consequently, the scope of informed consent requirements is set not by the demands of autonomy (however conceived) but by a wide range of ethical and legal norms which must be waived or set aside if invasive medical or research interventions are to be acceptable.

In setting out the reasons why we think that this is the way to understand the proper scope of informed consent requirements we begin by reconsidering the Nuremberg and Helsinki approaches to consent. Although the two documents take very different views of the standards to be met by informed consent requirements, they take a common stand on their scope. Both documents are drafted on the assumption that there can be a single set of standards for all invasive research on human subjects. We believe that it is hard to make a case that any common set of requirements should hold for all medical research, let alone for all medical treatment.

The Nuremberg Code views implied or tacit consent as setting an adequate standard for all medical research. It demands that the research subject:9

9 John Stuart Mill (On Liberty) introduced a useful distinction between other-regarding action, which may affect others, and merely self-regarding action which does not. It is basic to his well-known arguments for individual liberty.

... should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

This emphasis on capacities rather than on action may seem to demand too little. It perhaps sets plausible standards for routine

10 Permissible action that disappoints legitimate expectations may require consent, or at least agreement, even if it will wrong nobody. If Tom has come to rely on Sue’s being in the office across the lunch hour, so does not lock up when he goes out, she would have reason to seek his agreement or consent if she plans to change her use of her lunch hour.

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Aspects of research, where other safeguards are in place. Here, we may think, merely going along with proposals is treated as sufficient evidence of consent, although research that is done in the face of refusal is rightly prohibited. However, the Nuremberg Code's emphasis on 'capacity to consent' and on possession of 'sufficient knowledge and understanding' may seem to set too low a standard for more complex or risky interventions. Will assurance that an individual has the 'legal capacity to consent' (or refuse), is 'so situated' as to exercise this capacity, and 'has sufficient knowledge and comprehension to make an understanding and enlightened decision' show whether important norms or expectations have been waived or breached?

Yet, as we saw in Chapter 1, the more exacting standards proposed in the Declaration of Helsinki are also problematic. Fully explicit and specific acts of consent are never possible; even highly explicit and very specific consent is seldom feasible. Moreover, since highly explicit and very specific consent are particularly demanding for patients, the Helsinki standards, and similar standards, cannot plausibly be extended from research to medical practice. The scope of 'Helsinki-style' requirements is inevitably very narrow, precisely because the standards are set at an (unrealistically) high level. Indeed, they may be so exacting that very little falls within their scope.

These difficulties suggest that it is pointless to look for uniform standards for all informed consent transactions, for all consent procedures, or for all consent forms. If there are no uniform standards, then trying to fix the scope of informed consent requirements in the abstract may have little point — and little chance of success. Adequate consent requirements may legitimately differ for different sorts of intervention, depending on the norms that would otherwise be breached. So the thought that a single standard can be set for all research, or for all clinical interventions — let alone for both — may be illusory. Although it may be useful to devise standardised consent procedures or forms for certain routine and recurrent types of research, such as randomised clinical trials, there is little reason to think that research of all sorts can be brought within the scope of any uniform set of standards, or uniform consent procedures. (We return to this point in Chapters 5 and 6 in discussing retrospective research of the type commonly undertaken in epidemiology or secondary data analyses.)

Similarly, in clinical practice there are sharp contrasts between routine procedures and complex interventions. At the routine end of the spectrum consider the case of a nurse who takes blood on the basis of a patient rolling up his sleeve and extending his arm, but without offering any explicit explanation and without documenting the consent given. Although the consent is implied rather than explicit, the nurse (we may think) does no wrong. She neither forces nor uses duress, and she does not deceive or manipulate the patient, or breach other fundamental ethical or legal norms. If, on the other hand, the patient had objected, she could not have proceeded without violating important norms. If, on meeting objections, she had tied the patient down or administered a paralysing drug in order to take his blood, there would have been no implied consent, and the taking of blood would have wronged him, indeed violated legal rights not to be coerced or forced, which had evidently not been waived. Similarly, a doctor who offers a diagnosis and proposal for treatment in simplified language that omits much detail does not seek, and will not receive, highly specific consent to the proposed treatment: but this may be acceptable provided that the treatment does not deceive or manipulate the patient, and the subsequent treatment does not force or coerce.

More demanding standards may be relevant where interventions are less well understood, where going ahead without consent would violate important norms, and where risks are high. Complex medical interventions and research done without (relatively) explicit consent

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18 In these chapters we shall argue that the Helsinki standards are particularly implausible where research is not invasive, but merely intrusive or potentially intrusive, in that it uses (anonymised) information that has been legitimately obtained. Non-invasive retrospective research does not put patients at risk, since nothing is done to them. Retrospective research cannot use force, duress or coercion. If consent is relevant in this case, it must be in order to waive (supposed) rights to privacy.
may violate significant norms, and risk serious or long-term harm or injury. A doctor who proposes severe forms of chemotherapy with considerable ‘side-effects’ may need to make the nature of those effects very clear if she is not later to stand accused of having deceived the patient by prescribing a drug with effects that the patient neither understood nor would have found acceptable. Equally, a researcher who enrols subjects in a randomised trial may later stand accused of misleading them if he does not ensure that they understand that the efficacy of the drug they may receive is still unknown, and that they may receive a placebo rather than the drug. Those who consent to be research subjects need to know what will be done to them, what risks they are thought to run and what benefits they and others might gain. In complex, risky, unfamiliar cases there may be good reasons to seek relatively explicit and relatively specific consent.

However, a blanket approach to consent requirements that seeks to standardise procedures for consent for all treatment or all research shows a lack of understanding of the reasons why consent matters. Consent is a way of ensuring that those subjected to invasive interventions are not abused, manipulated or undermined, or wronged in comparably serious ways. It seeks to ensure that such action is done only when specific norms are waived, and is not undertaken if it would breach important ethical or legal requirements. This aim cannot be secured by making consent disclosures more and more ‘complete’, or by tailoring them to some uniform standard: what matters will vary depending on the case at hand; and more is not always better. Where research is non-invasive, as in the case of secondary research using anonymised data that have already been legitimately obtained and stored, nothing is done to the ‘research subjects’ to whom these data pertain and it may be hard to establish any case for requiring consent.13

We can perhaps imagine unusual cases in which respect for important norms might require researchers to meet the full Helsinki standards by informing prospective research subjects about the ‘aims, methods, sources of funding, and any possible conflicts of interest, institutional affiliations of the researcher and the anticipated benefits and potential risks of the study’. But in other cases subjects for medical research, very reasonably, want to base their consent to participate on rather less. They are likely to want to know how participating in the proposed research might affect them, and what its anticipated benefits and potential risks for them and for others with the same condition are thought to be. If these matters are not communicated to them intelligibly and accurately, they may reasonably think that requests for their consent have not met adequate standards, and that their ostensible consent was based on deception or manipulation, so did not justify the intervention. In such cases they might also reasonably argue that they had not given genuine informed consent, and perhaps (depending on the circumstances) that they had been forced or duped, deceived or coerced.

It is, we conclude, pointless to hunt for a uniform view of informed consent requirements for all invasive procedures, let alone for all clinical treatment or all research participation. Cases vary hugely, and while standardised consent procedures and forms may be useful for certain ranges of cases, there is no reason to think that standardised procedures and forms, let alone the same procedures and forms, will be adequate in all cases. So there is no simple way of fixing the scope of consent requirements, beyond noting that consent will always be irrelevant where no important norms would be breached. Equally there is no simple way of fixing the standards for consent procedures: consent procedures must be robust enough to ensure that action that would otherwise breach norms is not performed unless those norms have been waived – and this may demand different standards in different cases. A procedure for gaining consent for routine interventions from competent patients with robust cognitive capacities may be inadequate for other cases.

Rather than looking for a simple way of determining the scope of consent requirements (‘all medical interventions’; ‘all research on human subjects’), or searching for a uniform standard for all consent procedures, we need first to consider which norms are to be waived
by consenting, and will be breached if there is no consent in a particular situation. Consent matters most where the underlying norms that would be breached if they were not waived set important ethical, social or legal standards. The norms breached by going to the head of a queue without the consent of others in the queue are relatively trivial. The norms breached by administering drugs, performing surgery or detaining others for psychiatric treatment without consent are far more important. The most significant ethical and legal norms may be so important that they cannot be waived by the consent of those affected. For example, consensual killing, consensual torture and consensual cannibalism are widely seen as unacceptable, notwithstanding the consent obtained. Informed consent is indeed secondary, and lacks a context unless other norms and standards are seen as important. However, this does not show or suggest that informed consent is a trivial matter: rather the contrary.

**CONSENT TRANSACTIONS: STANDARDS FOR COMMUNICATION**

Where consent is used to waive other ethical or legal norms, it must be requested and given in ways that meet adequate standards. Although we do not think that it is possible to set uniform standards for all consent requirements, we hope to set out a range of considerations that are relevant if the communicative transactions by which consent is sought, given or refused are to succeed. We argued in Chapter 3 that speech acts can be used to express, convey and adjust agents' practical and cognitive commitments. Successful informed consent transactions communicate and adjust these commitments in a number of ways. In this section we shall explore some epistemic standards that successful communication, including successful informed consent transactions, must meet. In the next section we shall explore some other standards, including ethical standards, that successful consent transactions must meet.

We also saw in Chapter 3 that communication can succeed or fail in many ways. Many aspects of epistemic success in communication can be specified in terms of respect for certain norms, and communicative failure is likely where those norms are ignored or flouted. Since informed consent transactions are communicative transactions (of a specific sort), they too must respect the norms that are required or important for successful communication.

Successful communication must in the first place use a language that its audiences can follow, and make what is said intelligible to them. It must also be relevant to its audiences, rather than overwhelming them with a flood of irrelevant or distracting – even if intelligible – information. Would-be communication that flouts or disregards these norms fails because it is not adequately adjusted to its audiences. Audiences may find such communication obscure, diffuse, irrelevant and (at worst) wholly unintelligible.

If those who request consent and those who respond to their requests are to communicate in ways that are intelligible and relevant to one another they must have some grasp of one another's background knowledge. There is little point in communicating things that the other party already knows, or has no need to know in a particular context. Even where others grasp aspects of communicative acts that fail in these ways, they may be unable to follow them successfully, or may read in unintended content.

Intelligibility and relevance are not always enough for successful communication. For example, speech acts that make or incorporate truth-claims aim to inform or tell their audiences about something. They succeed (where they do) only if they respect specific epistemic norms, and in particular norms of truth and truthfulness. They are performed and received on the assumption that what is said is true, and what is done in saying it is truthful.

Of course, there are many complexities here, since what is said in some truth-claims may be untrue (or at least partially inaccurate), and what is done in saying it may be dishonest (or at least partially evasive). Some truth-claims are true, but not truthful; others are

14 In other contexts it might be useful to distinguish various types of norms that are essential to intelligibility, such as syntactic, semantic and pragmatic norms, and even norms of etiquette.

15 The speech acts which we, following Searle, Speech Acts, have referred to as 'representatives'.
truthful but not true; some are neither true nor truthful. Where
truth-claims are true but not truthful, audiences may accept what
was said as true, but fail to realise that it was said dishonestly;
alternatively they may realise that a claim was dishonestly made
and (mistakenly) refuse to accept what was in fact truly claimed.
Where truth-claims are truthful but not true, audiences may rely on
speakers' truthfulness and thereby acquire false beliefs; alternatively
they may (wrongly) assume that speakers are untruthful, reject their
claims, and thereby avoid false beliefs (by an unreliable method).
Where truth-claims are neither true nor truthful, audiences may
be misled in multiple ways. Norms of truth and truthfulness are
perhaps best thought of as regulative rather than constitutive norms
for making and responding to truth-claims, in that their violation
does not invariably undermine, but rather disrupts and damages both
communication of truth-claims and responses to others' truth-claims.

For these reasons, audiences are often cautious about others'
truth-claims. They may be concerned about the accuracy of partic­
ular claims, or the honesty of particular communicators; they may
suspect that certain speech acts are both inaccurate and dishonest.
Yet even in cases of (suspected) inaccuracy or dishonesty, truth-
claims have to be formulated and interpreted in the light of norms
and practices of truth and truthfulness. Successful deception of others
must simulate respect for truth and truthfulness; successful interpre­
tation of others' truth-claims must start from, even if it later discards,
a working assumption that what is said is true and truthfully said.
Audiences who assume that others are not even aiming at truth, or
that they are systematically dishonest, or both, no longer view their
communication as making truth-claims. They may understand what
is said by others, but not whether it was said to communicate fact or
fantasy, report or rumour, illusions or truth-claims.

These difficulties extend far beyond the canonical cases of decep­
tive communication that is wholly false, or entirely based on carefully
crafted lies, fraud, evasion and dishonesty. Deliberate deception fades
into exaggeration, omission of important qualifications and mere
confusion. For these reasons we often focus most intently on the
negative core of norms of truth and truthfulness. We take it that
communication of intelligible truth-claims is normatively adequate
provided it is at least adequately accurate for the purposes at hand and not
dishonest.

Even these stripped-down norms are demanding, not only for
those who seek to communicate truth-claims, but for those who seek
to understand and respond to them. Listeners and readers may reach
a mistaken view of truth-claims, even where they find their content is
fully intelligible, for many reasons. Despite adequate understanding,
they may fail to realise that a truth-claim is at stake, and may think
that what is said is intended (for example) as fiction or fantasy. In
other cases they may accept truth-claims with unreasonable credulity
or excessive deference to authority, or reject them with unreasonable
suspicion. Or they may place and refuse belief erratically, in response
to the whim of the moment. Equally, they may be excessively
confident or unreasonably suspicious about others' honesty, or
vacillate about the level of trust they place in others.

Informed consent transactions are communicative transactions
that include truth-claims. They will therefore succeed only if the
various parties to such transactions are epistemically responsible.
Consent transactions require agents to respect the epistemic norms
that are required for successful communication, including not only
norms of intelligibility and relevance, but also norms for making,
understanding and responding to truth-claims. Any request for
consent will include some account of a proposed action or inter­
vention, and of the effects – including risks and benefits – that are
thought likely. For example, a surgeon may explain what an oper­
ation involves, how it might benefit a patient and what its risks are
thought to be; a researcher recruiting for clinical trials may explain
the effects that the drug being trialled is likely to have and the
regimen of treatment to be followed by those recruited for the
trial. Informed consent transactions incorporate truth-claims, so
succeed only if they respect the norms for making successful truth-
claims.

These normative requirements are largely obscured if we rely
on the conduit/container model of information transfer. If we think
of consent transactions as based on disclosure of information (by
professionals) followed by decisions (by patients and research subjects) we will gloss over many of the norms that must be met by successful consent transactions. The point is not that disclosure is unnecessary for successful informed consent transactions. On the contrary, disclosure of information is necessary for consent: how else could anyone know to which proposal consent is sought, given or refused? But disclosure alone is not sufficient for successful communicative transactions, so in particular not enough for successful informed consent transactions. By emphasising content while neglecting agency, the conduit/container model downplays, even hides, some of the distinctive norms that must be met by effective communicative transactions, and in particular those that are essential for understanding and responding to the truth-claims contained within informed consent transactions.

So communicating in ways that are intelligible and relevant is not sufficient for epistemically responsible and successful communication. The truth-claims contained in proposals for action and responses to those proposals must also be adequately accurate. We noted in Chapter 3 that the agency model of communication sees communication as an activity that draws on each party’s background knowledge and inferential competencies. It follows that speech acts and, in particular, requests for consent and responses to requests for consent, cannot be fully explicit or fully specific. So we should not expect requests for consent to incorporate ‘the whole truth’ about proposed interventions, or expect those who respond to offer ‘fully specific’ consent. But we can expect requests for consent to be intelligible and relevant to those whose consent is sought, and we can expect the truth-claims they incorporate to be adequately accurate. Equally, we can expect those who respond to requests for consent to communicate their consent or refusal in ways that are intelligible, adequately accurate, and relevant to those who request consent. Such oversights have heavy costs. If patients or research subjects do not achieve adequate understanding of the proposals to which their consent is sought, or if they respond in ways that are not accessible to those who request consent, or if the truth-claims made by either party are not adequately accurate, ‘consent’ based on them will be defective, and will fail to legitimate the proposed intervention.

No doubt, those who think that disclosure is what matters for informed consent generally assume that what is disclosed will be intelligible and relevant to the audience, and adequately accurate. However, by focusing on disclosure at the expense of a fuller account of requirements for communicative transactions, they short-change the epistemic norms that are basic to adequate communication with others. In particular, they ignore the importance of reciprocal communication and the opportunities that it provides to check and
challenge, to correct and defend truth-claims. A 'blunderbuss' approach of disclosing 'everything' – the illusory ideal to which demands for (fully) specific informed consent disclosures gesture – may or may not meet the epistemic norms required of truth-claims. Adequate accuracy is more important that illusory completeness for communicating the truth-claims that are integral to the successive stages of successful informed consent transactions. Disclosure by itself does not ensure that the epistemic norms for successful communication are met. Nor, as we shall see in the next section, does the 'disclosure-for-decision-making' model of consent offer a clear view of other norms that are relevant to consent transactions.

CONSENT TRANSACTIONS: COMMITMENTS

In Chapter 3 we noted that speech acts are often used to make, to adjust and to convey practical and cognitive commitments. Consent transactions are not merely exchanges of semantic content. They consist of speech acts by which each party both communicates with the other, and reveals and makes commitments. Requests for consent are made in speech acts that communicate what is proposed and that the proposers commit themselves to act in accordance with any consent given, and not otherwise. Those who consent to others’ proposals do so in speech acts that convey that they understand what is proposed, and that they commit themselves to view subsequent action that accords with those proposals as acceptable. Those who refuse to consent convey that they understand what is proposed and warn that they are not committed to viewing action that satisfies the proposal as other than harm or injury, and so as grounds for objection, complaint or even litigation (thereby refusing to make conditional commitments). The speech acts by which consent and refusal are given thus have three functions: they communicate the patient or research subject’s grasp of what was proposed; they make, or refuse to make, a conditional commitment; and they communicate that commitment or lack of commitment.

Speech acts that request, give or refuse informed consent fail unless they meet not only the standards needed for effective communication of the content conveyed, but also those standards necessary for making the relevant (conditional) commitments. These standards, as we have seen, include a range of substantive and demanding epistemic norms, which set clearer and more differentiated standards for requesting informed consent than are set by appeals to respect individual autonomy, or by unrealisable aspirations to make consenting wholly explicit and specific. Communication that complies with these norms supports genuine consent or genuine refusal, without placing too much weight either on the cognitive capacities of patients and research subjects or on their capacities for voluntary action and choice. Such communication, as we have stressed, need not – indeed cannot – be fully explicit, or fully specific.

Successful communicative transactions must also meet a wider range of epistemic and ethical standards. In some contexts it may in fact be hard to say whether a given norm should be thought of as epistemic or ethical, but fortunately it is not generally necessary to decide the point. We note simply that some sorts of failure are more readily thought of as epistemic and others as ethical. For example, even when a proposal is intelligible and relevant to those whose consent is sought, is accurate and omits nothing substantive, the conditional commitments ostensibly made by proposers and by respondents may prove bogus or unreliable. A proposal that ostensibly meets standards for successful communication may fail if covert steps are taken to ensure that it is not really accessible to those whose consent is sought. More significantly, if a proposal is backed by coercion, duress, force or constraint, then any 'consent' it receives will be bogus, and any conditional commitment ostensibly made by those who 'consented' will be void. Genuine requests to waive important norms in particular cases will fail dismally if the requests themselves, or the commitments they ostensibly make, violate important epistemic and ethical norms, for example, by relying on elements of force, duress, constraint and coercion, or on forms of fraud and deceit.

Unfortunately, seeming requests for consent can easily be coupled with — and vitiated by — more or less overt uses of force, duress, constraint and coercion. Such bogus requests constitute 'offers you can't refuse', and by the same token offers that nobody can genuinely accept.17 Genuine, legitimating consent can only be achieved where proposals communicate effectively, and where commitments reliably match proposals. Consent can be given, but cannot be extracted.

Respondents too can undermine the adequacy of informed consent by disregarding relevant ethical and epistemic norms. They may do so even when proposals are intelligible, relevant and accurate and omit nothing substantive, and when the requester's commitments are reliable and not grounded in force, duress, constraint or coercion.

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Of course, even when requests and responses are epistemically impeccable, failure may subsequently arise if the commitments to action made by either party turn out to be unreliable. Requesters may fail to live up to the terms of the consent they received, or to respect a refusal that was clearly communicated. Such failures may be large or small, failures to observe some or many conditions, a trivial matter or a total failure of reliability, and at worst a matter of duress, force, constraint or coercion. Respondents too may fail to live up to the terms of the consent they offered, and may retrospectively claim that reliable action by requesters, which fully respected the consent they had given, was inadequate, or even an injury.

CONCLUSION: CONSENT IN PRACTICE

The conduit/container model of information and communication, coupled with the autonomy-based justification of informed consent disclosures, is apt to mislead, and to distort our thinking about informed consent. They promote a narrow focus on disclosure of information by one party, and ‘autonomous’ decision-making by the other. If we think of consent in this narrow way, we may forget that consent is sought, given or refused in communicative transactions that make truth-claims and commitments, and that this requires attention to a number of significant epistemic and ethical norms.

Such oversight is hardly surprising. If we think of consent merely as an exercise in individual autonomy, variously conceived, we need not take cognizance of the underlying norms that are waived in consent transactions, and can sideline the epistemic and ethical norms required for successful consent transactions. We may then come to think of requests for consent as achievable by self-regarding speech acts such as disclosing or disseminating information, and may overlook the norms that are basic to, and essential for, adequate communication. We may think of responding to requests to consent merely as a matter of autonomous decision-making, overlook the importance of communicating consent and refusal, and downplay the significance of the commitments made in consenting and refusing. We may ignore the background requirements, duties and rights, expectations and legislation against which informed consent operates, and some or many of the epistemic and the ethical norms that are constitutive of adequate communication.18 We may think that ‘autonomous decision-making’ can only be respected if full, explicit, information is disclosed. If we rely on the conduit/container model, we may think of full and explicit disclosure as an ideal to which informed consent practice should aspire, even if we know that neither is possible in practice.

By contrast, an approach to informed consent that takes norms for adequate communication seriously has a number of advantages. A brief list might include the following. First, the justification of medical and research practice need not place sole or excessive weight on appeals to individual autonomy, variously conceived. Second, a consideration of the normative underpinnings of consent shows why medical and research practice that provides public goods cannot be subject to informed consent requirements. Third, by thinking of informed consent as waiving important norms, it becomes clear that it can never provide a complete justification of any medical treatment or research proposal, since it presupposes other ethical, legal or professional standards, norms and rules. Fourth, if informed consent transactions are seen as waiving those standards, norms and rules in limited ways, a robust distinction can be drawn between genuine and bogus ways of requesting and giving consent. Fifth, it affords a relatively clear view – although not a uniform or simple view – of the standards that those who give and refuse consent must meet. Sixth, these standards avoid reliance on excessive and questionable conceptions of explicit or specific consent.

18 A nice example of a strategy that pretends to respect but in fact undermines the epistemic norms that are constitutive of good communication is the use of small print to disclaim responsibility, in, as it were, an aside. This approach, by which information is communicated, yet not really communicated, is in common use in activities ranging from marketing drugs to selling insurance to labelling products. Curiously, small print is deemed legally sufficient to transfer liability, even when it fails to communicate: disclosures count as disclaimers. Its ethical acceptability is another matter. See Michael Power, The Risk Management of Everything: Rethinking the Politics of Uncertainty (London: Demos, 2004), http://www.demos.co.uk/catalogue/riskmanagementofeverythingcatalogue/.
This understanding of informed consent transactions affirms the importance of informed consent, but traces its importance to the way in which informed consent transactions can provide protection against serious wrongs, evidence that such breaches have not occurred, and assurance that systematic ways of preventing them are in place. Successful consent transactions can protect against serious wrongs, by placing control of invasive interventions that might otherwise wrong and harm in the hands of those who would be wronged or harmed. Only those whose consent is requested can waive important ethical norms. Second, when they waive such norms, those who consent provide evidence that can later be cited to show that no serious wrong has been done, and used by those who perform invasive interventions to justify their action. Thirdly, the systematic use of informed consent procedures in medical and research practice can provide assurance to third parties that action that would otherwise be seriously wrong is routinely prevented. By contrast, where invasive treatment and research are practised without requirements of informed consent, individuals may not be protected against force or fraud, deceit or duress, constraint or coercion. In such a context, those who undertake the interventions may have no evidence to show that they did no wrong; and third parties may have no assurance that such wrongs are not routinely done.

In this chapter we turn to the ways in which informed consent can be used to waive prohibitions on action that would otherwise be intrusive rather than invasive. Where invasive action violates either others’ bodily integrity (it may force or restrain, injure or harm, even mutilate, poison or kill), or their liberty or property (it may threaten, enter, steal, damage or destroy property), intrusive action, by contrast, infringes a specific range of liberty rights, often referred to as privacy rights. There are many conceptions of privacy, and of privacy rights. For example, in the US discussions of privacy rights are often viewed very broadly as encompassing the liberty rights that protect individuals against invasive action, and have classically been seen as elements of a ‘right to be let alone’. In public debate in the UK privacy is typically understood in a more restricted way, as a right against action that is intrusive, but may not be invasive.