

Ethical Issues in Secondary Uses of Human Biological Materials from Mass Disasters

*Bartha Maria Knoppers,
Madelaine Saginur, and
Howard Cash*

In the trauma surrounding mass disasters, the need to identify victims accurately and as soon as possible is critical. DNA identification testing is increasingly used to identify human bodies and remains where the deceased cannot be identified by traditional means. This form of testing compares DNA taken from the body of the deceased with DNA taken from their personal items (e.g. hairbrush, toothbrush etc.) or from close biological relatives.¹ DNA identification testing was used to identify the victims of the terrorist attack on the World Trade Center in New York on September 11, 2001, and of the victims of the Tsunami that hit Asia on December 26, 2004. Shortly after the 9/11 attack, police investigators asked the victims' families for personal items belonging to the missing, and for DNA samples from family members themselves.² The New York medical examiner's office coordinated the DNA identification testing program; however, some of the identification work was contracted out to private laboratories.³ New York has ended, for now, its attempts to identify the remains of more than half of the 2,749 victims of 9/11. Having exhausted DNA technology as it currently exists, New York will preserve and store the unidentified remains.⁴ The state has attempted to preserve DNA samples of every single remain that came through their testing laboratories.⁵ For the Tsunami, many countries are contributing to the identification effort, including China, Sweden, and Finland.⁶ Even more recent events such as the July 7th London bombings, and Hurricane Katrina, which devastated New Orleans on August 28th, also necessitated large-scale identification efforts.

Once a DNA identification effort is largely completed, what happens to the DNA samples of both victims and their families? This paper addresses the ethical issues of secondary uses of samples collected for identification purposes following mass disasters, both of natural and "man-made" causes. Specifically, it examines whether, and if so what kind of research is ethically permissible on these samples. It does not address the ethical or legal constraints surrounding research uses of forensic DNA banks generally.⁷ Our research is based mainly on policy documents, legislation and international instruments on research ethics, and does not cover the literature.

Potential uses of biological samples go beyond research. For example, DNA analysis is used as an intel-

Bartha Maria Knoppers, J.D., is Canada Research Chair in Law and Medicine and Professor in the Faculties of Law and Medicine at the Centre de recherche en droit public, University of Montreal. **Madelaine Saginur, J.D.**, is Research Associate in the Faculty of Law at Centre de recherche en droit public, University of Montreal. **Howard Cash** is President, Gene Codes Forensics, in Ann Arbor, Michigan.

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ligence tool “to identify, confirm or eliminate a suspect in a criminal investigation, to identify victims of crime, or to link crimes by comparing profiles created from DNA samples found at different crime scenes.”⁸ The United States Federal Bureau of Investigation operates the Combined DNA Index System (CODIS), which comprises a hierarchy of DNA indexes at the local, state and national levels.⁹ In Canada, the Royal Canadian Mounted Police operates the national DNA databank which contains a crime scene index and an offenders index.¹⁰ Addressing the ethical or legal constraints surrounding biological samples in the context of forensic DNA databanks, however, is beyond the scope of this article.

The types of research most likely to be proposed for the DNA biobanks of victims of mass disasters fall into three major categories: forensic research to develop improved methods of identification, including identification by molecular methods; disease-related research such as susceptibility to common multi-factorial diseases like cancer, heart disease, or toxic substances; and epidemiological studies of diversity, possible due to the random genetic diversity of the samples. To situate the ethical norms governing these possible categories of use, we will first examine the ethical norms that already govern secondary use of samples obtained during routine medical care or during research, and then examine the research uses of samples obtained from vulnerable persons, defined broadly to include children, incompetent adults, and the deceased.

It should be mentioned at the outset that there is considerable confusion in the terminology used to describe genetic samples. For example, terms such as “identifiable,” “traceable,” “pseudonymized,” “proportional,” or “reasonable” anonymity are used interchangeably with the terms “coded” or “double-coded.” The term “anonymized,” called “unlinked,” or “de-identified,” is sometimes used to refer to samples that have been stripped of identifiers and sometimes used to refer also to samples that are double-coded.¹¹ For the purpose of clarity, we use the term *anonymized* to refer to samples that were originally identified or coded that are now stripped of all possible identifiers; and *coded* to refer to samples that are identifiable only through breaking the unique (single coded) or the two unique (double coded) codes given the sample.

The sole existing document which directly addresses secondary use of biological samples following mass disasters is the U.S. Genetic Privacy Bill, which holds that for the identification of dead bodies, “the analysis of a[n] [individually identifiable] DNA sample from the dead body is limited to that which is necessary to determine the identity of the dead body.”¹² The position we ultimately put forward is more permissive than that espoused by this Bill. We believe our position allows for some secondary research without compromising the dignity, autonomy and rights of victims and their families.

I Secondary Uses of Archived Biological Samples Generally (Medical Care or Research)¹³

During the last decade, international, regional (European) and national bodies have given much attention to the secondary use of archived biological samples for research. Awakened to their potential, and yet sensitive to the accompanying public concerns, recommendations for principled international and regional frameworks and more detailed national instruments were not long in coming.

A. International Positions

No international ethical guidelines specifically address the issue of research on biological samples obtained in mass disasters, whether from victims or from their families. Examining international ethical guidelines governing the secondary use of archived DNA samples originally collected in the course of medical care or research is nonetheless helpful.

(I) MEDICAL CARE SAMPLES

The World Health Organization specifically addressed the issue of research uses of archived material originating from medical care in its 2003 report on genetic databases. The report enables the use of such material (i.e. “pre-existing health records, specific health disorder databases or physical samples that have been retained”) when anonymized, and provided no future identification of the sample source is possible, notably through research results.¹⁴

HUGO,¹⁵ CIOMS,¹⁶ and UNESCO¹⁷ have adopted an even less restrictive approach, enabling stored samples and data to be used not only in an anonymized form, but also in a coded form, provided certain conditions are met. For example, the Human Genome Organization Ethics Committee held in 1998 that

[r]outine samples, obtained during medical care and stored may be used for research if: there is a general notification of such a policy, the patient has not objected, and the samples obtained during medical care and stored before notification of such a policy may be used for research if the sample has been anonymized prior to use.¹⁸

The Council for International Organizations of Medical Sciences, in its 2002 ethical guidelines for biomedical research, states that consent requirements can be waived provided individuals are notified and their confidentiality or anonymity is protected. However, it holds that “waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee.”¹⁹ It further maintains that such a committee can waive some or all requirements of informed consent only for studies that pose minimal risks, are expected to yield significant benefits, and could not realistically or reasonably take place were consent requirements to be imposed (impracticability). The guidelines specify that reluctance or refusal to participate is not sufficient to establish impracticability.²⁰ Epidemiological studies using record review are highlighted as an example of possible waiver.²¹ Further, in the absence of direct benefit for the individual, the risk must be minimized and reasonable in relation to the expected benefits.²²

UNESCO’s 2003 *International Declaration on Human Genetic Data* leaves to national legislation the task of implementing the specific conditions for the secondary use of samples and data collected in the course of medical care.²³ It holds that research can be undertaken without consent if the information is anonymized (“irretrievably unlinked to an identifiable individual”) or when consent cannot be obtained, provided proper ethical oversight occurs.²⁴ Waiver of informed consent may also be warranted when important public interests are at stake, assuming that fundamental human rights are respected.²⁵

(II) RESEARCH SAMPLES

Regarding samples and data collected for a specific research project that are to be used subsequently for other research purposes, similar waivers are contemplated.²⁶

The Council for International Organizations of Medical Sciences also specifies that subsequent research be circumscribed by the original consent, and that any conditions specified in that initial consent apply equally to secondary uses.²⁷ It affirms the critical need for anticipation of future uses when samples and data are first collected. Thus, investigators should, during the original consent process, inform potential partici-

pants about any foreseen secondary uses, privacy protection or destruction procedures that will be implemented, and of their rights to request destruction of any material or information they deem sensitive, or to opt out.²⁸ However, as for biological samples and data collected as part of clinical care, elements of informed consent can be waived by an ethical review committee in exceptional circumstances.²⁹ UNESCO’s 2003 *Declaration on Human Genetic Data* holds that, health emergencies excepted, secondary uses incompatible with the conditions set out in the initial consent form cannot proceed without renewed consent.³⁰ The possibility for stored samples and data to be secondarily used without consent upon ethical approval is encompassed when such information has medical or scientific significance.³¹

Notable is the movement at the international level to differentiate between data and samples that are anonymized, coded or identified. These distinctions affect the rules that apply to secondary uses of data and samples and the possibility of withdrawal by the research subject. Furthermore, UNESCO’s 2003 *Declaration on Human Genetic Data* holds that “[h]uman genetic data and human proteomic data should not be kept in a form which allows the data subject to be identified for any longer than is necessary for achieving the purposes for which they were collected or subsequently processed.”³² The World Health Organization, acknowledging the value of anonymization with regard to participants’ privacy, requires the anonymization process to be scrutinized by an ethics committee, a necessary intermediary to ensure its legitimacy and maintain adequate standards.³³

B. Regional Positions

At the European regional level, other than upholding the need for informed consent for all medical interventions including research, the Council of Europe’s Convention on Human Rights and Biomedicine³⁴ provides little guidance on genetic research with regard to either archived samples left over after clinical care, or research samples. Article 22 maintains that:

[w]hen in the course of an intervention any part of a human body is removed, it may be stored and used for purposes other than that for which it was removed only if this is done in conformity with appropriate information and consent procedures.

National states are left to decide what is appropriate. However, guidance may be found in the European Society of Human Genetics (ESHG) *2001 Recommendations on Data Storage and DNA Banking*,³⁵ in the Council of Europe’s *Proposal for an Instrument on the*

Use of Archived Human Biological Materials in Biomedical Research,³⁶ and the *25 Recommendations On The Ethical, Legal And Social Implications Of Genetic Testing* of the European Commission.³⁷

These texts do not specifically refer to samples left over from clinical care, but rather to archived samples or existing collections generally. The ESHG recommendations distinguish existing collections based on the degree of identifiability of the samples and data, and the length of storage.³⁸ The Society considers that consent requirement can be waived when samples are anonymized,³⁹ and, provided it is approved by an ethics committee, in situations where the collection can be considered as abandoned (“old collections”).⁴⁰ For collections of coded information, while in principle re-consent of participants for new studies is necessary, ethics review committees can waive the requirement for such consent when re-contact is impracticable and the study poses minimal risks.⁴¹

In contrast, the Council of Europe does not allow re-consent to be waived when stored biological clinical material and data are to be used subsequently for research.⁴² Consent can, however, be either implicit or explicit, depending on the intrusiveness of the study and the previous directives of the donor.⁴³ Individuals enjoy the right to withhold their sample from certain future research uses, and the right to consent to subsequent procedures.⁴⁴ The Council of Europe and the ESHG both insist on the need to differentiate data according to their possibility of identification.

The *25 Recommendations* of the European Commission also adopt an approach which differentiates samples based on the chances of them being identified.⁴⁵ Endorsing the protection of the rights of people whose samples and data have been archived with respect to autonomy, confidentiality and privacy, the *Recommendations* also seek to encourage research.

While international documents urge groups, communities, and populations to become involved in the discussion surrounding the establishment of large-scale population human genetic research databases, the ESHG goes one step further, requiring additional consent “at a group level through its cultural appropriate authorities” for population studies.⁴⁶ This latter consent bears examination. How it will be implemented in practice remains to be seen. Indeed, it might prove difficult to define what would amount to an adequate community or group consent, what degree of opposition would result in the study not being undertaken, and the consequences as far as other rights, notably that of withdrawal, are concerned.

C. Selected National Positions

In this section we analyze the ethical norms governing secondary use of genetic samples in the United Kingdom, France, Canada, the United States and Germany. We chose these countries because they are actively involved in genetic research and banking, and have recently addressed the ethical issues surrounding secondary use of samples. They represent a range of possible positions on the issue.

(I) UNITED KINGDOM

The Human Tissue Act 2004, which replaces the now-repealed Human Tissue Act 1961, is an extensive and comprehensive legislative framework, and is expected to come into force in April 2006.⁴⁷ It applies to a very broad category of human material, that is, all “relevant material of which the body consists, or which it contains.”⁴⁸ Relevant material is similarly broadly defined as, “material, other than gametes, which consists of, or includes human cells.”⁴⁹ Relevant material from a human body does not include, however, hair or nails from the body of a living person.⁵⁰

As mentioned by the Nuffield Council on Bioethics⁵¹ and the Medical Research Council,⁵² the less identifiable the data, the lower the risks of individual harms, and so the need for re-consent is also decreased. The Human Tissue Act 2004 recognizes this too, holding that with proper ethical approval, anonymized tissue samples from a living individual who is not incapacitated and when there is no reason to believe that the individual would refuse to consent to the use in question, can be used for research in connection with “disorders or functioning of the human body.” This includes genetic research, if the research is desirable in the interests of a person, including a future person.⁵³ Research is also permitted on samples which are not anonymized where reasonable efforts have been made to obtain the consent of the donor.⁵⁴ Unless all these conditions are met, the Act will criminalize the use of human tissue without prior consent.⁵⁵ Section 44 states that it is lawful for material from an individual, living or not, obtained in the course of treatment, diagnostic testing or participation in research, that has ceased to be used for a purpose specified in Schedule 1 to be dealt with as waste.⁵⁶ Requirements for being considered waste are not specified in the Act, but presumably some secondary uses would be possible.

(II) FRANCE

On August 6, 2004, a new law revising the 1994 Bioethics Laws of France was adopted. This law holds that, in principle, inclusion of an individual in biomedical research requires the obtaining of his/her explicit informed written consent.⁵⁷ However there are exceptions to this principle. According to article L. 1211-2,

the secondary use for medical or scientific purposes of elements or products of the human body collected for other purposes is permissible if the individuals from whom the material has been collected have been informed of the secondary use, and he/she (or his/her representative) has not objected to such use. The obligation to inform the individuals can be waived if it is impossible to find the person (practical impossibility to re-contact), or when an ethics committee is consulted by the research investigator, and concludes that such information is not necessary.⁵⁸ However, using germinal cells and tissues for secondary research without obtaining explicit consent is prohibited; this article applies primarily to surgical waste or bodily elements removed as part of care or collected for research purposes. With respect to tissues and cells, secondary use for scientific or therapeutic purposes requires notification of the individual (in the case of minors or incompetent individuals, notification of their legal representative), and absence of opposition by the individual (or by a minor and his/her representative, when applicable).⁵⁹ The secondary use of anonymized data falls outside the ambit of privacy laws, and is therefore allowed.⁶⁰

(III) CANADA

Canada's 1998 *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* addresses secondary use of data derived from biological material. Research Ethics Board approval is necessary for "any anticipated secondary uses of identifiable data from the research."⁶¹ But, REBs may waive some or all consent requirements if the research poses no more than minimal risk to the subject; the waiver is unlikely to adversely affect the rights and welfare of the subjects; and the research could not practicably be carried out without the waiver.⁶² Concerning human tissue, it states "when collected tissue has been provided by persons who are not individually identifiable (anonymous and anonymized), and when there are no potential harms to them, there is no need to seek donors' permission to use their tissue for research purposes, unless applicable law so requires."⁶³ Finally, researchers who propose research involving the banking of genetic material "have a duty to satisfy the REB and prospective research subjects that they have addressed the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, withdrawal by the subject, and future contact of subject, families and group."⁶⁴

The 2004 Canadian Biotechnology Advisory Committee's (CBAC) *Advisory Memorandum on Genetic Research and Privacy*⁶⁵ holds that, for biobank research to be most beneficial, the current norms of informed consent must be reviewed. Consideration should be given to establishing an "authorization model" of informed

consent specifically for prospective population genetic research. This model holds that informed consent must be required for the initial collection of the biological sample; authorization of subsequent research must be given (or denied) by the research participant at the time of the initial sample collection; individuals must be able to specify which uses of their biological material and associated data are permitted or excluded, as well as the degree of subsequent decision-making authority they want to retain; and individuals must have the option of giving general or "blanket consent" to any and all future uses, although this form of consent may not be recognized in all jurisdictions.⁶⁶ According to CBAC, this model "strikes a reasonable balance that is supportive of individual autonomy and of genetic research and is supported by the Tri-Council Policy Statement (Article 8.6) and accords with public opinion."⁶⁷ While not addressing secondary use of archived samples, this latter position is again indicative of a move towards a possible broad consent to future research uses.

In October 2005, the Canadian Institutes of Health Research released their finalized *Best Practices for Protecting Privacy in Health Research*. Some important guidelines include restricting possible identification and sensitivity of personal data collected, and restricting secondary use of data to what is necessary to achieve the research objectives.⁶⁸ Further, the *Best Practices* hold that "[v]oluntary and informed consent...is a fundamental principle in research involving humans, and specifically for the use of their personal data," and that an REB can waive all or parts of a consent requirement only under "specified circumstances, given a satisfactory rationale by the researcher."⁶⁹ The *Best Practices* repeat those factors listed in the Tri-Council Policy Statement regarding when the requirement of consent may be waived. In the context of secondary use, when determining whether consent may be waived in a given circumstance, an REB must consider the following factors: the necessity of the personal data; whether potential harm to individuals is minimized and potential benefits of the research outweigh potential harms; whether seeking consent is inappropriate (psychological harm, risk of threat to privacy, or contact with individuals not permitted under a previous data-sharing agreement, law or policy) or, impracticable; what the individuals' expectations are (no previous objections to the secondary use and expectations of a reasonable person); and what the views of relevant groups or communities are.⁷⁰ Further, any applicable legal requirements such as a data-sharing agreement, notification and/or approval by other relevant oversight bodies, and/or an agreement that personal data will not be used to contact individuals must be followed. The researcher should have an appropriate strategy for in-

forming the general public about the research.⁷¹ These *Best Practices* demonstrate a widening of the factors to consider in determining whether a research proposal meets the requirement for waiver of consent.

(IV) UNITED STATES

Federal regulations on the protection of human subjects permit the use of existing, anonymized, biological materials without consent for research, as this is not considered research on “human” subjects.⁷² No specific additional guidance is provided, and actual IRB practices and policies vary.⁷³ Consistent with ethical guidelines in other jurisdictions, REB review on the issue of re-consent is required only if the data is identifiable. An Investigational Review Board (IRB) may “approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent” or “waive the requirements to obtain informed consent if the research involves no more than minimal risk; the waiver or alteration will not affect the individual’s rights and welfare; and the research could not be carried out without waiver or alteration of consent requirements.”⁷⁴ Research with anonymized data or with tissue samples of deceased persons are not covered by this regulation, as this is not considered research involving human subjects.⁷⁵

The Genetic Privacy Bill takes a much more prohibitive stance. It generally forbids any secondary use of coded samples, holding that samples must be destroyed upon completion of the project. The sample may be anonymized only if not prohibited by its source.⁷⁶

In August 2004, the Office for Human Research Protections, Department of Health and Human Services, published a *Guidance Document on Research Involving Coded Private Information or Biological Specimens*. This document clarifies what comprises research involving human subjects. OHRP does not consider research to be research involving human subjects if the following two conditions are met: (1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and (2) the information or specimens are double-coded and there are assurances (either through private agreement, IRB policies or other legal requirements) that the key holder will not under any circumstances release the key to the investigators until the individuals are deceased.⁷⁷

(V) GERMANY

The 2004 opinion of the German National Ethics Council goes further than existing norms pertaining to biobanking in terms of the balance it achieves between patients’ rights, through respect for the most fundamental ethical principles, and freedom of research, through the adoption of a practical and sensible approach.⁷⁸ Recognizing the necessity for archived samples (obtained for diagnosis and treatment) to remain available for further use while respecting consent requirements, they hold that a “form-based” broad consent should be obtained at the time of collection.⁷⁹ This is consistent with other governance documents, such as CBAC. However, the Council further concludes that

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consent requirements can be waived when samples and data are anonymized, or even coded (“pseudonymized”) provided researchers do not have access to the code. A data protection officer is responsible to ensure respect for privacy requirements.⁸⁰ According to German data protection legislation, even where no “precautionary consent” is secured, consent can be waived for research on identified data and samples when donors’ interests are outweighed by the scientific importance of the research, and the research cannot proceed otherwise or can proceed only at a high cost.⁸¹ An ethics committee must approve such waiver.⁸²

For biobanks created for research purposes, consent can be general as to the type of research and length of storage; the information provided to the donors is limited to “personal risks to the donor arising directly in connection with the use of samples and data in biobanks” and does not extend to more general risks such as “the possibility that research results...might lead to undesirable societal trends,” such as discrimination or stigmatization.⁸³ All research projects intending to store samples in a biobank ought, however, to receive prior ethical approval.⁸⁴ Finally, donors have the right to withdraw, at any time, the research use of their data and samples. However, it is required to ask donors for consent for the use of their data and samples in an anonymized form, despite their withdrawal.⁸⁵

Part I Conclusion

In short, we note a gradual understanding by national policy-makers of the difference between the degrees of identification of samples and data, and corresponding levels of research access for secondary uses. There is also a move away from requiring an explicit re-consent for all secondary uses provided other safeguards are in place, such as double-coding, anonymization, data steward, and REB approval. We now turn to ethical guidance specific to the issues surrounding deceased individuals, as well as individuals who are incapable of providing consent, such guidance being particularly instructive for victims of mass disasters.

II

Use of Biological Samples of Deceased and Vulnerable Individuals

The term “vulnerable” is defined as “that may be wounded, susceptible of receiving wounds,” “open to attack or injury of a non-physical nature,”⁸⁶ and “liable to succumb, as to persuasion or temptation.”⁸⁷ There are two aspects to this word: risk of injury (physical or emotional) and inability to protect one’s own best interest. Protection of the vulnerable is a fundamental aspect of the rights of research subjects.⁸⁸ In its broadest sense, protection of the vulnerable entails protection of the deceased, as well as protection of children and incompetent adults. In the context of genetic research, these groups fall squarely within the definition of “vulnerable.”

Post Mortem

It is widely held that the death of a person does not extinguish the interests of that individual. Indeed, family members, and others who have physical possession or access to an individual’s body, tissue, or cells, have to respect certain obligations and rights following the death of the individual.

A. International and Regional Positions

The World Health Organization does hold, though, that death affects the primacy of this interest, and allows for the possibility, through appropriate ethical approval, of readjusting the balance of interests in light of death.⁸⁹

At the regional level, ESHG holds that post-mortem uses of samples are subject to the advance wishes of the donors.⁹⁰ In the absence of any known wishes, use of those samples should be regulated, a policy of unfettered use not being ethically justified.⁹¹ The Council of Europe does not explicitly differentiate between archived research material from living or deceased sources. It simply states that post-mortem uses have to meet satisfactory information and consent procedures.⁹²

In stark contrast, the European Commission recommends allowing samples from the deceased to be used for research for the development of genetic tests, as well as for teaching purposes, provided the sample is anonymized.⁹³ It does not recommend allowing research on samples which remain linked to the deceased.

B. Selected National Positions

At the national level, there is much variation concerning whether research can be performed on biological samples from deceased individuals, and if so under what circumstances. National positions cover the gamut from the theoretically unlimited power of officials to “deem” consent from the deceased, to the position that essentially disallows research on identifiable samples from the deceased unless the deceased previously consented to that research use.⁹⁴ Equally notable is the number of documents which do not address the issue at all.

(I) UNITED KINGDOM

The Human Tissue Act 2004 provides for powers to dispense with the need for consent, provided certain procedures are followed. More precisely, the Secretary of State may enable the High Court, in such circumstances as the regulations may provide, to make an order deeming the existence of appropriate consent to an activity consisting of

- (a) the storage of the body of a deceased person for use for the purpose of research in connection with disorders, or the functioning, of the human body,
- (b) the use of the body of a deceased person for that purpose;
- (c) the removal from the body of a deceased person, for use for that purpose, of any relevant material of which the body consists or which it contains;
- (d) the storage for use for that purpose of any relevant material which has come from a human body; or
- (e) the use for that purpose of any relevant material which has come from a human body.⁹⁵

In theory, then, there are wide powers in the UK to perform research on biological material from the deceased.

(II) FRANCE

In principle, biomedical research on a deceased individual can take place only if the individual had expressed his consent to such research while alive, or if his family members testify to the existence of such wishes.⁹⁶ However, some exceptions exist.

For example, when a person dies, consent to the collection of his/her organs for therapeutic or scientific

purposes is presumed in the absence of any known wishes to the contrary expressed by the person in their lifetime. In this absence, the physician must as far as possible contact family members to ascertain whether the deceased has expressed their opposition to this collection. He must inform family members of the purposes of the collection, and of their right to obtain information about the performance of such collection. The Agence de la Biomédecine must be informed of any contemplated post-mortem organ collection.⁹⁷ Post-mortem collection of cells, tissue and human body products is allowed only for therapeutic or scientific purposes, and only under certain conditions including absence of a prior opposition.⁹⁸

(III) CANADA

The Tri-Council Policy Statement provides that, for the collection of human tissue for research purposes in the case of deceased donors, “free and informed consent shall be expressed in a prior directive or through the exercise of free and informed consent by an authorized third party.”⁹⁹ The Tri-Council Policy Statement does not specifically address secondary use of archived human material when the donor is deceased; the same rules apply to secondary use of archived biological samples whether the donor is living or not.

(IV) UNITED STATES

As previously mentioned, research with tissue samples of deceased persons are not covered by the Federal regulations.¹⁰⁰ This is reiterated by the OHRP Guidance Document.¹⁰¹ Therefore, legally, research is permissible on tissue samples from deceased individuals.

The Genetic Privacy Bill, if passed into law, would not change what is allowable. Although for identifiable DNA samples it maintains a strict requirement for consent for collection,¹⁰² research on anonymized samples continues to be permissible in the absence of consent. And since, after the death of the individual who provided the sample, there is no longer the option of adding clinical data to the record, in practical terms, research on samples from deceased individuals could be performed by anonymizing the sample.

(V) GERMANY

The conditions imposed by Germany on collection and subsequent use in research are identical whether the individual is alive or deceased. If the deceased does not consent during his or her lifetime, the next of kin can provide consent, as long as this is not inconsistent with the wishes of the deceased as expressed or presumed during his or her lifetime.¹⁰³

Children and Incompetent Adults

A fundamental principle in the field of research and human rights is the protection of dependent or vulnerable persons and populations.¹⁰⁴ There is consensus at the international and national levels as to what research can be performed on individuals not able to consent for themselves, notably legally incapacitated adults or minor children.

A. International and Regional Positions

Generally, the following conditions must be met to conduct research with children or vulnerable adults: the research could not be carried out as effectively with less vulnerable subjects; the research is intended to ultimately benefit the class of which the subject is a part; research subjects and other members of the vulnerable class will ordinarily be assured reasonable access to any diagnostic, preventive, or therapeutic products that will become available as a consequence of the research; the risks attached to the research interventions or procedures that do not hold out the prospect of direct health-related benefit will not exceed those associated with routine medical or psychological examination of such persons unless an ethical review committee authorizes a slight increase over this level of risk; the agreement of the vulnerable individual is supplemented by the permission of their legal guardians or other appropriate representatives; and research ethics boards approve the research.¹⁰⁵

As noted by the Council of Europe, some legal systems distinguish between legal inability to consent and *de facto* inability to consent, where the relevant legal process to declare legal inability to consent has not been completed – for example, persons involved in a car accident, but who are not unconscious. Because of the shock caused by the emergency situation, any consent obtained would not be acceptable.¹⁰⁶ The Council of Europe holds that national law shall determine whether, and under which protective conditions, research in emergency situations may take place.¹⁰⁷ However, it enumerates specific conditions, which national law must include, which parallel those generally applicable to people legally unable to consent: research cannot be carried out on persons in non-emergency situations; the research project must be approved specifically for emergency situations by the competent body; any relevant previously expressed objections known to the researcher shall be respected; the research must have the potential to produce direct benefit to the health of the person concerned, or to persons in the same category or afflicted with the same disease or disorder or having the same condition; and the research entails only minimal risk and burden.¹⁰⁸

That both vulnerable individuals and individuals in emergency situations who are *de facto* unable to con-

sent to research are governed by very similar regimes is not surprising. For both groups, there are more stringent limitations on the permissible level of risk to which research subjects may be exposed due to the inability of obtaining valid consent from them.

Also of interest is the possibility that certain individuals or groups may share certain attributes with vulnerable individuals. As suggested by CIOMS, to the extent that a given class of people have attributes resembling those identified as vulnerable, “the need for special protection of their rights and welfare should be reviewed and applied, where relevant.”¹⁰⁹

B. Selected National Positions

(I) UNITED KINGDOM

The new Human Tissue Act 2004 allows storage of any relevant material which has come from a human body, for any uses including “research in connection with disorders, or the functioning of, the human body,¹¹⁰ as long as they are done with appropriate consent. This is true both of capable individuals and of minors; the difference, however, lies in the definition of “appropriate consent” for the two groups. “Appropriate consent” for children means consent of the minor, but where a child provides neither consent nor dissent for the research, or if the child is not competent to deal with consent in relation to the activity, or if he is competent but fails to make a decision, “appropriate consent” means the consent of a person who has parental responsibility for him.¹¹¹

Where research is in connection with disorders, or the functioning of the human body, and involves an adult who lacks capacity to consent to the research, and the adult neither consents to the research nor dissents to it, the Human Tissue Act 2004 deems there to be consent to the activity if it is done in circumstances of a kind specified by regulations made by the Secretary of State.¹¹²

(II) FRANCE

With respect to tissues and cells, article L. 1245-2, on the secondary use for scientific or therapeutic purposes, requires notification of the individual whether or not legally incompetent or a minor; in the case of minors or incompetent individuals notification of their legal representative; absence of opposition by the individual whether or not legally incompetent or a minor; and finally in the case of minors or incompetent individuals, absence of opposition by their legal representative. The secondary use of anonymized data falls outside the ambit of privacy laws and is therefore allowed.¹¹³

For the post-mortem collection of tissues, cells, body products or derivatives, if the deceased is a minor or incompetent adult, in the absence of a known prior opposition, secondary use is not possible without notification.¹¹⁴

(III) CANADA

The Tri-Council Policy statement permits individuals who are not legally competent to become research subjects only when (a) the research question can only be addressed using the identified groups; (b) free and informed consent from their authorized representative(s) is obtained; and (c) there is no more than minimal risks without the potential for direct benefits for them;¹¹⁵ and the potential incompetent subject does not dissent.¹¹⁶

Only the United States maintains that the research use of samples and data from deceased individuals does not fall under the ambit of “human subject” research.

Lastly, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved.¹¹⁷ The Canadian Biotechnology Advisory Committee’s 2004 *Genetic Research and Privacy – Advisory Memorandum*¹¹⁸ does not mention minors or incapable adults; CIHR’s 2005 *Best Practices* simply refer to the Tri-Council Policy Statement.¹¹⁹

(IV) UNITED STATES

The Department of Health and Human Services will conduct or fund research with children if the research falls into one of the following four categories: (1) the research involves not more than minimal risk;¹²⁰ (2) the risk is greater than minimal but presents the prospect of direct benefit to the individual subjects, the risk is justified by the anticipated benefit, and the anticipated benefit is at least as favorable as that presented by available alternatives;¹²¹ (3) the research, while involving only a minor increase over minimal risk to the subject and no prospect of direct benefit to individual subjects, is likely to yield general knowledge about the subject’s disorder or condition;¹²² or (4) the research, while not falling in any of the above-mentioned categories, presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.¹²³ In all four cases, it is required that the assent of children, if capable of assenting, and the permission of their parents or guardians is obtained.¹²⁴

Consent can be waived under the same conditions for research involving humans generally.¹²⁵

The Genetic Privacy Bill specifies that for individually identifiable DNA samples, when the sample source is under the age of eighteen, it is necessary to obtain the authorization of the parent or guardian as well as obtaining the written consent of the individual.¹²⁶ Once again, anonymized samples are beyond the ambit of the Bill. As research on anonymized samples is not considered “human subject research,” consent is not required for it.

(V) GERMANY

According to the German National Ethics Council, decisions on behalf of someone incapable of giving consent, due to age, disability, disease, or accident, are made by the individual’s legal representative. However, in the case of collection and use of samples and data, the individual’s consent must, as much as possible, be obtained. At a minimum, there must be no sign of refusal. Acknowledging the controversy surrounding the acceptability for those unable to consent for themselves to participate in research that will not directly benefit them, it ultimately does not take a stance on this matter. It concludes it is necessary for Germany to develop generally applicable principles that both protect research subjects who are unable to provide consent, and to the maximum extent possible, take into account the importance of research for the benefit of others.¹²⁷

Part II Conclusion

There is no doubt that overall, secondary research use of archived samples from legally incompetent individuals is much more restricted than that pertaining to samples archived following medical care or research protocols. Generally, an explicit consent is required from the legal representative. The texts which summarize the conditions governing secondary research involving this vulnerable group, in general, appear to have paid insufficient attention to this specific issue.

Yet, even in this area, secondary use of samples from deceased individuals is more permissive provided the samples or data are anonymized. Since no further downloading of data from the medical record would be necessary, this would be a reasonable position. Only the United States maintains that the research use of samples and data from deceased individuals does not fall under the ambit of “human subject” research.

III

Conclusion: Secondary Research on Samples Arising from Mass Disasters

Recent events have unfortunately demonstrated the necessity of addressing ethical issues surrounding sec-

ondary use of samples following mass disasters, and providing guidance to researchers and research ethics boards.

At the level of principle, everything discussed above in respect of secondary uses generally, and research on vulnerable individuals in particular, applies to collections of materials from mass disasters. In the end, each country mentioned seeks to protect autonomy and prevent exploitation of vulnerable potential research subjects, while facilitating research that will ultimately benefit society. As stated by CIOMS,

[t]he ethical justification of biomedical research involving human subjects is the prospect of discovering new ways of benefiting people’s health. Such research can be ethically justifiable only if it is carried out in ways that respect and protect, and are fair to, the subjects of that research and are morally acceptable within the communities in which the research is carried out.¹²⁸

However, due to the unique circumstances giving rise to the collection, secondary use of samples collected for identification purposes following mass disasters cannot simply be subsumed in existing regimes for deceased or vulnerable individuals. For example, as stated in the Australian Law Reform Commission,

[it] is easier to argue that consent should be waived for research purposes than for research on tissue originally collected for other purposes (therapeutic or diagnostic). In the latter case, (...), research is an unrelated secondary purpose [not] within expectations of the individual concerned.¹²⁹

Arguably, for the relatives of victims of mass disasters, research use is even further unrelated to the primary purpose of identification, and therefore waiving consent requirements for secondary research uses should occur even more rarely.

Another issue unique to mass disaster victims and their relatives is privacy and confidentiality. Victims’ and relatives’ names or personal identifiers may be leaked by the media or others.¹³⁰ Even for those who have not been individually identified, true confidentiality is not possible. It is understood that the victims form part of a group who lost their lives in the mass disaster; and it is understood that victims’ relatives form part of a group of people who lost family members in the mass disaster. Although the groups are not delineated on an ethnic or geographic basis, identification as forming part of a definable aggregate still occurs even absent individual identification. This is not to say that membership in this group implies that the privacy of

information, other than the fact of membership itself, is inherently contaminated. Indeed, privacy must be scrupulously protected to ensure the confidentiality of medical data, including genetic data.

It has been suggested that to research victims of terror, a system should be in place to declare a mass disaster, and to contact all research ethics boards asking them to carefully consider any research proposals in light of the unique circumstances.¹³¹ Another important procedural mechanism is informing the public, most specifically the victims' families, so that they have the opportunity of withdrawing from the research.¹³²

It must be noted that, at the time of collection, asking family members for written consent for the future use of their samples or that of their relatives who were direct victims of the disaster, either for a specific research project or broad consent for research uses, is neither a feasible nor an ethical solution. The sheer quantity of individuals who donate their samples, coupled with the urgency of the identification effort and the as yet unknown nature of future research would render it unworkable to obtain a prospective informed consent from relatives for use of such samples in research. More importantly, the traumatic nature of the situation, and the state of mind of the family would, in all likelihood, vitiate any consent that they would give. In a review of literature from 1981 to 2001 describing over 50,000 individuals who experienced eighty different disasters, seventy-four percent showed psychological problems such as post-traumatic stress or depression.¹³³ This psychological and emotional distress may impact the ability of individuals to genuinely consent to research.¹³⁴

Furthermore, secondary use of biological samples without obtaining specific re-consent, or even a broad consent from family members for the research use of their samples or those of their deceased relatives, may undermine public trust, a reality that not only infringes the dignity, autonomy, and privacy of research participants, but also harms research in the long run. We conclude, then, that there are two types of research that are acceptable on samples originally collected for the purpose of identifying victims of mass disasters.

The first is research to improve methods of DNA identification. This type of research is closer to being within the reasonable expectation of family members. What family members consent to, by providing their DNA, is identification. Thus, research into methods for the continuing refinement of DNA identification is not contrary to the original consent. Yet, in conformity with the international and national positions described above, we argue that once a victim has been positively identified, their DNA and that of their family members can be used for researching methods of improving identification only if the sample is anonymized and ethics

approval has been granted. Until such time, samples must remain double coded, for obvious reasons.

The second type of research is that which is intended to ultimately benefit the class of which the research subject is a part. For example, during the attacks on the World Trade Center, the public may have needed to know about the toxicity of the fires that continued to burn, to know how to best protect themselves from contaminants, and if it was safe to go outside.¹³⁵ Research on the effects of exposure to large fires, or to compounds produced when buildings burn down, could also benefit people similar to those whose remains are being studied. This would apply equally if, for example, a new fire retardant was developed specifically to prevent massive office fires, and research was needed to determine the risks to human health and survival. Furthermore, in a different kind of mass fatality, studies of the effects of a pathogen or environmental contaminant might not only be ethical, but essential for public safety.¹³⁶

For any research that does not fall squarely into the two categories described above, we recommend the following: during the time period that the DNA of living relatives is still coded, no further research be undertaken without an explicit, written consent. Even so, independent ethical review would need to determine whether the harm caused through the act of re-contacting living relatives (e.g. invasion of privacy, rekindled grief) outweighs intended scientific benefits or even social benefits to the relatives (recognition of altruism, social utility etc.) before such research is undertaken.

We conclude that for other research proposed for anonymized samples outside of the two categories described, whether from victims or their families, the unusual situation of their procurement and the fact that it is impossible to fully anonymize the samples¹³⁷ again mandates at a minimum independent ethical review, even if, strictly speaking, research with anonymized samples is not considered research involving human subjects. There should therefore be an ethical presumption against such research.

Missing from this analysis is any empirical evidence on the views of society in general, and of family members in particular on this issue. In this, we should be inspired by UNESCO's 2005 Universal Declaration on Bioethics and Human Rights, which states that "[p]ersons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis," and "[o]pportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted."¹³⁸

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