IRISH MEDICAL ORGANISATION
Ceardchumann Dochtúirí na hÉireann

IMO Submission to the Oireachtas Health Committee on the **Health Information and Patient Safety Bill – Revised General Scheme**

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IMO Submission to the Oireachtas Health Committee on the Health Information and Patient Safety Bill - Revised General Scheme

The Irish Medical Organisation (IMO) welcomes the opportunity to comment on the Health Information and Patient Safety Bill – Revised General Scheme. Since 2008 the IMO has been calling for legislation to bring legal clarity to the secondary use of personal health data. However the IMO believes that the Bill requires substantial work to ensure the legislation is fit for purpose. In particular the IMO has a number of concerns in relation to the buying and selling of personal health data without consent, compliance with the new EU regulations on Data Protection, how the draft Bill will impact on the statutory duties of public health doctors and upon health research using anonymised patient data. Also of concern is the failure to provide a mechanism for establishing a prescribed data matching programme or a prescribed health information resource.

Please find below comments on specific Heads of the Bill.

PART 1: PRELIMINARY MATTERS

Part 1 of the Draft Bill includes the short title and commencement, interpretation, the provision for the Minister for Health to make regulations under the act and expenses.

Under Head 2 the definition of "data set" does not explicitly state that it includes both manual and electronic records and any combination of both. This definition requires some expansion.

PART 2: PERSONAL DATA, PERSONAL HEALTH DATA AND PERSONAL HEALTH INFORMATION

Head 6 – Copies of Medical and other records to be furnished at patient's request
Under the provisions of Head 6 an individual will be able to request from a health service provider a copy of any patient records relating to that individual and a service provider will be required to furnish the individual with a copy within 40 days. The provider can refuse under a number of circumstances for example if it would be physically detrimental to the individual or if it conflicts with a legal duty or obligation.

Paragraph 33.5 of the Guide to Professional Conduct and Ethics for Registered Medical Practitioners 8th Ed 2016 states:

> Patients have a right to get copies of their medical records except where this is likely to cause serious harm to their physical or mental health. Before giving copies of the records to the patient, you must remove information relating to other people, unless those people have given consent to the disclosure.

The IMO would like to make the following suggested changes to Head 6, paragraph (5) (c) and (d):

> (c) the copying of the health records is not possible or would be ~~physically~~ detrimental to the~~m~~ **individual's physical or mental health,**
>
> (d) the furnishing of the health records by the health services provider would conflict with a legal **or ethical** duty or ~~legal~~ obligation of the health services provider,

Head 6 ignores a critical issue in relation to third party information contained within a medical record. Examples include (1) statements where a patient reports that a family member has a medical illness. These are often inaccurate or the family member does not wish others to know that he/she has been assigned a diagnosis. (2) Allegations by a patient in relation to assault by a third party. (3) Where a third party has revealed information to the treating practitioner or team in confidence or which may or may not cause harm to a patient. Head 6 must require the removal of information in relation to a third party, or given by a third party in confidence, unless that person has given consent to the disclosure.

Head 7 - Notification of cessation of provision of health services
Head 7 lays out duties and requirements for healthcare providers in cessation, including duties and requirements in the event of death of the healthcare provider. There is however no provision in the Bill as how long patient medical records should be held following the death of a patient.

Head 9 - **Buying or selling of personal health information.**
Confidentiality is a key tenet of the doctor-patient relationship. While the IMO welcomes the provisions under Head 9 which creates an offence to buy or sell personal health information, the IMO is extremely concerned about the discrepancy in the definition of "*health related information"* under Part 2 Head 9 and the definition of "*health related data"* under Part 1 Head 2. The discrepancy in the definition appears to allow for the buying and selling of health data that is collected for the

management of health services (including data collected for the investigation and resolution of complaints), data collected in relation to carrying out of health research, data collected in relation to the provision of a health or health-related insurance scheme or any data in a data matching programme or health information resource prescribed by the Minister for health under Parts 4 and 5 of the Bill. The IMO is extremely concerned that this legislation would allow for the buying or selling of this personal health data without the explicit informed consent of individuals.

Head 10 - Disclosure of personal data by statutory regulatory bodies
Head 10 allows for the sharing of personal healthcare data between regulatory bodies if it is relevant to the performance of the regulatory body's functions. While the Bill provides that the disclosure "shall go no further than is reasonably necessary for the attainment of the relevant purpose", there is no reference to seeking consent from the individual to the sharing of this information.

Head 11 - **Standards for electronic exchange of information**
IT systems in the healthcare services have been developed on an ad hoc basis and the vast majority of GPs have invested in electronic practice management systems including electronic health records. In light of the roll out of a national system of electronic health records prioritising hospital services, standards must ensure operability between national IT systems and other IT systems already in place in General Practice and community settings.

Head 12 - **Standards for the management of health data**
Head 12 – provides for HIQA to set standards for the processing and management of health data in the health services in consultation with the Data Protection Commissioner, however there is no reference to the monitoring of standards either by HIQA or the Mental Health Commission. It would seem logical that Head 12 in relation to the development of standards for the processing and management of data should precede Head 11 which relates to standards for the electronic exchange of information.

On the 4th May 2016, the new EU General Data Protection Regulation 2016/679 (GDPR) was published in the Official Journal of the EU with particular provisions for special categories of data including health data. In two years' time, the GDPR will be directly applicable in all Member states. The EU legislation will apply differently to large hospitals than to smaller medical practices in the community. The IMO would welcome detailed guidance for health care providers/data controllers both in the acute hospital setting as well as in general practice and the community on this important piece of EU legislation.

Processing of data for the purposes of public health
There is no reference in the Draft Bill as to what impact the proposed legislation will have on public health functions including the statutory function of Medical Officer of Health (MOH). The processing of identifiable patient data is required to perform the statutory functions of health surveillance, epidemiology and birth notification, for example under the Infectious Diseases Regulations 1981 an MoH has responsibility to investigate, prevent and control notifiable infections and outbreaks, under the Health (Duties of Officers) Order 1949 an MOH has the duty to inform himself of the causes origin and distribution of all disease affecting or threatening to affect injuriously the public health in the county. MOHs also oversee universal child health services, MOH require access to birth notification and child health records for the provision of neo-natal and child health services, screening for developmental issues, immunisation, congenital anomaly registries. (See Response by Public Health Medicine to HIPS Bill Revised General Scheme).

In addition, experts in public health medicine process patient data for health service evaluation, health needs assessment and other activities that do not fall under the definition of health research.

The proposed Bill must be consistent with existing statutory MOH legislation and ensure that the public health function has access to appropriate data while at the same time ensuring confidential patient data are protected.

The GDPR, provides a derogation from the prohibition of processing confidential health data for public health purposes under specific conditions. The Health Information and Patient Safety Bill should be compliant with the provisions in the GDPR.

PART 3: RESEARCH ETHICS APPROVAL

> Part 3 provides for a voluntary, national, streamlined research ethics approval structure for health research not already governed by other legislation. This Part does not apply to clinical trials of medicinal products or medical devices as these are already governed under other legislation. A major benefit for health researchers in this Part will be the creation of a single point of contact via HIQA (which will be the supervisory body for approved research ethics committees (ARECs) under this Part) as well as obtaining a single ethical approval for national or regional health research. It will also provide an avenue for researchers to apply for a data protection consent exemption in certain limited and restricted circumstances.

The IMO supports, in principle, the objectives of Part 3 to standardise the process of ethical approval for health research, however the IMO is concerned about certain aspects of the legislation as follows:

Head 24 – Membership of approved research ethics committee (AREC)
Membership of approved research ethics committees (AREC) will consist of no more than 21 persons and no less than 12. ARECs shall consist of expert and lay members and at least one quarter shall be lay members. An expert member should be appointed as chairperson of the AREC and a lay person should be appointed as deputy.

Under Head 13 an "expert member" is described as follows:

> a member of the committee who–
> (a) is a practising or retired health practitioner,
> (b) has qualifications or experience relating to the conduct of health research (other than as a member of a research ethics committee),
> (c) has qualifications or experience in the area of ethics, statistics, social sciences, philosophy or theology,
> (d) is a practising or retired barrister or solicitor, or
> (e) belongs to a class or category of persons prescribed by the Minister for the purposes of this definition;

There is no specification for a member of an AREC to be a registered medical practitioner. Given the importance of the role of the doctor in clinical trials the IMO recommends that Head 24 should provide for both a minimum number of expert members of ARECs including a minimum number of medical professionals with qualifications and experience in the conduct of health research.
In the interests of transparency members of ARECs should make an annual declaration of their financial interests.

In addition, many non-governmental organisations have senior staff who trained as health professionals but are working in a managerial or advocacy role. They are neither practising nor retired and should not be considered as 'experts' in this context because they can make an important contribution from a lay perspective.

Head 27 – Information available on internet
HIQA will establish, maintain and publish a register of ARECs. HIQA will also publish on its website information in relation to approved research proposals. The information includes the name and business address of the applicant, a brief description of the research proposal, the name of the AREC and whether it was subject to appeal and where an application has been made to the Commissioner and the decision from the Commissioner.

The IMO supports the Alltrials movement which calls for all clinical trials past and present to be registered and their results reported.

> "The Declaration of Helsinki, which is the World Medical Association's statement of principles for medical research involving people, states that every investigator running a clinical trial should register it and report its results. Millions of volunteers have participated in clinical trials to help find out more about the effects of treatments on disease, yet that important ethical principle about reporting has been widely ignored. Information on what was done and what was found in these trials could be lost forever to doctors and researchers, leading to bad treatment decisions, missed opportunities for good medicine, and trials being repeated."

Head 27 provides that HIQA will establish, maintain and publish a register of ARECs. HIQA will also publish on its website information in relation to approved research proposals. However, Head 27 does not provide for a register of clinical trials or for the mandatory publication of the results of clinical trials. The IMO notes that Part 3 of the Bill does not apply to the clinical trials of medicinal products and medical devices which is governed by EU legislation, nonetheless**,** in line with the recommendations of the Alltrials movement, Head 27 should provide that HIQA will establish an on-line register of clinical trials. Planned clinical trials should be registered with a summary of the research protocol, prior to the recruitment of the first subject. The register should also allow for the retrospective registration of past trials. A summary of the results should be published on the register within one year of completion of the clinical trial. The publication of results should be included as a condition of approval under Head 29. Full reports (excluding individual patient data) should be available to researchers on request.

Head 29- Decision on ethics of proposed health research proposal
Head 29 provides that ARECs will make decisions to give (with or without conditions) or refuse ethical approval of health research proposals based on the following matters:

> (2) An approved research ethics committee shall, in considering any proposal, consider the following matters to the extent that they are relevant to the proposal concerned-
>
> (a) whether the health research is likely to assist in–
>
> (i) the advancement or protection of human health, whether of the population as a whole or of any part of the population,
> (ii) the scientific understanding of human health,
> (iii) the understanding of social factors affecting human health,
> (iv) the identification, prevention or treatment of illness, disease or other medical impairment, or

(v) the effective management of health services, including improvements in the delivery of those services,

(b) whether the person making the proposal has identified and assessed the potential benefits and risks associated with the carrying out of the health research,

(c) whether the person making the proposal will make every effort to ensure that the participation of individuals in the health research will be informed and voluntary,

(d) whether the person making the proposal is qualified to carry out the health research concerned,

(e) whether there are adequate safeguards in place to protect the privacy of individuals participating in the health research and the confidentiality of their personal data, including, where appropriate, that any conditions imposed by the Commissioner under *Head 33* have been complied with as required,

(f) whether there is anything in the health research concerned that will undermine or decrease public confidence in health research generally,

(g) whether the research methodology proposed is appropriate,

(h) any guidelines issued by the Authority under *Head 18*.

When considering research proposals some distinction should be made between

1. Medical Research involving human subjects including research on identifiable human material and data and
2. Research using non-identifiable patient data.

1. Medical research involving human subjects including research on identifiable human material and data.

The World Medical Association Declaration of Helsinki lays out the ethical principles for medical research involving human subjects and research on identifiable human material and data**.** While the Declaration of Helsinki is aimed at physicians, decisions to give or refuse ethical approval for health research, in particular (b) and (c) above, should be strengthened to reflect these internationally agreed principles.

In relation to (b) identifying and assessing potential risks and benefits, approval should only be granted where the benefits outweigh the risks and where measures are to be taken to continuously monitor and minimise the risks.

In relation to (c) informed consent, the Declaration of Helsinki states that "Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary" and that "no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees". Where patients lack capacity to give informed consent, consent must be sought from a legally authorised representative.

Individuals participating in health research 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. Informed consent should be documented and must be sought by an appropriately qualified individual. Patients must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time.

The full text of the WMA Declaration of Helsinki is attached as Annex 1.

2. Research using non-identifiable patient data.

While it is always advisable to seek patient consent for research purposes, it is not always feasible. Under current Data Protection Guidelines on research in the Health Sector and the HSE National consent policy informed patient consent is not required where anonymised data are used and where no potential harm arises from the use of the data obtained. The Bill as drafted will require patient consent for every research proposal regardless of whether information has been anonymised or not.

Much of our health research in Ireland relies upon data which are collected retrospectively, which inform audit and clinical practice. These observational data often have the greatest impact in relation to:

1. Day-to-day clinical practice
2. Informing clinical and scientific research design
3. Improving patient experience and outcome
4. Informing clinical and cost-efficacy of current approaches.

Retrospective analyses of this nature are carried out on high volumes of patients whose data may have been collected many years in advance. Contacting these individuals for consent purposes is not always possible. To lose access to this repository of data for analysis would indeed have a devastating impact on clinical and research practices in Ireland going forward. Retrospective data analysis on anonymised data are also a requirement for good clinical practice and continuing medical education.

We recommend strongly that a consultative process is instituted around this area, drawing from the experience and requirements in other jurisdictions.

Head 30 - Effect of approval

Head 30 relates to approval at state or regional level. Where an AREC has given approval at state or regional level no other AREC or REC established by an appointing authority in receipt of state funding can require any examination of matters under Head 29 (2). Where research is approved under head 29 or head 32 in relation to a part of the state, it is only valid in that part of the state. Where research is approved in relation to the state generally, it is approved in the whole state.

The IMO welcomes Head 30 as this will reduce the duplication of work by health research proposers and approved research ethics committees

Head 31 – Decision-making.

Under Head 31 an AREC may consult with an external expert if required. A Member of an AREC may not partake in the consideration of a proposal if the member has an interest or is connected to a person with an interest in the proposal. Decisions made by an AREC shall be made by a quorum of half the membership of the committee and of which at least one quarter of the membership making the decision must be lay.

As per Head 24, Head 31 should define a minimum reasonable number of expert members required to make a decision rather than the number of lay persons.

Head 33 – **Processing of personal data without consent**– This Head provides a mechanism for a person proposing to carry out health research to apply to the Data Protection Commissioner for a data protection consent exemption in certain strict and limited circumstances.

PART 4 DATA MATCHING PROGRAMMES

Part 4 sets out the rules and principles that will apply to a prescribed data matching programme by the Minister and requires data controllers to provide information to a prescribed data matching programme.

Head 50 - **Prescribed data matching programmes**
Under Head 50 the Minister is to consult with HIQA and the Data Protection Commissioner with regard to regulations for a prescribed data matching programme at national level. The Minister may prescribe a data matching programme provided he is satisfied on a number of matters. Regulations will provide for the manner in which a data matching programme is to be carried out and the information in relation to the data matching programme that must be published on a website maintained by the Minister.

The draft Bill does not lay out a procedure for establishing a prescribed data matching programme. In the explanatory note it is stated that:

> "It is important to emphasise that the prescribing of a data matching programme under this Part is intended to be at the discretion of the Minister where he or she identifies a need for a prescribed programme, rather than an application based tick box exercise. That is why there is no formal application process provided for in this Part. Neither is it intended that the Minister should prescribe a programme under his or her control."

The absence of a formal application process implies that informal approaches may be made to the Minister. Limiting this power to the Minister without the potential to apply for permission to match data sets is undemocratic, lacks transparency and limits the potential for population health research.

Head 50 Subhead (1) (a) states that;

> The Minister may, after consultation with-
>
> (i) the Commissioner on matters regarding the protection of personal data, and
>
> (ii) the Authority on matters relating to the likelihood of a person complying with standards,
>
> make regulations prescribing a data matching programme to be carried out on a national basis.

It is unclear why a data matching programme must be carried out at national level. Valuable information can be gleaned from regional information systems, demonstrating feasibility and initiating programmes at lower cost than is possible for national systems.

PART 5 HEALTH INFORMATION RESOURCES

Similarly to Part 4, Part 5 sets out the rules and principles that will apply to a prescribed health information resource set by the Minister and requires data controllers to provide information to a prescribed health information resource.

Part 5 provides no formal process for the establishment of a prescribed health information resource and, as per Part 4 above, opens up the possibility of informal approaches to be made to the Minister that lack transparency. Where identifiable patient data are to be used in the establishment of a prescribed health information resource the principles laid out in the WMA Declaration of Taipei on

ethical considerations regarding health databases and biobanks should apply. In particular the WMA Declaration of Taipei states:

> "An independent ethics committee must approve the establishment of Health Databases and Biobanks used for research and other purposes. In addition the ethics committee must approve use of data and biological material and check whether the consent given at the time of collection is sufficient for the planned use or if other measures have to be taken to protect the donor."

The WMA Declaration of Taipei is attached as Annex 2.

Again it is unclear why a prescribed health information source should be prescribed at national level. Valuable information can be gleaned from regional information systems, demonstrating feasibility and initiating programmes at lower cost than is possible for national systems. The National Cancer Registry started out as the Southern Tumour Registry.

PART 6: PATIENT SAFETY INCIDENTS

Head 70 - Reportable incidents

Under Head 70 the Minister will prescribe patient safety incidents which are to be reportable, including serious harm events and no harm events under paragraphs (a) and (b) the definition of a patient safety incident. Reportable incidents will not include near miss events, paragraph (c), although these can be reported voluntarily.

- ***Definition of "patient safety incident"***

"*patient safety incident*" means, in relation to a health service provider,

> (a) an unintended or unanticipated injury or harm in respect of a service user that occurred during the provision of a health service to a service user,
>
> (b) an event that occurred in respect of a service user during the provision of a health service to that user that did not result in actual injury or harm but there are reasonable grounds to believe placed the service user at risk of unintended or unanticipated injury or harm,
>
> (c) an incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user;

Patient care is increasingly complex and there are certain risks attached. Not all events that cause harm are the result of patient safety issues. The definition of a patient safety incident must ensure the following events are excluded:

- events which can cause harm to the patient which are either unpredictable (for example, an allergic reaction to a medication that the patient had never taken before);
- known side effects of treatment which were fully discussed with the patient in advance but can occur for an unknown reason (for example, a side effect of a medication which occurs in x% of the population but there is currently no way of determining who would suffer that side effect);
- adverse events which occurred as a result of something either not discovered at the time of the event, or not accepted into general medical thinking should also be excluded (for example if a patient contracted a disease from a virus which was unknown at the time of the event).

Similarly in clinical practice doctors are trained to monitor patient responses and react to clinical feedback. The definition of c), which describes near harm events, must ensure that the following events are excluded:

- clinical events or reactions that are known and where all necessary action was taken to prevent any harm;
- other adverse events that were avoided because risk assessment procedures ensured that the necessary actions were taken to reduce the risk of these events occurring.

Head 71 - Notification of reportable incidents
Head 71 places obligations on persons to notify reportable incidents to the State Claims Agency, HIQA, the Chief Inspector of Social Services and the Mental Health Commission.

Varying definitions in the Draft Bill of "relevant body", "relevant provider", "registered provider" and "service provider" are confusing and it is very difficult to establish who is responsible for notifying reportable incidents or if medical practitioners are to be required to notify reportable incidents.

Head 76 - Patient safety incident notifications not admissible in certain civil proceedings
The explanatory note under Head 68 recognises that fear of litigation and damage to reputation as significant challenges for engaging with incident reporting, open disclosure and audit processes. However under Head 76, Patient Safety Incident notifications are not admissible in civil proceedings against certain service providers.

The confusion over definitions of service providers suggests that patient safety incident notifications will be admissible in civil proceedings against medical practitioners and fitness to practise procedures. In order to support a culture of blame-free reporting and learning following adverse events, patient safety incident notifications should not be admissible in civil proceedings against medical practitioners or Medical Council fitness to practise procedures. This would not prevent civil proceedings or fitness to practise procedures from being instigated independently.

PART 7 - CLINICAL AUDIT
Under Part 7 the Minister is to issue Guidance for clinical audit to be applicable to different categories of health service provider, specify the timing, frequency and for publishing aggregate results of clinical audit.

Again the definition of "service provider" under Part 6 and Part 7 varies from the definition used under Part 1 of the Bill and creates confusion as to who is responsible for carrying out clinical audit and publishing the results. No obligation is placed on the Minister to fund the clinical guidelines against which the clinical audit is to take place.

Head 82 – Evidence
Again the confusion over definitions of service providers suggests that records created for the purpose of clinical audit will not be admissible in civil proceedings where the audit has been carried out and published in accordance with Heads 80 and 81. It would seem however that records created for the purpose of clinical audit will be admissible in civil proceedings against medical practitioners and fitness to practise procedures. Again in order to support a culture of blame-free reporting and learning, records created for the purpose of clinical audit should not be admissible in civil proceedings against medical practitioners or Medical Council fitness to practise procedures. This would not prevent civil proceedings or fitness to practise procedures from being instigated independently.

PART 9 AMENDMENT OF HEALTH ACT 2007

The IMO welcomes the provisions under Part 9 which extends HIQA's remit to cover private health services in particular private facilities providing aesthetic surgery and non-surgery services.

The Bill amendment intends to include particular high risk services where the use of a general anaesthetic is required to be administered to the patient. The IMO question as to why this is the chosen criterion as there are a wide range of private healthcare services that may not fall into this category including privately provided telemedicine services, slimming clinics, dermatology clinics, private ultrasound services, screening services. These services should also be required to comply with HIQA national healthcare standards.

The IMO would also consider that the remit of the Mental Health Commission should be extended to cover privately provided psychotherapy and counselling services.

Summary of Recommendations

PART 2: PERSONAL DATA, PERSONAL HEALTH DATA AND PERSONAL HEALTH INFORMATION

- **The provisions under head 6 in relation to copies of medical and other records to be furnished at a patient's request, should reflect the provisions in Paragraph 33.5 of the Guide to Professional Conduct and Ethics for Registered Medical Practitioners 8th Ed 2016;**
- **Discrepancies in the definition of "*health related information*" under Part 2 Head 9 and the definition of "*health related data*" under Part 1 Head 2 should be clarified. Where the buying and selling of health data is permissible it should only take place with the explicit and informed consent of individuals;**
- **The proposed Bill must be consistent with existing statutory MOH legislation and ensure that the public health function has access to appropriate data while at the same time ensuring confidential patient data are protected;**
- **The Health Information and Patient Safety Bill should be compliant with the provisions in the new EU General Data Protection Regulations 2016/679;**

PART 3: RESEARCH ETHICS APPROVAL

- **Head 24 should provide for both a minimum number of expert members of approved research ethics committees (ARECs) including a minimum number of medical professionals with qualifications and experience in the conduct of health research;**
- **In the interests of transparency members of ARECs should make an annual declaration of their financial interests;**
- **Head 27 should provide that HIQA will establish an on-line register of clinical trials. Planned clinical trials should be registered with a summary of the research protocol, prior to the recruitment of the first subject. A summary of the results should be published on the register within one year of completion of the clinical trial;**
- **Ethical approval by an AREC of medical research involving human subjects including research on identifiable human material and data should reflect the internationally agreed principles laid out in the WMA Declaration of Helsinki;**
- **Research using non-identifiable patient data should reflect current Data Protection Guidelines on Research in the Health Sector and the HSE National Consent Policy. The IMO also recommend strongly that a consultative process is instituted around this area, drawing from the experience and requirements in other jurisdictions;**

PART 4: DATA MATCHING PROGRAMMES & PART 5: HEALTH INFORMATION RESOURCES

- **In the interest of transparency procedures should be put in place for the establishment of a prescribed data matching programme a prescribed health information resource;**
- **The Bill should allow the establishment of prescribed data matching programmes at regional as well as national level;**
- **Where identifiable patient data are to be used in the establishment of a prescribed health information resource the principles laid out in the WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks should apply;**

PART 6: PATIENT SAFETY INCIDENTS & PART 7: CLINICAL AUDIT

- **Varying definitions in the Draft Bill of "relevant body", "relevant provider", "registered provider" and "service provider" should be clarified;**
- **In order to support a culture of blame-free reporting and learning, patient safety incident notifications and records created for the purpose of clinical audit should not be admissible in civil proceedings against medical practitioners or Medical Council fitness to practise procedures. This would not prevent civil proceedings or fitness to practise procedures from being instigated independently;**

PART 9 AMENDMENT OF HEALTH ACT 2007

- **The IMO welcomes the provisions under Part 9 which extends HIQA's remit to cover private health services. Consideration should be given to expanding HIQAs remit beyond services where the use of a general anaesthetic is required to be administered to the patient.**
- **The remit of the Mental Health Commission should be extended to cover privately provided psychotherapy and counselling services.**

Annex **1**

WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. 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.”

4. 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 fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimises possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After

the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. 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.

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.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make

publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

Annex 2

WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks

Adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002
and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016

PREAMBLE

1. The Declaration of Helsinki lays down ethical principles for medical research involving human subjects, including the importance of protecting the dignity, autonomy, privacy and confidentiality of research subjects, and obtaining informed consent for using identifiable human biological material and data.
2. In health care provision, health information is gathered by physicians or other members of the medical team to record health care events and to aid physicians in the on-going care of their patient.

3. This Declaration is intended to cover the collection, storage and use of identifiable data and biological material beyond the individual care of patients. In concordance with the Declaration of Helsinki, it provides additional ethical principles for their use in Health Databases and Biobanks.

This Declaration should be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

4. A Health Database is a system for collecting, organizing and storing health information. A Biobank is a collection of biological material and associated data. Biological material refers to a sample obtained from an individual human being, living or deceased, which can provide biological information, including genetic information, about that individual. Health Databases and Biobanks are both collections on individuals and population, and both give rise to the similar concerns about dignity, autonomy, privacy, confidentiality and discrimination.

5. Research using Health Databases and Biobanks can often significantly accelerate the improvement in the understanding of health, diseases, and the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic interventions. Health research represents a common good that is in the interest of individual patients, as well as the population and the society.

6. Physicians must consider the ethical, legal and regulatory norms and standards for Health Database and Biobanks in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for individuals and population set forth in this Declaration.

When authorized by a national law adopted through a democratic process in respect of human rights, other procedures could be adopted to protect the dignity, autonomy and privacy of the individuals. Such procedures are only acceptable when strict rules on data protection are implemented.

7. Consistent with the mandate of WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in using data or biological material in Health Databases and Biobanks to adopt these principles.

ETHICAL PRINCIPLES

8. Research and other Health Databases and Biobanks related activities should contribute to the benefit of society, in particular public health objectives.

9. Respecting the dignity, autonomy, privacy and confidentiality of individuals, physicians have specific obligations, both ethical and legal, as stewards protecting information provided by their patients. The rights to autonomy, privacy and confidentiality also entitle individuals to exercise control over the use of their personal data and biological material.

10. Confidentiality is essential for maintaining trust and integrity in Health Databases and Biobanks. Knowing that their privacy will be respected gives patients and donors the confidence to share sensitive personal data. Their privacy is protected by the duty of confidentiality of all who are involved in handling data and biological material.

11. The collection, storage and use of data and biological material from individuals capable of giving consent must be voluntary. If the data and biological material are collected for a given research project, the specific, free and informed consent of the participants must be obtained in accordance with the Declaration of Helsinki.

12. If the data or biological material are collected and stored in a Health Database or a Biobank for multiple and indefinite uses, consent is only valid if the concerned individuals have been adequately informed about:

- The purpose of the Health Database or Biobank;
- The risks and burdens associated with collection, storage and use of data and material;
- The nature of the data or material to be collected;
- The procedures for return of results including incidental findings;
- The rules of access to the Health Database or Biobank;
- How privacy is protected;
- The governance arrangements as stipulated in paragraph 21;
- That in case the data and material are made non-identifiable the individual may not be able to know what is done with their data/material and that they will not have the option of withdrawing their consent;
- Their fundamental rights and safeguards established in this Declaration; and
- When applicable, commercial use and benefit sharing, intellectual property issues and the transfer of data or material to other institutions or third countries.

13. In addition to the requirements set forth in the Declaration of Helsinki, when persons who were not able to consent, whose data and biological materials have been stored for future research, attain or regain the capacity to consent, reasonable efforts should be made to seek the consent of those persons for continued storage and research use of their data and biological materials.

14. Individuals have the right to request for and be provided with information about their data and its use as well as to request corrections of mistakes or omissions. Health Databases and Biobanks should adopt adequate measures to inform the concerned individuals about their activities.

15. Individuals have the right, at any time and without reprisal, to alter their consent or to ask for their identifiable data to be withdrawn from the Health Database and their biological material to be withdrawn from a Biobank. This applies to future use of the data and biological materials.

16. In the event of a clearly identified, serious and immediate threat where anonymous data will not suffice, the requirements for consent may be waived to protect the health of the population. An independent ethics committee should confirm that each exceptional case is justifiable.

17. The interests and rights of the communities concerned, in particular when vulnerable, must be protected, especially in terms of benefit sharing.

18. Special considerations should be given to the possible exploitation of intellectual property. Protections for ownership of materials, rights and privileges must be considered and contractually defined before collecting and sharing the material. Intellectual property issues should be addressed in a policy, which covers the rights of all stakeholders and communicated in a transparent manner.

19. An independent ethics committee must approve the establishment of Health Databases and Biobanks used for research and other purposes. In addition the ethics committee must approve use of data and biological material and check whether the consent given at the time of collection is sufficient for the planned use or if other measures have to be taken to protect the donor. The committee must have the right to monitor on-going activities. Other ethical review mechanisms that are in accordance to par 6 can be established.

GOVERNANCE

20. In order to foster trustworthiness, Health Databases and Biobanks must be governed by internal and external mechanisms based on the following principles:

- Protection of individuals: Governance should be designed so the rights of individuals prevail over the interests of other stakeholders and science;
- Transparency: any relevant information on Health Databases and Biobanks must be made available to the public;
- Participation and inclusion: Custodians of Health Databases and Biobanks must consult and engage with individuals and their communities.
- Accountability: Custodians of Health Databases and Biobanks must be accessible and responsive to all stakeholders.

21. Governance arrangements must include the following elements:

- The purpose of the Health Database or Biobank;
- The nature of health data and biological material that will be contained in the Health Database or Biobank;
- Arrangements for the length of time for which the data or material will be stored;
- Arrangements for regulations of the disposal and destruction of data or material;
- Arrangement for how the data and material will be documented and traceable in accordance with the consent of the concerned persons;
- Arrangement for how the data and material will be dealt with in the event of change of ownership or closure;
- Arrangement for obtaining appropriate consent or other legal basis for data or material collection;
- Arrangements for protecting dignity, autonomy, privacy and preventing discrimination;
- Criteria and procedures concerning the access to and the sharing of the health data or biological material including the systematic use of Material Transfer Agreement (MTA) when necessary;
- The person or persons who are responsible for the governance;

- The security measures to prevent unauthorized access or inappropriate sharing;
- The procedures for re-contacting participants where relevant;
- The procedures for receiving and addressing enquiries and complaints.

22. Those professionals contributing to or working with Health Databases and Biobanks must comply with the appropriate governance arrangements.

23. Health Databases and Biobanks must be operated under the responsibility of an appropriately qualified professional assuring compliance with this Declaration.

24. The WMA urges relevant authorities to formulate policies and law that protect health data and biological material on the basis of the principles set forth in this document.