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## IRB/EC REVEALED

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DECEMBER 2016

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## THE LEGAL STATUS, COMPOSITION, FUNCTION, OPERATION, AND REGULATORY REQUIREMENTS PERTAINING TO IRBs/ECs DIFFER WIDELY AMONG COUNTRIES.

Trying to get IRB or EC approval is increasingly common in healthcare research. But what exactly is an IRB or EC? Healthcare research ranges from clinical trials, to real-world research (RWR), to observational studies, to opinion-based market research; which should obtain IRB/EC approval? Are all research types treated equally? How are IRBs/ECs set up, and do they vary by country? This paper attempts to help healthcare researchers navigate through this topic.

### WHAT IS AN IRB/EC?

An Institutional Review Board (IRB) (U.S. term), also known as an Independent Review Board or Clinical Research Ethics Committee (EU term), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.<sup>1</sup>

The purpose of IRB/EC review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as research subjects.

### WHAT DO IRB/ECs EXAMINE?

To accomplish its purpose, IRB/ECs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

IRBs often conduct some form of risk-benefit analysis in an attempt to determine whether research should be done. IRBs are responsible for critical oversight functions for research conducted on human subjects that are “scientific,” “ethical,” and “regulatory.”

IRB/EC reviews, approves, and provides favorable opinion on the trial protocol, the suitability of the investigators, facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

### WHAT CONSTITUTES AN IRB/EC?

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.

Some IRBs/ECs may involve lay members (previously registered as healthcare providers (HCPs) or involved in the conduct of clinical research other than as a research subject<sup>2</sup>); some only include medical professionals.

In the United States, some IRBs are affiliated with an academic institution (which could be public or private); some are independent, private organizations, which are more approachable by an independent research agency like Kantar Health.

### IS THERE A VARIANCE OF IRB/EC BY COUNTRY?

Yes, there are many variances. The legal status, composition, function, operations, and regulatory requirements pertaining to independent ECs differ widely among countries. However, most IRBs/ECs act in agreement with the Declaration of Helsinki and Good Clinical Practices (GCP) as described in ICH Topic E6 Guide for Good Clinical Practice (ICH-GCP).

IRB or EC is country-specific. There is no IRB in the EU, nor is there EC in the United States. There is neither a single

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## MOST COMPETENT AUTHORITIES REQUIRE ALL STUDIES THAT INVOLVE "HUMAN SUBJECT RESEARCH" TO SEEK IRB/EC APPROVAL, ALTHOUGH APPLICATION PROCESSES AND CRITERIA FROM EACH IRB/EC VARY.

EC covering all EU countries nor an international IRB.

### WHO GOVERNS AN IRB/EC?

In the United States, the Food and Drug Administration (FDA) and Department of Health and Human Services (HHS) (specifically Office for Human Research Protections) regulations have empowered IRBs to approve, require modifications in planned research prior to approval, or disapprove research.

The FDA will issue warning letters if any IRB is providing less than satisfactory service or does not meet ethical standard. All warning letters are published on the FDA's website.

In the EU, the central EC is often governed by the ministry of health or the respective competent authority. Some local IRBs/ECs will be governed the board of academic institutions or hospitals to which they belong.

In the United States, IRBs are governed by Title 45 Code of Federal Regulations Part 46. These regulations implement provisions of the National Research Act of 1974, for example defining IRBs and requiring them for all research that receives support, directly or indirectly, from HHS.

Title 21 Part 56 has additional requirements for IRBs that oversee clinical trials of drugs involved in new drug applications.

### BACKGROUND - WHY DO WE NEED IRBS/ECs?

Most countries set up IRBs/ECs in direct response to research abuses earlier in the 20th century. Two of the most notorious of these abuses were the experiments of Nazi physicians that became a focus of the post-World War II Doctors' Trial, and the Tuskegee Syphilis Study, a project

conducted between 1932 and 1972 by the U.S. Public Health Service on black men in rural Alabama. Nuremberg Code (1947)<sup>3</sup> and the Declaration of Helsinki (1964 first version to 2013)<sup>4</sup> were introduced, and over 100 countries<sup>5</sup> agreed to them and adapted them into their own legislation.

As the background of IRBs/ECs is set up to evaluate clinical trials, it is only in recent years that IRB/EC approval moved into the non-clinical space. The demand of an "IRB/EC stamp" is to prove gold standard of ethical application of a study by researchers, yet not all IRBs/ECs are familiar with applications without intervention.

### FOR WHAT TYPES OF STUDIES DO WE NEED IRBS/ECs?

Application criteria from IRBs/ECs vary by their set up; however, most competent authorities require all studies that involve "human subject research" to seek IRB/EC approval. However, the term "human subject research" has specific interpretations and may be contradictory to some healthcare researchers' practices on the daily basis.

A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information. Based on this definition, an opinion-based study with no intervention that involves only anonymized information will not require IRB/EC approval.

## THE DEFINITION OF “RESEARCH” USED BY KEY REGULATORS MIGHT NOT BE WHAT SOME HEALTHCARE RESEARCHERS USE.

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.<sup>6</sup> A “systemic investigation” can be either qualitative or quantitative, and it can involve any mode of data collection including a chart review, interviews, online survey, etc.

Some key discriminants are as follows:<sup>7</sup>

### 1. INTENT

The primary aim of research is to derive generalizable new knowledge, whereas the aim of audit and service evaluation projects is to measure standards of care. Research is to find out what you should be doing; audit is to find out if you are doing a planned activity and assesses whether it is working. Some projects may have more than one “intent,” in which case a judgment will need to be made on the primary aim of the project.

### 2. TREATMENT/SERVICE

Neither audit nor service evaluation uses an intervention without a firm basis of support in the clinical or health community.

### 3. ALLOCATION

Neither audit nor service evaluation allocates treatment or service by protocol. It is a joint decision by the clinician and patient.

### 4. RANDOMIZATION

If randomization is used, it is research.

Based on these criteria, clinical trials and non-interventional studies aimed for publication (generalization of findings) will need IRB/EC approval.

## WILL MARKET RESEARCH NEED IRB/EC APPROVAL?

Not in general. Market research associations such as the European Pharmaceutical Market Research Association (EphMRA)<sup>8</sup> have a clear position that market research (as defined above) relating to market or consumer behavior of the sort that pharmaceutical companies routinely commission, whether involving healthcare professionals, patients, carers, or members of the public, does not require Clinical Research Ethics Committee or Independent Review Board approval (Institutional Review Board in the United States).

Key regulators have made it clear what distinguishes research that requires IRB/EC approval, i.e., clinical/medical research, from research that does not include market research, which are opinion-based studies.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) requires non-interventional research studies to meet specific criteria that are not required of market research:<sup>9</sup>

- + The study is conducted for a scientific purpose.
- + There is a written protocol.
- + The study protocol must be approved by, and the study conduct supervised by, the company’s Scientific Service.
- + The study results should be analyzed and made available within a reasonable period of time to the company’s Scientific Service and the healthcare professionals who participated in the study.

## WE SHOULD ASK IF THE CLIENT INTENDS TO PUBLISH WHEN CONSIDERING WHETHER A STUDY SHOULD BE SUBMITTED FOR IRB/EC.

- + If the study shows results that are important for the assessment of benefit-risk profile of the medicinal product, the summary report should be immediately forwarded to the relevant competent authority.
- + Companies publicly disclose the summary details and results of non-interventional studies in a manner consistent with the parallel obligations for clinical trials.
- + Companies apply the same requirements (to the extent applicable) to all other types of studies, including epidemiological studies, registries, and other studies that are retrospective in nature.

However, sometimes a market research study may be requested for publication purposes. If that is “generalization of knowledge,” an IRB/EC approval will be needed. But then, this is no longer market research that is aimed for internal business decision making.

### DO I NEED AN IRB/EC FOR PILOT OR PRETEST?

It depends on whether the pilot or pretest is used for market research or human subject research. Often when a pilot or pretest will be part of or lead to larger-scale research, its intent, study design, and other factors are included as the main study protocol or proposal. The consideration criteria should be no different.

### IF I WANT THE STUDY RESULTS TO BE PUBLISHED, DO I NEED AN IRB/EC?

This is the reason that we often ask if the client intends to publish when considering whether a study should be submitted for IRB/EC – because intent to publish means that the project is designed to contribute to generalizable knowledge.

If a study result will be submitted as an abstract or manuscript to a conference or medical journal for publication purposes, the answer is to check the requirements of the publication. There is usually a note of contribution or guidelines for authors to check. Different publications have different requirements, ranging from no specific requirement, to one central IRB/EC, to local IRB/EC per country. In general, publication to a medical conference or peer-reviewed journal contributes to generalizable knowledge; hence, IRB/EC approval will be needed. If published on a personal blog, social media space, or company white paper, there is no requirement on IRB/EC approval.

From an IRB/EC point of view, different countries have their own requirements. In countries where healthcare is managed by the public sector, such as the EU, requirements may also include use public health resource.

### DO I NEED IRB/EC FOR CHART REVIEW STUDY?

Chart review is a widely used methodology in different research types, not a single consideration for whether IRB/EC is needed.

1. Do the charts include any identifiable patient information? If yes, we will need IRB/EC as the study will be “human subject.” The Health Insurance Portability and Accountability Act of 1996 (HIPAA) 18 identifiers<sup>10</sup> are a good resource to check whether any identifiable patient information is included in the chart design in the United States. In EU countries, the General Data Protection Regulation (GDPR)<sup>11</sup> does not specify the exact identifiers but defines “personal data” as any information relating to an identified or identifiable natural person (“data subject”); an identifiable natural

## IRB/EC APPROVAL SHOULD BE GRANTED PRIOR TO RESEARCH EXECUTION. IF NOT, THE IRB/EC COULD DEEM THE STUDY TO BE "UNETHICAL" OR ANY STUDY ALREADY CARRIED OUT INVALID.

person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier, or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. Care should be taken for studies on rare disease, as even without name and contact information, the patient might still be identifiable.

2. Will this study use public healthcare resources? For example, will it have a public hospital site set up and have doctors in the site as investigators? If yes, countries that have large public health services such as in the EU will require EC approval. If HCPs are recruited via online doctors' panels, IRB/EC may not be required.
3. Is this study research? See previous section for details. If yes, IRB/EC will be needed. Most market research is not classified as "research." Even anonymized chart reviews might be used for sponsors' internal business decision making.
4. Will the sponsor aim to publish the study to a peer-reviewed medical journal? See previous section for details. If yes, this could be "generalization of knowledge." Depending on the requirements of the publication this study might need IRB/EC.

### IT SEEMS MY STUDY DOESN'T NEED IRB/EC, BUT MY CLIENT WANTS TO APPLY ANYWAY. WILL THIS BE A PROBLEM?

Most IRBs/ECs will accept all applications even they are not human subject research. Some will review even it is not "research" or does not involve "human subject" and provide an opinion, such as "exempted" or "approved as no ethical issues." For example, UK research

ethics committees (REC) and most U.S. IRBs will accept all applications and provide an opinion. However, some local IRBs/ECs will reject on the basis on applications for "not being in the scope." Contacting the IRB/EC is highly recommended before applying. After all, an unfavorable opinion is not desirable to any study. In addition, all applications will take time, some will charge a fee, and expectations on time and investment must be set in advance for all IRB/EC applications.

### I THINK A STUDY SHOULD GET IRB/EC, BUT WE ARE PRESSED ON TIME. WHAT WILL HAPPEN IF WE DON'T GET IRB/EC APPROVAL?

IRB/EC approval should be granted prior to research execution. If not, the IRB/EC could deem the study to be "unethical" or any study already carried out invalid. If a study is intended for scientific publication, researchers might find that few publications will consider a human subject research without IRB/EC approval, which will be disappointing at the back end. Please note that it is very rare for an IRB/EC to accept retrospective applications (study already carried out).

### WHAT IS THE DIFFERENCE BETWEEN A CENTRAL AND LOCAL IRB/EC?

Central IRBs/ECs can be on the country level (not all countries offer this); they can approve studies for multiple sites. Local IRBs/ECs are often attached to a hospital for public service entity, which only have authority to approve studies in their own site. For most clinical or non-interventional studies, both central and local IRBs/ECs need to be obtained. As not all countries have central IRB/EC, some applications can only be submitted to local IRBs/ECs.

## EXEMPTIONS TO IRB/EC COULD BE GRANTED IF RESEARCH INVOLVES THE USE OF EDUCATIONAL TESTS, SURVEY PROCEDURES, INTERVIEW PROCEDURES, OR OBSERVATION OF PUBLIC BEHAVIOR.

### WHAT IS EXEMPT, EXPEDITED, PROPORTIONATE, OR FULL REVIEW?

They are different categories of the IRB/EC review. Some human subject research may be considered exempt if "research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation" (HHS 45 CFR §46.101).<sup>12</sup>

UK REC will approve studies with no material ethical issues<sup>13</sup> through proportionate review, which is faster than full review. Some U.S. IRBs will offer expedited review for studies with minimal risks.

For example, Kantar Health's National Health and Wellness Survey (NHWS) utilize a CAWI-based survey with LightSpeed's U.S. and 5EU panel sample. Pearl IRB (U.S.) has reviewed the documents submitted for exemption determination in accordance with FDA 21 CFR56.104 and DHHS 45 CFR46.101 regulations and has approved the request.

### WHICH TYPES OF STUDIES ARE IRB EXEMPTED?

Exemptions to IRB approval include research activities in which the only involvement of human subjects will be in one or more of the following categories:<sup>14</sup>

A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- + Research on regular and special education instructional strategies, or
- + Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- + Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- + Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation

C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (B) (2) of this section, if:

- + The human subjects are elected or appointed public officials or candidates for public office
- + Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter

## IT IS INCREASINGLY POPULAR FOR STUDIES THAT ARE NOT HUMAN SUBJECT RESEARCH TO OBTAIN AN IRB/EC OPINION.

**D.** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects

**E.** Market research relating to market or consumer behavior of the sort that pharmaceutical companies routinely commission, whether involving healthcare professionals, patients, carers, or members of the public does not require IRB approval.

**F.** Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine:

- + Public benefit or service programs
- + Procedures for obtaining benefits or services under those programs
- + Possible changes in or alternatives to those programs or procedures
- + Possible changes in methods or levels of payment for benefits or services under those programs

**G.** Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

## DO I NEED A COUNTRY-LEVEL IRB/EC, OR IS A CENTRAL IRB/EC FROM ONE COUNTRY SUFFICIENT?

In general, all countries that carry out human subject research should have their own IRB/EC. It is increasingly popular for studies that are not human subject research to obtain an IRB/EC opinion; often an exemption or approval will be granted. The exemption or approval status can be submitted to other countries' IRB/EC or publication for reference. In addition, an IRB may require a letter from the principal investigator (who leads the analysis) to ensure that the study will be conducted in line with the law of the IRB location and regulations and that the International Conference on Harmonization and Good Clinical Practice Guidelines will be followed so that there is no ethical consideration for this study to be applied globally.

## CAN WE APPLY U.S. EXEMPTION IN THE EU AND OTHER COUNTRIES?

It depends on the study type and whether the country exemptions have similar setups as the United States. Each country has different jurisdictions and different IRB/EC setups. However, depending on the exemption determination the decision can be applicable. For example, if the exemption is based on similar legislation issued by OHRP (Office for Human Research Protection)<sup>15</sup> or in compliance with principles of the Declaration of Helsinki 2013 by the World Medicine Association,<sup>16</sup> which is applicable to over 100 countries who signed it, including the United States and EU.

## NOT ALL STUDIES HAVE CLEAR BOUNDARIES OF WHETHER IRB/EC INVOLVEMENT IS NEEDED, BENEFICIAL, OR EVEN POSSIBLE.

If a human subject research involves site investigation and interventional measures, it will be necessary to obtain local IRB/EC approval.

For some RWR studies involving no intervention, or individual identifiable patient records (low risk studies), a nominative data protection law need to be applied in the countries exemption intended to apply, e.g., GDPR or UK Data Protection Act 1998. Such nominative data protection law must be mentioned during scientific publication process.

### DOES IRB/EC MEAN THE STUDY IS CONDUCTED IN AN ETHICAL MANNER?

There is no monitoring, inspection, audit, source data verification from EC. IRB/EC only examines a study based on submitted documents on its ethical consideration.

### ARE THE DATA OF BETTER QUALITY WITH IRB/EC?

A favorable REC opinion does not guarantee data quality.

Were the rights and safety of the study participants better protected with IRB/EC approval?

Protection of participants' rights and safety are fundamental principles for all studies, including clinical and market research. No studies we do can compromise that. Because of the clinical root of IRB/EC, intervention is common in study design, hence the explicit mention on participants' safety and rights.

## FINAL NOTES

Healthcare researchers might find different IRBs/ECs offer different advice or acceptance conditions. Not all studies have clear boundaries of whether IRB/EC involvement is needed, beneficial, or even possible.

As IRBs/ECs are set up for clinical trials, they may only be familiar with applications that do not involve intervention. Researchers shall define study background and intention and clarify whether it fits into the IRB/EC scope with the sponsor. Specific application processes and consideration criteria change quickly. The application processes, fees involved and timing vary dramatically by country and IRB/EC. It is highly recommended to check the local IRB/EC before submission.

## FURTHER READING

### INTERNATIONAL PRINCIPLES

- + Nuremberg Code: [www.hhs.gov/ohrp/archive/nurcode.html](http://www.hhs.gov/ohrp/archive/nurcode.html)
- + Council of Europe: Convention of Human Rights and Fundamental Freedoms <http://conventions.coe.int/Treaty/en/Treaties/html/005.htm>
- + Declaration of Helsinki: [www.wma.net/en/30publications/10policies/b3/](http://www.wma.net/en/30publications/10policies/b3/)

### INTERNATIONAL GUIDELINES

- + Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects: [www.cioms.ch/publications/guidelines/guidelines\\_nov\\_2002\\_blurb.htm](http://www.cioms.ch/publications/guidelines/guidelines_nov_2002_blurb.htm)
- + UNESCO Universal Declaration on Bioethics and Human Rights: [www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/](http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/)
- + The International Conference on Harmonisation's Guide to Good Clinical Practice (GCP): [www.emea.europa.eu/pdfs/human/ich/013595en.pdf](http://www.emea.europa.eu/pdfs/human/ich/013595en.pdf)
- + World Health Organization Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants: [http://whqlibdoc.who.int/publications/2011/9789241502948\\_eng.pdf](http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf)

### EUROPE

- + European Tissues and Cells Directive (2004/23/EC) [www.hfea.gov.uk/2072.html](http://www.hfea.gov.uk/2072.html)
- + Council of Europe's Convention on Human Rights and Biomedicine: <http://conventions.coe.int>

### UK

- + Human Tissue Authority [www.hta.gov.uk](http://www.hta.gov.uk)
- + Department of Health Human Fertilisation and Embryology Act 2008: [www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH\\_080211](http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_080211)
- + National Health Service (NHS) National Research Ethics Service (NRES): [www.nres.nhs.uk/aboutus/about-nres](http://www.nres.nhs.uk/aboutus/about-nres)
- + A universal ethical code for scientists: [www.bis.gov.uk/policies/science/science-and-society/communication-and-engagement/universal-ethical-code](http://www.bis.gov.uk/policies/science/science-and-society/communication-and-engagement/universal-ethical-code)

See the 'Guide to Policies and Guidelines' at the end of this course for further links to relevant legislation.

### IRELAND

- + Irish Council for Bioethics: [www.bioethics.ie](http://www.bioethics.ie)
- + Irish Medicines Board: [www.imb.ie](http://www.imb.ie)

## AUSTRALIA

- + Prohibition of Human Cloning Act (2002): [www.austlii.edu.au/au/legis/cth/consol\\_act/pohcfra2002465/](http://www.austlii.edu.au/au/legis/cth/consol_act/pohcfra2002465/)
- + Research Involving Human Embryos Act (2002): [www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/03F95E485D04231DCA2572F80003B1C3/\\$file/ResearchInvolvingHumanEmbryosAct2002](http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilation1.nsf/0/03F95E485D04231DCA2572F80003B1C3/$file/ResearchInvolvingHumanEmbryosAct2002)
- + 2007 Revised National Statement on Ethical Conduct in Research involving humans: [www.nhmrc.gov.au/guidelines/publications/e35](http://www.nhmrc.gov.au/guidelines/publications/e35)
- + National Statement on Ethical Conduct in Human Research [www.nhmrc.gov.au/guidelines/publications/e72](http://www.nhmrc.gov.au/guidelines/publications/e72)
- + Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research [www.nhmrc.gov.au/guidelines/publications/e52](http://www.nhmrc.gov.au/guidelines/publications/e52)
- + TGA (Therapeutic Goods Administration), Australian Government Department of Health, <https://www.tga.gov.au/>

## SINGAPORE

- + [www.bioethics-singapore.org](http://www.bioethics-singapore.org)
- + Human Cloning and Other Prohibited Practices Act (2005): <http://statutes.agc.gov.sg/aol/search/display/view.w3p;query=DocId%3A2afd7a69-d851-4c4c-a8de-3202bc23a724%20Depth%3A0%20ValidTime%3A31%2F07%2F2005%20TransactionTime%3A31%2F07%2F2005%20Status%3Ainforce;rec=0>

## US

- + The Belmont Report: [www.hhs.gov/ohrp/humansubjects/guidance/belmont.html](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)
- + <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm>
- + The Office of Human Research Protection. Institutional Review Board Guidebook. "Chapter 3, Section A: Risk/Benefit Analysis." pp. 1-10 Retrieved May 30, 2012

## CANADA

- + Health Canada <http://www.hc-sc.gc.ca/index-eng.php>
- + Public Health Agency of Canada's (PHAC) Research Ethics Board <http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/index-eng.php>
- + Research Ethics, Canada <https://researchethics.ca/canada/>

## GENERAL SOURCE

- + International Compilation of Human Research Standards covering over 100 countries: [www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html](http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html)
- + [https://www.epigeum.com/downloads/ri\\_accessible/uk/01\\_biomed/html/course\\_files/bi\\_2\\_30.html](https://www.epigeum.com/downloads/ri_accessible/uk/01_biomed/html/course_files/bi_2_30.html) .
- + [https://www.epigeum.com/downloads/ri\\_accessible/uk/01\\_biomed/html/course\\_files/bi\\_2\\_30.html](https://www.epigeum.com/downloads/ri_accessible/uk/01_biomed/html/course_files/bi_2_30.html) .

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3. <http://www.bmj.com/content/313/7070/1448.1>
4. <http://www.wma.net/en/30publications/10policies/b3/>
5. [https://www.epigeum.com/downloads/ri\\_accessible/uk/01\\_biomed/html/course\\_files/bi\\_2\\_30.html](https://www.epigeum.com/downloads/ri_accessible/uk/01_biomed/html/course_files/bi_2_30.html)
6. <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/>
7. <http://www.hra.nhs.uk/documents/2016/06/defining-research.pdf>
8. [http://www.ephmra.org/user\\_uploads/2016%20code%20of%20conduct%20february%202016.pdf](http://www.ephmra.org/user_uploads/2016%20code%20of%20conduct%20february%202016.pdf)
9. [http://transparency.efpia.eu/countries/download/30/document/july-2014-version-inovia\\_code\\_2014\\_english.pdf](http://transparency.efpia.eu/countries/download/30/document/july-2014-version-inovia_code_2014_english.pdf)
10. <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>, page 19
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12. <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/>
13. <http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-proportionate-review-service/>
14. <http://www.motherjones.com/environment/2010/09/institutional-review-boards;>  
<http://www.hhs.gov/ohrp/>
15. [http://www.hhs.gov/ohrp/about-ohrp/history/index.html;](http://www.hhs.gov/ohrp/about-ohrp/history/index.html) <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>

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## ABOUT THE AUTHOR

### JESSICA SANTOS, PH.D.

Dr. Jessica Santos is the Global Compliance and Quality Director at Kantar Health, the largest custom market research company focused on the life sciences industry. She is primarily responsible for providing oversight and support across the 40+ Kantar Health global offices in the areas of regulation, interaction with clients, suppliers and others within Kantar Health, Kantar and WPP. Dr. Santos is responsible for maintaining, anticipating and coordinating all activities with regard to compliance laws/regulations, industry guidelines, pharmacovigilance and client contracts, defining and driving the execution of Kantar Health's Quality Strategy – our approach to measuring and improving our quality efforts.

Dr. Santos is an experienced statistician, analyst, methodologist and market research scientist. She gained her reputation through her publications and professional committee work in the industry. She is a frequent speaker and contributor in major conferences and has a Ph.D. in Marketing, an MRS fellowship and Chartered Marketer status.

Dr. Santos is a member of UK Research Ethics Committee, EphMRA, BHBIA and PMRG Government Affairs Committee, reviewer and co-chair of ISPOR, and MRS Professional Development Advisory Board and Examiner.

### FOR MORE INFORMATION

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### WHY KANTAR HEALTH?

Kantar Health is a leading global healthcare consulting firm and trusted advisor to many of the world's leading pharmaceutical, biotech and medical device and diagnostic companies. It combines evidence-based research capabilities with deep scientific, therapeutic and clinical knowledge, commercial development know-how, and brand and marketing expertise to help clients evaluate opportunities, launch products and maintain brand and market leadership. Our advisory services span three areas critical to bringing new medicines and pharmaceutical products to market – commercial development, clinical strategies and marketing effectiveness.