12 Liability and the legal duty to inform in research

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12.1 Introduction

Early medicine was characterized by paternalistic medical practices. The Ancient Greek physician Hippocrates, for example, opined that '[physicians] will apply dietetic measures for the benefit of the sick according to [their] ability and judgment. [They] will keep them from harm and justice' (Hippocratic Oath 1943). In the modern era, medical paternalism continued to be legitimized through a combination of medical beneficence and a 'pledge [from physicians] to do their best to protect patients from harm' (Chin 2002: 152; Gillon 1985: 1971; Weiss 1985: 184–5; Husak 1981: 27). Contemporary authors have defined paternalism as an 'interference with a person’s freedom of action or freedom of information, or the deliberate dissemination of misinformation, where the alleged justification of interfering or misinforming is that it is for the good of the person who is interfered with or misinformed' (Buchanan 1978: 372; McCoy 2008; Rich 2006). Consider, for example, the 1847 Code of Ethics of the American Medical Association (AMA), which reads:

The obedience of a patient to the prescriptions of his physician should be prompt and implicit. He should never permit his own crude opinions as to their fitness, to influence his attention to them. A failure in one particular may render an otherwise judicious treatment dangerous, and even fatal.

(Chin 2002: 152, our emphasis)

Similarly, in 1903, the AMA’s Principles of Medical Ethics explained that '[o]rdinarily, the physician should not be forward to make gloomy prognostications, but should not fail, on proper occasions to give timely notice of dangerous manifestations to the friends of the patient; and even to the patient, if absolutely necessary …’ (section 5, our emphasis).

In the second half of the twentieth century, the rise of Western individualism (Childress 1982: 66) coupled with the mounting influence of the civil rights movement (Philips-Nootens et al. 2007: 139) led to a decline in paternalistic medical practices. Today, the principle of autonomy has become the main ethos of healthcare provision. In medicine, the right (of a patient) to make an informed choice about his or her medical care, without undue interference from others, characterizes this principle (Laurie 2002: 186–7). Physicians are encouraged to consider whether ‘withholding … information [would] result in less harm on balance than divulging it’ (Buchanan 1978: 377–8).
Patients have thus become central contributors to the therapeutic decision-making process. Respect for patient autonomy has generated a new duty for physicians – that of adequately informing their patients prior to and during the delivery of medical care (Dworkin 2002, 2003: 235; McCullough and Wear 1985: 285).

In the research setting, this duty to inform takes a different shape. The lower the therapeutic benefit of a medical intervention, the greater the duty to inform; this is true for cosmetic surgery, organ donation, and non-therapeutic research (Philips-Nootens et al. 2007: 204–15; Picard and Robertson 2007: 176–8). In other words, compared to a clinician, a researcher will be held to a higher duty of care when informing a participant. A breach of this duty could potentially give rise to legal liability if it causes bodily, material, or psychological injury.

Legal liability offers claimants compensation for (1) actual losses incurred and (2) loss of potential gain. This principle is true for medical malpractice claims, which have come a long way since the days of Hammurabi and his Code of Laws (circa 1780 BCE), which states: ‘[i]f a physician make[s] a large incision with the operating knife, and kill[s] [the patient], or open[s] a tumor with the operating knife, and cut[s] out the eye, his hands shall be cut off’ (article 218). Indeed, the aim of liability suits is not to punish defendants (although punitive damages are sometimes accorded by the courts), but rather to promote a culture of prevention (Baudouin and Deslauriers 2007a: 7).

But why is the issue of liability pertinent to the duty to inform in the context of medical research? The answer relates to a critical but largely neglected outcome of liability: education. Although much ink has been spilled in the past on the physician’s duty to inform in the clinical setting (McGivern and Ivolgina 2013), much less time has been devoted to the ever-changing field of medical research. Consider, for example, the issue of population biobanks, which study data and samples collected on a large population scale over long periods of time (Knoppers et al. 2012). Due to the very nature of these biobanks, participants are informed that the aim of the research study is to establish a resource for future research in health and genomics (following ethics approval) (CARTaGENE 2012). Given that such biorepositories are built for future, unspecified research by as-yet unnamed researchers, full disclosure in such cases can be difficult to achieve. What is the scope of the duty to inform and what are the consequences of its breach? Is the duty to inform monolithic, or can it change in conformity with different jurisdictions? These are just a few examples of the panoply of questions surrounding medical research, made even more complicated by their increasingly longitudinal and international nature (Knoppers and Zawati 2011: 1181), in which researchers rely less on constant intervention and more on cutting-edge technologies that generate vast amounts of often uninterpretable data (Levy et al. 2007: 254). Whole-genome sequencing is but one example of such new technologies, where the information produced could reveal serious health risks for the research participant requiring clinical care. This puts researchers in a difficult position: that of having to make decisions in situations where their obligations are not necessarily well defined.

This chapter will focus on the duty to inform in the context of medical research, and will highlight the risks of liability that researchers face as a consequence of the increasingly blurred lines between research and clinical care. Section 12.2 of this chapter will discuss the duty to inform as enunciated in international normative documents that frame medical research. Although the duty to inform is often linked with the notion of consent (see Chapter 3), it should be noted that these two concepts are not synonymous, and should be considered as interrelated but ultimately separate. While consent is seen to crystallize the duty to inform, the latter encompasses a number of additional elements. These elements will be presented through a review of regional and national laws and regulations.
In order to provide a concrete illustration of the principles examined in section 12.2, section 12.3 will examine how Canadian case law has dealt with the duty to inform in the context of research. Finally, section 12.4 will address the increasingly blurred lines between the clinical and research settings through a succinct overview of recent developments in genomic research. More precisely, this section will discuss emerging issues of liability that researchers face in the fulfillment of their duty to inform.

12.2 The duty to inform in normative documents

12.2.1 International instruments: the consent process and beyond

A comparative review of international norms reveals that the duty to inform has been consistently referenced in the context of research (see Table 12.1). For example, the Nuremberg Code of 1949 asserts in its first article that ‘the duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment’ (Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 1949, article 1 (Nuremberg)). The article also affirms that the duty to inform is a ‘personal duty and responsibility, which may not be delegated to another with impunity’ (Nuremberg, article 1). In this example, a link is forged between the duty to inform and its most common crystallization, participant consent. Similarly, the 2013 version of the Declaration of Helsinki stipulates that:

Each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study.

(article 26)

However, in this case, consent does not entirely confine the duty to inform, but rather also applies to later phases of research projects. Indeed, article 26 of the Declaration of Helsinki requires that research participants ‘be given the option of being informed about the general outcome and results of the study.’ The use of the keywords ‘general’ and ‘outcome’ foresees the application of the duty to inform even at the very end of the research project.

Likewise, the Council for International Organizations of Medical Sciences’ (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects adopts a similar stance with regard to general results, but adds an additional duty to inform participants ‘of any finding that relates to their particular health status’ that could manifest at any time during the research project (2002: guideline 5(7)). The United Nations Educational, Scientific and Cultural Organization’s (UNESCO) International Declaration on Human Genetic Data also encapsulates this duty to inform, and provides for the right of a participant to decide whether or not he or she is informed of research results (2003: article 10); this stance has been held by UNESCO since the publication of its 1997 Universal Declaration on the Human Genome and Human Rights (article 5(c)).

12.2.2 Regional normative instruments: from the duty to inform to a duty of care

In the context of research, regional normative instruments are relatively similar to international documents in their treatment of the duty to inform (see Table 12.2). The seminal Convention on Human Rights and Biomedicine (Oviedo Convention) of the Council of Europe states...
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<th>Table 12.1 Selected international norms</th>
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<tr>
<td><strong>Nuremberg Code</strong></td>
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<td><strong>Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10</strong> <em>(1949).</em></td>
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<td><strong>Article 1</strong></td>
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<td>The voluntary consent of the human subject is absolutely essential.</td>
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<td>This means that the person involved 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 latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.</td>
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<td>The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.</td>
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<td><strong>Declaration of Helsinki</strong></td>
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<td>World Medical Association (WMA) <em>(2013)</em> Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.</td>
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<td><strong>Article 26</strong></td>
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<td>In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.</td>
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<td>After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject’s freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.</td>
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<td>All medical research subjects should be given the option of being informed about the general outcome and results of the study.</td>
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<td><strong>Declaration on Human Genetic Data</strong></td>
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<td><strong>Article 8</strong></td>
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<td><em>(a)</em> Prior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for the collection of human genetic data, human proteomic data or biological samples, whether through invasive or non-invasive procedures, and for their subsequent processing, use and storage, whether carried out by public or private institutions. Limitations on this principle of consent should only be prescribed for compelling reasons by domestic law consistent with the international law of human rights.</td>
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<td>[…]</td>
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<td><strong>Article 10</strong></td>
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<td>When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. This does not apply to research on data irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons who have participated in such a research. Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results.</td>
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### Article 13
No one should be denied access to his or her own genetic data or proteomic data unless such data are irretrievably unlinked to that person as the identifiable source or unless domestic law limits such access in the interest of public health, public order or national security.[…]

### Ethical Guidelines for Biomedical Research Involving Human Subjects

**Guideline 5**

Before requesting an individual's consent to participate in research, the investigator must provide the following information, in language or another form of communication that the individual can understand;

1. the purpose of the research, the procedures to be carried out by the investigator and the subject, and an explanation of how the research differs from routine medical care;
2. that, after the completion of the study, subjects will be informed of the findings of the research in general, and individual subjects will be informed of any finding that relates to their particular health status;
3. that subjects have the right of access to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed of, and given, the reasons for such non-disclosure);
4. any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research, including risks to the health or well-being of a subject's spouse or partner;
5. the direct benefits, if any, expected to result to subjects from participating in the research;
6. the expected benefits of the research to the community or to society at large, or contributions to scientific knowledge;
7. any currently available alternative interventions or courses of treatment;
8. policy with regard to the use of results of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives or to others (e.g. insurance companies or employers) without the consent of the subject;
9. whether it is planned that biological specimens collected in the research will be destroyed at its conclusion, and, if not, details about their storage (where, how, for how long, and final disposition) and possible future use, and that subjects have the right to decide about such future use, to refuse storage, and to have the material destroyed (see Guideline 4 Commentary);
10. the extent of the investigator's responsibility to provide medical services to the participant;
11. any other information that the subject needs in order to make an informed decision about participation in the research.

### Declaration on the Human Genome

**Article 5**

(a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.

(b) In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest.

(c) The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.
### Table 12.2  Selected regional norms

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<th>Recommendation on Research on Biological Materials of Human Origin</th>
<th>Article 14</th>
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<td>Council of Europe (2006) Recommendation Rec(2006)4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin (EU).</td>
<td>[...] 2. The purpose(s) of a collection should be specified. The principles of transparency and accountability should govern its management, including access to and use and transfer of its biological materials and disclosure of information. 3. Each sample of biological material in the collection should be appropriately documented, including information on any relevant consent or authorization. [...]</td>
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| Convention on Human Rights and Biomedicine | Article 5  An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purposes and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.  Article 10  [...] 2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed. 3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient. |

| Clinical Trials Directive | Article 3 2. A clinical trial may be undertaken only if, in particular: [...] (b) the trial subject or, when the person is not able to give informed consent, his legal representative has had the opportunity, in a prior interview with the investigator or a member of the investigating team, to understand the objectives, risks and inconveniences of the trial, and the conditions under which it is to be conducted and has also been informed of his right to withdraw from the trial at any time; [...] (d) the trial subject or, when the person is not able to give informed consent, his legal representative has given his written consent after being informed of the nature, significance, implications and risks of the clinical trial; if the individual is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation; (e) the subject may without any resulting detriment withdraw from the clinical trial at any time by revoking his informed consent; [...] |
### Additional Protocol
Council of Europe (2005) *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (EU).*

| Article 13 | 1. The persons being asked to participate in a research project shall be given adequate information in a comprehensible form. This information shall be documented.  
2. The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee. Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research:  
(i) of the nature, extent and duration of the procedures involved, in particular, details of any burden imposed by the research project;  
(ii) of available preventive, diagnostic and therapeutic procedures;  
(iii) of the arrangements for responding to adverse events or the concerns of research participants;  
(iv) of arrangements to ensure respect for private life and ensure the confidentiality of personal data;  
(v) of arrangements for access to information relevant to the participant arising from the research and to its overall results;  
(vi) of the arrangements for fair compensation in the case of damage;  
(vii) of any foreseen potential further uses, including commercial uses, of the research results, data or biological materials;  
(viii) of the source of funding of the research project.  
3. In addition, the persons being asked to participate in a research project shall be informed of the rights and safeguards prescribed by law for their protection, and specifically of their right to refuse consent or to withdraw consent at any time without being subject to any form of discrimination, in particular regarding the right to medical care.  

| Article 26 | 1. Research participants shall be entitled to know any information collected on their health in conformity with the provisions of Article 10 of the Convention.  
2. Other personal information collected for a research project will be accessible to them in conformity with the law on the protection of individuals with regard to processing of personal data.  

| Article 27 | If research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them. That shall be done within a framework of health care or counseling. In communication of such information, due care must be taken in order to protect confidentiality and to respect any wish of a participant not to receive such information.  
[...]}
that participants in a research project ‘shall beforehand be given appropriate information as to the purposes and nature of the intervention as well as on its consequences and risks’ (1997: article 5). This principle is reiterated in other European norms, such as Directive 2001/20/EC (2001: article 3) and the Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin (2006: article 14).

Article 10 of the Oviedo Convention recognizes a ‘right to information,’ such that participants ‘[are] entitled to know information collected about [their] health’ unless they exercise their right not to know. However, this right is not absolute, and may be restricted in the interests of the patient (Oviedo Convention, article 10(3)). These restrictions may be invoked, for example, where clinically significant information is discovered about a child participant that could be actionable during childhood (Hens et al. 2013: 6).

The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (Additional Protocol) emphasizes the importance of providing participants with ‘adequate information in a comprehensible form’ (2005: article 13(1)), and confirms that patients are entitled to know ‘any information collected on their health in conformity with the provisions of Article 10 of the Convention’ (article 26(1)). Furthermore, the Additional Protocol creates a ‘duty of care,’ such that ‘[i]f research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them’ (article 27). The Additional Protocol specifies that this information must be disseminated through a framework of healthcare or counseling, and a researcher is obliged to protect both the confidentiality of the information and the participants’ wishes (article 27).

Thus, according to the regional documents, as reviewed above, the duty to inform not only includes the provision of adequate information to participants during the consent process, but also enshrines a ‘right to information’ that requires researchers to disclose specific findings to participants throughout a research project.

12.2.3 National perspectives: liability and the duty to inform

Legal liability is a jurisdiction-specific branch of law, whose more comprehensive parameters can only be gleaned from a review of national legal instruments. While it is possible to undertake the daunting task of reviewing and analyzing hundreds of laws and regulations from numerous countries around the world, this section will only highlight the legal duty to inform and legal liability in a few civil and common law countries. The common law review will focus on the United Kingdom and Australia, while the civil law review will include France and the province of Quebec in Canada.

12.2.3.1 Common law jurisdictions: the tort of negligence

In the United Kingdom, the duty to inform/duty to disclose is primarily discussed in the context of clinical care, and is usually subsumed within the broader duty of care. In order to determine the type of information that should be disclosed in this context, English courts follow the ‘professional standard’ test as articulated in the seminal Bolam v. Friern Hospital Management Committee [1957] 2 All ER (Bolam) case. In Bolam, the court established:

A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art … Putting it
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the other way round, a doctor is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view.

(p. 122)

This standard refers to ‘what professionals would generally view as appropriate disclosure, as opposed to a patient-oriented standard based upon either what the particular patient (a subjective standard) would wish to know or what patients in general wish to be made aware of (an objective standard)’ (Price 2002: 150). The English courts reaffirmed the Bolam principle in Sidaway v. Bethlem Royal Hospital Governors [1985] 1 All ER 643 (Sidaway). However, in that case, a justice for the majority noted an exception to this test where there is a ‘substantial risk of grave adverse consequences’ (Sidaway, p. 663). In such cases, a physician could be found negligent if he or she fails to disclose patient information even if the professional standard is non-disclosure. Disclosure requirements in the context of research are considered greater than those required during treatment ‘by virtue of the additional contribution to the public interest in particular’ (Price 2002: 261) – and thus create an even higher duty of ‘subjective’ disclosure. This is the case for both therapeutic and non-therapeutic research (Price 2002: 261, 263–4).

In Australia, a clear distinction is made between the duty to inform and the duty to obtain consent for a given medical procedure (Chalmers 1998: 69). Despite the existence of legislation to this effect, ‘the law has developed judicially’ on this topic (Chalmers 1998: 69). In contrast with the United Kingdom, Australian courts have not always applied the Bolam principle:

In Australia, it has been accepted that the standard of care to be observed by a person with some special skill or competence is that of the ordinary skilled person exercising and professing to have that special skill. But, that standard is not determined solely or even primarily by reference to the practice followed or supported by a reasonable body of opinion in the relevant profession or trade. Even in the sphere of diagnosis and treatment, the heartland of the skilled medical practitioner, the Bolam principle has not always been applied.


Instead, the standard of reasonable care is not ‘owned’ by professional bodies:

Further, and more importantly, particularly in the field of non-disclosure of risk and the provision of advice and information, the Bolam principle has been discarded and, instead, the courts have adopted the principle that, while evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to ‘the paramount consideration that a person is entitled to make his own decisions about his life’.

(Rogers 1992: 631)

According to Australia’s National Health Medical Research Council Act, the National Health and Medical Research Council (NHMRC) regulates research studies (1992: article 7; Chalmers 1998: 111). Section 2.2.4 of the NHMRC’s National Statement on Ethical Conduct in Human Research (National Statement) states, in reference to the duty to inform:

The process of communicating information to participants … should not be merely a matter of satisfying a formal requirement. The aim is mutual understanding between
researchers and participants. This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish.

(2007)

Article 2.2.6 of the National Statement enumerates those elements that should be disclosed to research participants, including (but not limited to) alternatives to participation and the likelihood or form of the dissemination of research results (NHMRC 2007).

In view of the foregoing, how can a researcher be sued for failing to meet the duty to inform? In such cases, negligence is the most probable cause of action in both the Australian and English contexts. In order to recover under the tort of negligence, a claimant must satisfy the four following elements: (1) the existence of a duty of care; (2) a breach of that duty; (3) harm; and (4) causation. This text will focus on the first two elements. In both Australia and the United Kingdom, the 1932 case of Donoghue (or McAlister) v. Stevenson [1932] All ER Rep 1 provides guidance on determining whether an individual owes a duty of care:

Who, then, in law is my neighbour? The answer seems to be – persons who are so closely and directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question.

(p. 11)

Plaintiffs must therefore demonstrate that the researcher owed a duty of care, and that he or she breached this duty by failing to adequately satisfy his or her duty to inform. As previously mentioned, the English standard of care is that of the ‘medical [professional] skilled in the art’ (Bolam, p. 122). In Australia, the Civil Liability Act 2002 specifies that:

A person practising a profession (‘a professional’) does not incur a liability in negligence arising from the provision of a professional service if it is established that the professional acted in a manner that (at the time the service was provided) was widely accepted in Australia by peer professional opinion as competent professional practice.

(section 50(1))

That being said, the court in Rogers v. Whitaker held that professional opinion is not the determining factor in the establishment of civil liability (p. 631). In point of fact, the Civil Liability Act states: ‘[h]owever, peer professional opinion cannot be relied on for the purposes of this section if the court considers that the opinion is irrational’ (section 50(2)).

12.2.3.2 Civil law jurisdictions: la responsabilité civile

In civil law jurisdictions, the duty to inform has been advanced through civil codes. For example, in the Canadian province of Québec, the duty to inform has been incorporated in both the Civil Code of Québec 1991 (CCQ) and under professional norms, such as the Code of Ethics of Physicians 2008. The latter enshrines the legal duty to provide the patient/participant with explanations that are pertinent to their ‘understanding of the nature, purpose and possible consequences of the examination, investigation, treatment or research which [the physician] plans to carry out’ (Code of Ethics of Physicians, article 29). The physician–patient relationship, which is classified as a contractual relationship, is bound by the Civil Code of Québec’s chapter on contract for services, which specifies that a contractor ‘… is bound to provide the client, as far as circumstances
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permit, with any useful information concerning the nature of the task which he undertakes to perform’ (article 2102). Similar to the UK, the duty to inform in research is as great as, if not greater than, in the clinical setting (Weiss v. Solomon [1989] RJQ 731 (Weiss)). In Quebec, a physician is expected to disclose the patient’s diagnosis (Laferrière v. Lawon [1991] 1 SCR 541); the nature and objectives of the intervention or treatment (Baudouin and Deslauriers 2007b: 49); risks (Chouinard v. Landry [1987] RJQ 1954); and the existence of any other possible therapeutic options (Reibl v. Hughes [1980] 2 SCR 880 [Reibl]; Schierz v. Dodds [1986] RJQ 2623, in Philips-Nootens et al. 2007: 145). Additionally, health professionals must be able and available to answer patient questions (Philips-Nootens et al. 2007: 145; Hopp v. Lepp [1980] 2 SCR 192 (Hopp)). These duties to inform are amplified in the context of research, and will be discussed in detail in section 12.3 of this chapter.

In France, the duty to inform is enshrined in the Code de la santé publique (CSP) 2013. This law states that every person has the right to be informed about his or her state of health (article L1111-2), which would also include information pertaining to the proposed treatment, investigation, the potential benefits and the foreseeable risks.

The Code de la santé publique also discusses the duty to inform in the context of research. Similar to the requirements in the clinical setting, ‘investigators’ are asked to inform their participants about the objectives, methodology, and length of the research project as well as medical alternatives, the expected benefits, and the foreseeable risks (CSP, article L1122-1). Additionally, the same article provides that participants have the right to be informed of general research results at the end of research projects, according to the modalities outlined during the informed consent process. The new Loi Jardé 2012 (which has been adopted but is not yet in force) specifically addresses the return of research results. These new provisions mandate that researchers provide participants with feedback during baseline assessments (CSP, article L1121-1), as well as feedback concerning general research results (CSP, article L1121-1). Moreover, participants have a right to information concerning their health during and at the conclusion of the research project; this information must be presented as a written document, and must be given to the individual who has consented to receive the information (e.g. guardians/parents) (CSP, article L-1122-1).

Similar to common law jurisdictions, a breach of the duty to inform in civil law could result in the liability of researchers for damages. Actions in such cases will not necessarily be those of ‘negligence,’ but of medical malpractice under the general rules of civil liability or responsabilité civile. These actions will require the presence of: (1) fault; (2) injury; and (3) a causal link. Plaintiffs must prove the existence of each of these components: ‘[e]very person has a duty to honour his contractual undertakings. Where he fails in this duty, he is liable for any bodily, moral or material injury he causes to the other contracting party and is liable to reparation for the injury’ (CCQ, article 1458). This same standard applies in France, where article 1382 of the French Code civil states that ‘[a]ny act whatever of man [sic], which causes damage to another, obliges the one by whose fault it occurred, to compensate it.’ Article 1383 further explains that a person is ‘liable for the damage he causes not only by his intentional act, but also by his negligent conduct or by his imprudence’ (Code civil).

The duty to inform in France also finds a jurisprudential basis in the Arrêt Teyssier 1942 DC 63, Gaz. Pal. 1 decision, in which the Cour de Cassation held that the duty to inform is a necessary corollary of the right to respect for persons, and violating this duty would amount to a serious violation of patient rights (p. 63).

It should also be noted that ‘fault’ is differentiated from ‘error’ in the context of the duty to inform. An error becomes a fault where a reasonable person in the same circumstances would have acted or omitted to act in a different manner (Philips-Nootens et al. 2007: 47–9).
For example, a researcher who fails to adequately inform his research participant about the risks of a particular project could be found liable if: (1) this omission has caused damage; and (2) if a reasonable researcher in the same circumstances would have disclosed these risks. The reasonable researcher should be vested with comparable experience and, more importantly, comparable expertise. Professional guidelines as well as ethical normative documents play a role in determining the standard of care. Expert witnesses may also refer to these documents in support of their testimony.

### 12.3 Legal duty to inform in research: a Canadian common law and civil law perspective

In the Canadian common law context, the therapeutic duty to inform is the provision of sufficient information (i.e. material risks, as well as special or unusual risks) (Reibl, para. 4; Picard and Robertson 2007: 134–49) to enable patients to make the best decision possible. In Reibl v. Hughes, a landmark common law decision, Judge Laskin of the Supreme Court of Canada wrote: ‘[w]hat the doctor knows or should know that the particular patient deems relevant to a decision whether to undergo prescribed treatment goes equally to his duty of disclosure as do the material risks recognized as a matter of required medical knowledge’ (para. 16). In Hopp v. Lepp, the Supreme Court specified that the scope of the duty to inform includes answering ‘any specific questions posed by the patient as to the risks involved … [and] … without being questioned, [disclosing] to [their patients] the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation’ (para. 29). This articulation has since become the minimum standard with which physicians are expected to comply in the common law provinces. However, in Quebec, civil law courts have tended to reject the ‘reasonable patient’ threshold as proposed in Reibl v. Hughes and have instead upheld a test that focuses on what a reasonable physician would disclose in the circumstances (Pelletier v. Roberge [1991] 41 QAC 161, para. 51; Chouinard v. Landry 1987; Philips-Nootens et al. 2007: 149–55).

As previously mentioned, the amount of information needed to satisfy the requirements of the duty to inform in the clinical setting is quite minimal compared to the requirements in cases of non-therapeutic research. This differential duty stems from two Canadian decisions: Halushka v. University of Saskatchewan [1965] 53 DLR (2d) 436 (Halushka) and, from Quebec civil law, the case of Weiss v. Solomon.

In the 1965 case of Halushka, a student was paid fifty dollars to be part of an experiment at the University Hospital, which involved the administration of a new anesthetic and the insertion of a catheter. The participant was informed that the procedure would last a couple of hours, and that this was a ‘perfectly safe test … conducted many times before’ (Halushka, para. 3) and that ‘there was nothing to worry about’ (para. 2). During the procedure, the participant suffered a complete cardiac arrest and remained unconscious for four days. As a result, the new anesthetic was withdrawn from clinical use. The participant subsequently sued for damages. The Saskatchewan Court of Appeal held that the disclosure of information in this case was inappropriate, incorrect, and ultimately constituted non-disclosure. The court contrasted the duty to inform in research with the duty to inform in clinical care by stating that ‘the duty imposed upon those engaged in medical research … to those who offer themselves as subjects for experimentation, as the respondent did here, is at least as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient’ (Halushka, para. 29).

The Court then justified its elevation of the duty to inform by explaining that:
There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice. The researcher does not have to balance the probable effect of lack of treatment against the risk involved in the treatment itself. The example of risks being properly hidden from a patient when it is important that he should not worry can have no application in the field of research. The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent.

(Halushka, para. 29, our emphasis)

Taking these arguments together, the Court articulated a standard whereby the fewer the therapeutic benefits derived from a medical procedure, the greater the duty to inform.

In the 1988 case of Weiss v. Solomon, the Superior Court of Quebec restated the elevation of the duty to disclose in research. In this case, a patient who underwent cataract surgery was invited to participate in a research project (distinct from his surgery) involving the administration of ophthalmological drops and a fluorescein angiography. Following the injection of the fluorescein, the patient suffered a ventricular fibrillation and died (Weiss, para. 4). It was determined, among other things, that the patient’s risk of collapse or death due to his pre-existing heart problem was not sufficiently disclosed. The Court referred to both the Halushka case and the Civil Code of Lower Canada (CCLC) 1866, the precursor to the Civil Code of Québec (which is currently in force). The Court relied upon articles 19 and 20 of the CCLC, which enshrined the inviolability of the person and the issue of majority consent to medical experimentation, respectively. The Court then reiterated the importance of full disclosure in the context of non-therapeutic research (Weiss, para. 89). It also characterized full disclosure as going beyond the disclosure requirements of clinical settings.

Together, Halushka and Weiss represent the state of Canadian common and civil law in matters relating to the disclosure of information in research; however, their respective standards are subject to challenge in an era when non-therapeutic research is becoming increasingly international, collaborative, longitudinal, and less individually-oriented. Can we hold a researcher undertaking observational studies to the same duty to inform? For now, the answer is yes. In fact, the standard required by these two decisions contains two important limitations: (1) research typology; and (2) the scope of the duty to inform. First, at a time when research methodologies are becoming increasingly diversified and research is producing more and more uninterpretable data, a one-size-fits-all legal approach to research typology becomes problematic. For example, the research featured in Halushka and Weiss is very different from research concerning population biobanks, where no drugs are administered, no devices are inserted, and no toxicity is assessed. Second, although Halushka and Weiss provide guidance on the duty to inform in the context of consent, they fail to address the issue of return of results in the context of research. Does the return of findings fall within the scope of the duty to inform? Given the increasingly blurred lines between research and clinical care, this issue has become all the more important.

12.4 Blurring the lines between research and clinical care: genomic research as a case study

With its sequencing of the human genome over a decade ago (International Human Genome Consortium 2001; Collins et al. 2003), the Human Genome Project (HGP) influenced the practice of medicine (Collins and McKusick 2001) by opening ‘huge potential for research into the ways in which genes relate to human conditions, diseases, capacities, impairments
and susceptibilities’ (Australian Law Reform Commission 2003: 379). Although the Project’s outcomes have yet to directly affect the healthcare of most people (Collins 2010: 674), it is fair to say the human genome has catalyzed, albeit humbly, the translation of knowledge from the bench (research) to the bedside (clinic), such that ‘powerful drugs have been developed for some cancers; genetic tests can predict whether people with breast cancer need chemotherapy … and drug response can be predicted accurately for more than a dozen drugs’ (Collins 2010: 674).

Mere decades ago, the practice of medical genetics was limited to the study of Mendelian disorders and to chromosomal anomalies (Collins and McCusick 2001: 540). Even though practitioners knew most common diseases had both hereditary and environmental factors, they were often limited to the analysis of family history (Collins and McCusick 2001: 540), which was ‘largely unsuccessful in uncovering the basis of common diseases that afflicted most of the population’ (Lander 2011: 191). Today, ‘more than 1,100 loci [locations of genes on a chromosome] affecting more than 165 diseases and traits have been associated with common traits and diseases’ (Lander 2011: 191) thanks to genome-wide association studies (GWAS) (Collins 2010: 674). Despite this, many challenges in the field of human genetics persist (Green et al. 2011), not the least of which include legal challenges facing genomic researchers.

Often, there is a fine line between what constitutes research and clinical care. Conflation of the two can create problems in fact and in law, especially if the researcher happens to be a clinician. An example of this conflict is apparent where a researcher is faced with validated research findings that have potential clinical value. This section will not delve into the larger discussion around the return of research results and incidental findings (see such analysis in Chapter 18 of this Handbook), but rather will use this topic to further the analysis in section 12.3 on the clinician-researcher’s duty to inform, using Quebec civil law as a case study. Could a researcher holding a PhD in genetics be held to the same duty to inform standard as a clinician-researcher? Is a clinician-researcher first and foremost a researcher, or a clinician held to a clinical duty to inform or to an elevated standard? In order to answer these questions, it is necessary to review the dual roles and responsibilities of the clinician-researcher.

12.4.1 The curious case of the clinician-researcher

There is no consensus in the literature as to the extent of the dual role of the clinician-researcher. Some authors stress that the research setting is a natural extension of medical care and similar obligations are generated as a result (Czoli et al. 2011, p. 2). Under this interpretation, medical research is considered to be a subset of medical practice; if a conflict arises, the ‘obligations of clinical care trump research obligations’ (Czoli et al. 2011: 3). Proponents of this position find support in the Preamble of the Declaration of Helsinki, which states:

The Declaration of Geneva of the WMA binds the physician with the words, ‘The health of my patient will be my first consideration,’ and the International Code of Medical Ethics declares that, ‘A physician shall act in the patient’s best interest when providing medical care.’

It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician’s knowledge and conscience are dedicated to the fulfillment of this duty.

(2013, articles 3–4)

A second group of authors adopt a contrary stance, and maintain that the duties of physicians and researchers are distinct (Henderson et al. 2007: 1736). This distinction arises from the differences
between the aims of research and clinical care. While the former seeks to produce generalizable results, the latter seeks to benefit individual patients (Miller and Brody 2003: 21). Obligations in medical research must reflect these differences, and must thereby dispel the therapeutic misconception (de Melo-Martín and Ho: 2008: 202–3), where a ‘research subject … inaccurately attributes therapeutic intent to research procedures’ (Lidz and Appelbaum 2002: V55).

Although the literature surrounding this topic articulates a number of ‘middle-ground’ positions (Czoli et al. 2011: 5–7), a recent study surveying physicians concluded:

Although several physician-researchers referred to a fundamental difference between the practices of medical care and research, and even devised strategies to help keep the two roles separate, we heard little that directly aligns with a strict difference position, perhaps indicating that a complete divorce between the two practices is uncomfortable for or undesired by physician researchers.

(Czoli et al. 2011: 5)

In brief, while there exists a difference between the research and clinical settings, this distinction does not generate differing obligations.

12.4.2 Return of research results and incidental findings in Quebec: a case study

In genomic research, the potential for discovering health-related findings of clinical significance to research participants is becoming ever more prevalent (Cho 2008). Large-scale human genomic research has been made possible by powerful technologies (such as genomic microarrays, scanning technologies, and other research instruments) that can generate massive amounts of information (Wolf et al. 2008). The issue of how to handle these findings is not only topical, but also increasingly challenging for researchers.

In contrast with the international and regional documents reviewed here, as well as France’s Loi Jardé, the province of Quebec does not outline any legislative norms surrounding the return of research results and incidental findings. This legislative lacuna begs the question of whether clinician–researchers are under any legal obligation to return results derived from research projects. If so, does this obligation form part of the duty to inform under Quebec law? At present, the duty to inform in Quebec pertains to patient consent and does not adequately contemplate the issue of return of results (Weiss).

The case of a clinician–researcher involved in a rare diseases study can be used to illustrate the issue at hand. In such research projects, whole-genome and whole-exome sequencing may be used to determine the causative gene for a given disorder (Choi et al. 2009). While some individual findings may be pertinent to the research study, others may be completely incidental to the study’s original purpose. Is there a legal obligation to return these incidental results to participants, especially if they prove to be analytically valid, clinically significant, and potentially actionable (Wolf et al. 2012)? In such cases, ‘analytical validity’ refers to the ability to precisely and reliably identify a particular genetic characteristic (Knoppers et al. 2013), while ‘clinically significant’ and ‘actionable’ findings have a ‘well-recognized and significant risk’ for which an accepted therapeutic or preventive intervention is available (Knoppers et al. 2013, p. 246).

It should be noted that, in all likelihood, the return of results does not fall under the civil law’s duty to rescue. The duty to rescue is enshrined in Quebec’s Charter of Human Rights and Freedoms 1975, which states:
Every person must come to the aid of anyone whose life is in peril, either personally or calling for aid, by giving him the necessary and immediate physical assistance, unless it involves danger to himself or a third person, or he has another valid reason.

(article 2)

The relevant keywords in article 2 are ‘life is in peril’ and ‘immediate.’ Given these stringent requirements, it is very unlikely that the type of findings derived from whole-genome or whole-exome sequencing would fall under Quebec’s duty to rescue. At most, a genetic condition could be said to have imminent health consequences – ‘imminent’ but not ‘immediate.’ This same principle is applicable to article 38 of Quebec’s Code of Ethics of Physicians, which provides:

A physician must come to the assistance of a patient and provide the best possible care when he has reason to believe that the patient presents with a condition that could entail serious consequences if immediate medical attention is not given.

(our emphasis)

In the absence of any clear legislative norms surrounding the issue of return of results, a duty to inform may be inferred from two sources: (1) research protocols; and (2) ‘the standard of care,’ or more precisely, ‘les règles de l’art’ (the rules of the art). Research protocols play an important role in determining the procedures for a given research project. That research protocols are reviewed by Research Ethics Boards is evidence of their importance to research and its processes (Canadian Institutes of Health Research et al. 2010 (TCPS): Chapter 6). As ruled in Weiss v. Solomon (para. 115), it is important to abide by research protocols. If protocols foresee the return of certain results under certain conditions, then this obligation should be respected, particularly if the participant previously consented to this obligation. In this case, failure to return participant results and incidental findings may constitute fault under the principles of civil liability.

In cases where the research protocol is silent on the issue of return of results, the researcher can always defer to the Research Ethics Board (REB) for advice on how to manage his or her findings. That said, the implication of REBs in such cases could result in the liability of the host institution. According to Weiss v. Solomon (para. 116) and the Civil Code of Québec (article 1463), the principal (in this case the hospital or the institution) is liable for damages stemming from injuries that are caused by its agents (in this case, the REB).

Regardless of whether research protocols consider the return of research results and incidental findings, much of the proof still depends upon expert court testimony, which is typically based on general practice, professional guidelines, and ethical norms. Professional guidelines and ethical norms are particularly important where there is an absence of applicable legislation. For example, the Tri-Council Policy Statement (TCPS), a pan-Canadian guideline governing human research, creates an onerous obligation for researchers to return material incidental findings discovered in the course of research. Although ‘incidental findings’ are those findings that are beyond the scope of any given research study, the term ‘material’ has been broadly defined as having significant welfare implications for the participant, whether ‘health-related, psychological or social’ (TCPS, article 3.4). Unless the research community collectively distances itself from the above approach, courts may choose to consider such an obligation in the context of civil liability for negligence in research. Recently, the Panel on Research Ethics (a group of experts tasked with developing the TCPS) has proposed that article 3.4 be amended to permit the REB to decide whether an obligation to return incidental findings exists (Interagency Advisory Panel on Research Ethics 2013). Here again, however, if the REB is negligent in the course of its
review, the host institution may be liable for damages (provided that all the elements of article 1463 of the Civil Code of Québec are satisfied).

Researchers are not a homogenous community. Could a researcher with a PhD in genetics be held to the same standard as a clinician–researcher in the context of return of results? While some authors believe researchers should be held to the same standards as physicians on grounds of public order (Kouri 1991: 94), the equation of expectations with standards is unreasonable given the circumstances. A physician will interpret clinical findings very differently from a researcher. Consequently, the standard of liability in such cases should be a researcher with similar expertise and experience – and not a clinician.

12.5 Conclusion

Winston Churchill once said, ‘… this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning’ (1942). In response to the questions raised in the introduction, this text has demonstrated that the duty to inform can adapt to different jurisdictions. However, the scope of this duty is far more nebulous. A review of international and regional normative documents in section 12.2 indicates that the duty to inform has been consistently referenced in the context of research. The scope of this duty not only includes the provision of adequate information during the process of consent, but also involves the disclosure of research results and incidental findings to participants. A few regional norms have gone so far as to create a ‘right to information’ and a ‘duty of care,’ which require a researcher to disclose information that may be of relevance to the participant’s current or future health or quality of life (Additional Protocol, article 27). A review of national norms indicates that disclosure requirements in research are considered greater than those required during treatment.

What are the consequences of breaching the duty to inform? Depending on the jurisdiction, an action in negligence (common law) or in ‘fault’ (civil law) can be the result. Both legal traditions require the presence of a duty and necessitate a breach (common law) or fault (civil law). Also in both legal traditions, the standard of care will be determined by expert testimony that relies on common practice, professional guidance, and/or ethical norms.

Section 12.3 of this text analyzed the duty to inform in Canada through a review of two seminal cases from 1965 and 1989, respectively. These decisions were, however, limited in two ways: first, they did not consider whether the duty to inform should be applied beyond the purview of initial consent; and second, they envisaged a ‘one-size-fits-all’ approach to research typology.

Section 12.4 discussed these limitations in light of the emerging issues concerning the return of research results and incidental findings. Although no clear legislative obligation exists, the return of results could be subsumed under a broader duty to inform if: (1) the return of results is mentioned in the research protocol; and/or (2) the return of results forms part of the standard of care as determined by reasonable experts in the same circumstances. Section 12.4 also highlighted the potential role of ethical norms in the absence of a clear legislative text. On that note, in his list of five lessons learned from the first decade of the genome era, Francis Collins called for ‘good policy decisions … crucial to reaping the benefits that should flow from the coming revelations about the genome’ (Collins 2010: 675). It seems fitting to conclude with a similar call for policymakers to develop both prospective and participatory guidance that is not unduly onerous for researchers (Knoppers and Zawati 2011). Investigators who are asked to abide by reasonable obligations will be able to bring their research projects to completion in an ethical and efficient manner. Given the high level of trust the public places in research endeavors, responding to these obligations can only sustain research for the future.
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