ISSN: 2155-9627
Journal of Clinical Research & Bioethics

OPEN ACCESS Freely available online

Research Article

Informed Consent in Human Subjects Research: A Comparison of International and Saudi Arabian Guidelines

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Additional file: Comparison of 44 informed consent elements from different ethical guidelines.

IC Components	Informed consent elements	Declaration of Helsinki (DoH)	International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)	International Conference of Harmonization Guidelines for Good Clinical Practice (ICH-GCP)
		2013	2016	2016
Disclosure to participants	The fact that this is a scientific research	Yes: (Paragraph 25):➢ "Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although....No individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees. " (Paragraph 31): ➢"The physician must fully inform the patient which aspects of their care are related to the research."	Yes: (GUIDELINE9): INDIVIDUALS CAPABLE OF GIVING INFORMED CONSENT Researchers have a duty to provide potential research participants with the information and the opportunity to give their free and informed consent to participate in research, (APPENDIX 2): (2) That the individual is invited to participate in research,.... suitable for the research, (Guideline 9);	Yes: Paragraph (4.8.10) (a) That the trial involves research
	Aims of the study	Yes: (Paragraph 26): "In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims....of the study."	Yes: (GUIDELINE 9): INDIVIDUALS CAPABLE OF GIVING INFORMED CONSENT (Commentary on Guideline 9) Contents of the information. "Elements that need to be included in the....,information about the aims, methods..." (APPENDIX 2): (1) The purpose of the research, its methods, the procedures to be carried out by the researcher and the participant, and an explanation of how the research differs from routine medical care (Guideline 9);	Yes: Paragraph (4.8.10) (b) The purpose of the trial
	Possible benefit and risks of the study intervention	Yes: (Paragraph 26): "In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of... The anticipated benefits and potential risks of the study and the discomfort it may entail."	Yes: (GUIDELINE 4): ➢"The potential individual benefits and risks of research studies must be evaluated in consultation with the communities to be involved in the research." (GUIDELINE 9): Contents of the information. ➢"The anticipated benefits and potential risks of the study and the discomfort it may entail, post-trial access and any other relevant aspects of the study" (APPENDIX 2): (10) "Pain and discomfort of experimental interventions, known risks and possible hazards, to the individual (or others) associated with participation in the research, including risks to the health or well-being of a participant's direct relatives (Guideline 4); "(11)" the potential clinical benefits, if any, expected to result to participants from participating in the research (Guidelines 4 and 9);"	Yes: Paragraph (4.8.10) (g) The reasonably foreseeable risks or inconveniences to the subject (h) The reasonably expected benefits."

	Trial-related injury treatment and/ or compensation	Yes: (Paragraph 15): "Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured."	Yes: (GUIDELINE 14): TREATMENT AND COMPENSATION FOR RESEARCH-RELATED HARMS. ➢"Researchers must ensure that research participants who suffer physical,...harm as a result of participating in health-related research receive free treatment and rehabilitation for such harms, as well as compensation for lost wages, as appropriate. Such treatment and compensation are owed to research participants who are harmed physically. As a consequence of interventions performed solely to accomplish the purposes of research, regardless of fault." ➢"This Guideline focuses on the entitlement to free treatment and additional compensation when research participants are harmed by research interventions or procedures." (APPENDIX 1): (27) "For research carrying more than minimal risk of physical injury, details of plans, including insurance coverage, to provide treatment for such injury, including the funding of treatment, and to provide compensation for research-related disability or death (Guideline 14);"	Yes: Paragraph (4.8.10) (j) The compensation and/or treatment available to the subject in the event of trial-related injury"
	Right of the participant to withdraw the consent at any time without receiving any drawbacks	Yes: (Paragraph 26): "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."	Yes: (GUIDELINE 9) INDIVIDUALS CAPABLE OF GIVING INFORMED CONSENT. "Informed consent should be understood as a process, and participants have a right to withdraw at any point in the study without retribution. (APPENDIX 2): (3) "that the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled"	Yes: Paragraph (4.8.10) (m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled."
	Record confidentiality for identifying information	Yes: (Paragraph 24) Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.	Yes: (GUIDELINE 22): “Obtain data for health- related research they should use privacy-protective measures to protect individuals from the possibility that their personal information is directly revealed or otherwise inferred when datasets are published, shared, combined or linked.” (GUIDELINE 11) Confidentiality. An important aspect of storing human biological material is confidentiality guaranteed to the donor...During the process of obtaining informed consent, those responsible for the biobank must inform the potential donors about the safeguards that will be taken to protect confidentiality as well as their limitations. (APPENDIX 2): (17) "The provisions that will be made to ensure respect for the privacy of participants, and for the confidentiality of records in which participants are identified (Guidelines 11 and 22);"	Yes: Paragraph (4.8.10): (o) "That records identifying the subject will be kept confidential"

	Research participation invitation	not explicitly	Yes: (GUIDELINE 9): "The individual is invited to participate in research, the reasons for considering the individual suitable for the research." (GUIDELINE 4): "Before inviting potential participants to join a study, the researcher, sponsor and the research ethics committee must ensure that risks to participants are minimized and appropriately balanced in relation to the prospect of potential individual benefit and the social and scientific value of the research". (APPENDIX 2): (2) that the individual is invited to participate in research, the reasons for considering the individual suitable for the research, and that participation is voluntary (Guideline 9);	not explicitly
	Research title	not explicitly	Yes: (APPENDIX 1) ITEMS TO BE INCLUDED IN A (ASSOCIATED DOCUMENTS) FOR HEALTH-RELATED RESEARCH INVOLVING HUMANS (1). Title of the study;	not explicitly
	Methods of the study e.g. randomization	not explicitly	Yes: (GUIDELINE 9): INDIVIDUALS CAPABLE OF GIVING INFORMED CONSENT "Elements that need to be included in the information..... contains the details of information that must be provided, as well as possible supplementary information. This list mentions, but is not limited to, information about the aims, methods, sources of funding, possible conflicts of interest". (APPENDIX 2): Before requesting an individual's consent to participate in research, the researcher must provide the following information: (1) for controlled trials, an explanation of features of the research design (e.g., randomization, double-blinding), that the participant will not be told of the assigned treatment until the study has been completed and the blind has been broken;	Yes: Paragraph (4.8.10) (c) The trial treatment(s) and the probability for random assignment to each treatment."
	Duties and functions of the participants connected to the study including follow-up appointments	Yes: (Paragraph 26): In medical research involving human subjects capable of giving informed consent,each potential subject must be adequately informed of ... the anticipated benefits and potential risks of the study and the discomfort it may entail	Yes: (GUIDELINE 9) INDIVIDUALS CAPABLE OF GIVING INFORMED CONSENT. "Researchers have a duty to provide potential research participants with the information and the opportunity to give their free and informed consent to participate in research... Informed consent should be understood as a process, and participants have a right to withdraw at any point in the study without retribution." (APPENDIX 2): Before requesting an individual's consent to participate in research, the researcher must provide the following information: (1) "an explanation of how the research differs from routine medical care." (Guideline 9); (4) "The expected duration of the individual's participation (including number and duration of visits to the research centre and the total time involved) and the possibility of early termination of the trial or of the individual's participation in it;"	Yes: Paragraph (4.8.10) (d) The trial procedures to be followed, including all invasive procedures. (e) The subject's responsibilitie

Possible discomfort or burden	Yes: (Paragraph 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."	Yes: (GUIDELINE 4): "This understanding of risk implies that discomfort, inconvenience or burdens are harms of a very small magnitude that are almost certain to occur. The ethical justification for exposing participants to risks is the social and scientific value of research." (GUIDELINE 9): "This list mentions, information about the..... and potential risks of the study and the discomfort it may entail, post-trial access and any other relevant aspects of the study." (APPENDIX 2) (10) "pain and discomfort of experimental interventions, known risks and possible hazards, to the individual (or others) associated with participation in the research, including risks to the health or well-being of a participant's direct relatives" (Guideline 4);	Yes: Paragraph (4.8.10) (g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable"
Alternative interventions, that are available outside the study and its potential benefit and risks	not explicitly	Yes: (GUIDELINE 4): For research interventions or procedures that have the potential to benefit participants, risks are acceptable if they are minimized and outweighed by the prospect of potential individual benefit and the available evidence suggests that the intervention will be at least as advantageous, in the light of foreseeable risks and benefits, as any established effective alternative. (GUIDELINE 9): "new information may have come to light, either from the study itself or other sources, about the risks or benefits of products being tested or about alternatives to them. Participants must be given such information promptly." (APPENDIX 2): (11) the potential clinical benefits, if any, expected to result to participants from participating in the research (Guidelines 4 & 9); (15) any currently available alternative interventions or courses of treatment;	Yes: Paragraph (4.8.10) (i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks."
Different interventions of the study arms	not explicitly	Yes: (GUIDELINE 5): General considerations for controlled clinical trials. The conduct of controlled clinical trials is methodologically essential in order to test the relative merits of investigational interventions. To obtain valid results in a controlled trial, researchers must compare the effects of an experimental intervention on participants assigned to the investigational arm (or arms) of a trial with the effects that a control intervention produces in persons drawn from the same population. Randomization is the preferred method for assigning participants to the arms of controlled trials. Assignment to treatment arms by randomization tends to produce study groups comparable with respect to factors that might influence study outcomes, removes researcher bias in the allocation of participants. (APPENDIX 2): (1) for controlled trials, an explanation of features of the research design (e.g., randomization, double-blinding), that the participant will not be told of the assigned treatment until the study has been completed and the blind has been broken;	Yes: Paragraph (4.8.10)(c) The trial treatment(s)"

	Trial participation payment as prorated (if any)	not explicitly	Yes: (GUIDELINE 13): ➢ "Research participants should be reasonably reimbursed for costs directly incurred during the research, such as travel costs, and compensated reasonably for their inconvenience and time spent." Compensation can be monetary or non-monetary. ➢"participants must be appropriately compensated for the time spent and other inconveniences resulting from study participation. The amount of compensation should be proportional to the time spent for research purposes and for travel to the research site. This amount should be calculated using the minimum hourly wage in the region or country as a reference value." (APPENDIX 2): (5) whether money or other forms of material goods will be provided in return for the individual's participation, and, if so, the kind and amount, and that the time spent on the research and other inconveniences resulting from study participation will be appropriately compensated, monetary or non-monetary (Guideline 13).	Yes: Paragraph (4.8.10) (k) The anticipated prorated payment, if any, to the subject for participating in the trial.
	The chance to receive a placebo intervention or no intervention	not explicitly	not explicitly	not explicitly
	Blinding of the participant or the physician	not explicitly	Yes: (GUIDELINE 6) Providing continued access to a beneficial study intervention. "In the case of blinded controlled trials, it may take time to unblind the results and find out who has received which intervention. Researchers and sponsors should make provisions for this transition period and inform participants if they will be temporarily receiving the current standard of care before the study intervention can be administered." (APPENDIX 2): (1) for controlled trials, an explanation of features of the research design (e.g., randomization, double-blinding), that the participant will not be told of the assigned treatment until the study has been completed and the blind has been broken;	not explicitly
	Ethics committee approval	not explicitly	Yes: (GUIDELINE 23): All proposals to conduct health-related research involving humans must be submitted to a research ethics committee to determine whether they qualify for ethical review and to assess their ethical acceptability, unless they qualify for an exemption from ethical review (which may depend upon the nature of the research and upon applicable law or regulations). The researcher must obtain approval or clearance by such a committee before beginning the research. The research ethics committee should conduct further reviews as necessary, for example, when there are significant changes in the protocol. (APPENDIX 2) (25) That a research ethics committee has approved or cleared the research protocol (Guideline 23).	not explicitly

	The existence of another study group that may receive a seemingly more attractive intervention in the case the participant was allocated to the control group	not explicitly	not explicitly	Yes: Paragraph (4.8.10) (c) The trial treatment(s) and the probability for random assignment to each treatment"
	The fact that a new treatment can cause unwanted effects that one cannot reliably predict and, which can harm the participant	not explicitly	not explicitly	not explicitly
	Source of funding of the study	Yes: (Paragraph 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 re- searcher, the anticipated benefits and potential risks of the study".	Yes: (GUIDELINE 9): "The details of information that must be provided, as well as possible supplementary information. This list mentions, but is not limited to, information about the aims, methods, sources of funding, possible conflicts of interest, institutional affiliations of the researcher," (GUIDELINE 25): "This goes beyond describing “the nature and sources of funding for the research,” which is an element of informed consent". (APPENDIX 2) (19) "Before requesting an individual’s consent to participate in research, the researcher must provide the following information and the nature and sources of funding for the research, and, when they exist," (Guidelines 9 and 25);"	not explicitly
	Potential conflicts of interest	Yes: (Paragraph 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 re- searcher, the anticipated benefits and potential risks of the study"	Yes: (GUIDELINE 9): "contains the details of information that must be provided, as well as possible supplementary information. This list mentions, but is not limited to, information about the aims, methods, sources of funding, possible conflicts of interest, institutional affiliations of the researcher." (GUIDELINE 25): Disclosure of interests to participants. Research ethics committees may require that conflicts of interest be disclosed to potential study participants in the informed consent discussion and documents". (APPENDIX 2): (19) "Before requesting an individual’s consent to participate in research, the researcher must provide the following information. The nature and sources of funding for the research, and, when they exist, any conflicts of interest of researchers, research institutions and research ethics committees and how these conflicts will be managed (Guidelines 9 and 25);"	not explicitly
	Researches' institutional affiliations	Yes: (Paragraph 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 re- searcher, the anticipated benefits and potential risks of the study”	Yes: (GUIDELINE 9): ➢ "Elements that need to be included in the information.... contains the details of information that must be provided,....information about the aims, methods, sources of funding, possible conflicts of interest, institutional affiliations of the researcher," (APPENDIX 2) (19) "Before requesting an individual’s consent to participate in research, the researcher must provide the following information....., the institutional affiliation of the researchers, and the nature and sources of funding for the research,..."	not explicitly

	The name of the institution approving the research (that is, IRB)	not explicitly	not explicitly	not explicitly
	The contact person(s) for further information	not explicitly	not explicitly	Yes: Paragraph (4.8.10) (q) "The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury."
	Informing participants of new findings that might affect their willingness to participate in the research	not explicitly	Yes: (GUIDELINE 9): ➢ "Researchers must renew the informed consent of each participant if there is a substantive change in the conditions or procedures of the research, or if new information becomes available that could affect the willingness of participants to continue. In long-term studies, researchers should ensure at pre-determined intervals that each participant is willing to stay in the study, even if there are no changes in the design or objectives of the research." (APPENDIX 2): (6) "That, after the completion of the study, participants will be informed of the outcomes of the research in general, if they so wish;" (16) "new information that may have come to light, either from the study itself or other sources (Guideline 9);	Yes: Paragraph (4.8.10): (p) "That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial."
	Receiving the results of the study	Yes: (Paragraph 26): "All medical research subjects should be given the option of being informed about the general" outcome and results of the study."	Yes: (GUIDELINE 9): Contents of the information. ➢ "elements that need to be included in the information.... contains the details of information that must be provided, as well as possible supplementary information..about...post-trial access and any other relevant aspects of the study." ➢ "New information may have come to light, either from the study itself or other sources, about the risks or benefits of products being tested or about alternatives to them. Participants must be given such information promptly. In most clinical trials, interim results are not disclosed to researchers or participants until the study has been concluded. (APPENDIX 2): (6) after the completion of the study, participants will be informed of the outcomes of the research in general, if they so wish;	not explicitly
	Termination of participation without the subject's consent for foreseeable reasons and/ or circumstances	not explicitly	Yes: (GUIDELINE 4): Risks to research participants. ➢ excluding participants who are at a significantly increased risk of being harmed from an intervention or procedure. APPENDIX (2): (4) the expected duration of the individual's participation (including number and duration of visits to the research centre and the total time involved) and the possibility of early termination of the trial or of the individual's participation in it;	Yes: Paragraph (4.8.10) (r) The foreseeable circumstances and/ or reasons under which the subject's participation in the trial may be terminated.

	The approximate number of subjects involved in the trial	not explicitly	not explicitly	Yes: Paragraph (4.8.10) (t) The approximate number of subjects involved in the trial.
	The trial participation duration	not explicitly	Yes: (GUIDELINE 9): Researchers have a duty to: ensure that the potential participant has been given sufficient opportunity and time to consider whether to participate; (APPENDIX 2): (4) the expected duration of the individual's participation (including number and duration of visits to the research centre and the total time involved) and the possibility of early termination of the trial or of the individual's participation in it;	Yes: Paragraph (4.8.10) (s) The expected duration of the subject's participation in the trial.
	The need for further details in the case of genetic research and the possible future use of biological materials collected during the research	Yes: (Paragraph 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.	Yes: (GUIDELINE 11): COLLECTION, STORAGE AND USE OF BIOLOGICAL MATERIALS AND RELATED DATA. When biological materials and related data, such as health or employment records, are collected and stored, institutions must have a governance system to obtain authorization for future use of these materials in research. Researchers must not adversely affect the rights and welfare of individuals from whom the materials were collected. When specimens are collected for research purposes, either specific informed consent for a particular use or broad informed consent for unspecified future use must be obtained from the person from whom the material originally is obtained. (APPENDIX 2): (3) policy with regard to the use of results of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of the results of a participant's genetic tests to immediate family relatives or to others (e.g. insurance companies or employers) without the consent of the participant.	not explicitly
Comprehension	The information should be given in a language and at a level of understanding appropriate to the research subject (The informed consent doucument should be simplified as much as possible)	Yes: (Paragraph 26): "In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the ..... 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".	Yes: (GUIDELINE 9): INDIVIDUALS CAPABLE OF GIVING INFORMED CONSENT (Commentary on Guideline 9) General considerations. The information must be provided in plain language understandable by the potential participant. Individual informed consent....In some populations, the use of local languages may facilitate the communication of information to potential participants and the ability of a researcher to ensure that individuals truly understand the material facts.	Yes: Paragraph (4.8.6) The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.

	Comprehension verification through questions and clarifications	Yes: (Paragraph 26): "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".	Yes: (GUIDELINE 9): INDIVIDUALS CAPABLE OF GIVING INFORMED CONSENT. General considerations. The information must be provided in plain language understandable by the potential participant. The person obtaining informed consent must be knowledgeable about the research and capable of answering any questions from potential participants. Researchers in charge of the study must make themselves available to answer questions at the request of participants. Participants should be offered the opportunity to ask questions and receive answers before or during the research. Researchers should make every effort to address those questions in a timely and comprehensive manner.	not explicitly
Voluntariness	Voluntariness of the participation/ right of the participant to refuse participation	Yes: (Paragraph 25): "Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although..... giving informed consent may be enrolled in a research study unless he or she freely agrees. (Paragraph 26): "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."	Yes: (GUIDELINE 9): INDIVIDUALS CAPABLE OF GIVING INFORMED CONSENT. ➢ Voluntariness and undue influence. Informed consent is voluntary if an individual's decision to participate is free from undue influence. A variety of factors may affect the voluntariness with which consent is provided. ➢ Dependent relationship. They must emphasize the voluntary nature of participation and the right to refuse or withdraw from the research. They must also assure patients that their decision whether to enrol or refuse participation will not affect the therapeutic relationship or other benefits to which they are entitled. (APPENDIX 2): (2) That the individual is invited to participate in research, the reasons for considering the individual suitable for the research, and that participation is voluntary (3). that the individual is free to refuse to participate	Yes: Paragraph (4.8.10) (m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
	The physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress	Yes: (Paragraph 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".	Yes: (GUIDELINE 9): INDIVIDUALS CAPABLE OF GIVING INFORMED CONSENT. Dependent relationship. "In the context of clinical research, dependent relationships can result from pre-existing relationships between a treating physician and a patient, who becomes a potential participant when his or her treating physician assumes the role of researcher. The dependent relationship between patients and clinician-researchers may compromise the voluntariness of informed consent, since potential participants who are patients depend on the clinician-researcher for medical care and may be reluctant to refuse an invitation to enrol in research in which the treating clinician is involved."	Yes: Paragraph (1.61) Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical....."

competence	Potential research subjects who are incapable of giving informed consent (incompetent/ vulnerable subjects and minors): the physician must seek informed consent from the legally authorized representative	Yes: (Paragraph 28): For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. (Paragraphs 28-30)	Yes: (GUIDELINE 16): RESEARCH INVOLVING ADULTS INCAPABLE OF GIVING INFORMED CONSENT. Before undertaking research with adults who are not capable of giving informed consent, the researcher and the research ethics committee must ensure that: ➢ a legally authorized representative of the person who is incapable of giving informed consent has given permission and this permission takes account of the participant's previously formed preferences and values (if any); ➢ the assent of the subject has been obtained to the extent of that person's capacity, after having been provided with adequate information about the research at the level of the subject's capacity for understanding this information.	Yes: Paragraph (4.8.5) The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval/ favourable opinion by the IRB/IEC."
Formal requirements of consent	The informed consent in written format	Yes: (Paragraph 26): "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"	Yes: (GUIDELINE 9): (Commentary on Guideline 9) Language of the information. Informing the individual participant must not be simply a ritual recitation of the contents of a written document. Documentation of consent. Consent may be indicated in a number of ways. The participant may express consent orally, or sign a consent form. As a general rule, the participant should sign a consent form,"	Yes: Paragraph (4.8.6) "The language used in the oral and written information about the trial, including the written informed consent form," Paragraph (4.8.8): "Prior to a subject's participation in the trial, the written informed consent form," Paragraph (4.8.9): " After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject"
	Signature of the human subject	not explicitly	Yes: (GUIDELINE 9): Documentation of consent. Consent may be indicated in a number of ways. The subject may imply consent by voluntary actions, express consent orally, or sign a consent form. As a general rule, the subject should sign a consent form,	Yes: Paragraph (4.8.11) "Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects."

Before a decision on consent is made by the persons concerned, they must be allowed an appropriate period for reflection	not explicitly	Yes: (GUIDELINE 9): Researchers have a duty to: ensure that the potential participant has been given sufficient opportunity and time to consider whether to participate; (GUIDELINE 25): In the case of serious conflicts of interest, studies suggest that disclosure works best when it is provided by a health professional independent of the study team and potential participants are given time to reflect.	Yes: Paragraph (4.8.7) Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.
Reassurance by the physician that the participant understood the information	Yes: (Paragraph 26): "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".	Yes: (GUIDELINE 9): Process. Obtaining informed consent. is a process that is begun when initial contact is made with a prospective subject and continues throughout the course of the study. By informing the prospective subjects, by repetition and explanation, by answering their questions as they arise, and by ensuring that each individual understands each procedure, investigators elicit their informed consent and in so doing manifest respect for their dignity and autonomy. Each individual must be given as much time as is needed to reach a decision, including time for consultation with family members or others. Adequate time and resources should be set aside for informed-consent procedures.	not explicitly
Providing a copy of the infomed consent form and explanations about the study	not explicitly	not explicitly	Yes: Paragraph (4.8.11) Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.

	Date and place of the "Informed Consent"	not explicitly	not explicitly	not explicitly
	The study is conducted by experts according to ethics guidelines	not explicitly	not explicitly	not explicitly
	The principal investigator obtains the informed consent or assignes a delegate	Yes: (Paragraph 26): 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"	Yes: (GUIDELINE 9): It is the principal investigator's responsibility to ensure that all personnel obtaining informed consent for a study comply with this Guideline.	Yes: Paragraph (4.8.5) The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial". Paragraph (4.1.5): The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.
	Consent renewal when needed	not explicitly	Yes: (GUIDELINE 9) With the approval of the research ethics committee, researchers must renew the informed consent of each participant if there is a substantive change in the conditions or procedures of the research, or if new information becomes available that could affect the willingness of participants to continue. Renewing consent: When substantive changes occur in any aspect of a study, the researcher must again seek informed consent from the participants. For example, new information may have come to light, either from the study itself or other sources, about the risks or benefits of products being tested or about alternatives to them.	Yes: Paragraph (4.8.2) The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent. Any revised written informed consent form, and written information should receive the IRB/IEC's approval/favourable opinion in advance of use. The subject or the subject's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented.
Total items	44	21	28	35

IC Components	Informed consent elements	Convention on Human Rights and Biomedicine (CHRB), Council of Europe	Code of Federal Regulations (CFR), United States	Human Research Act of Switzerland (HRA)	Implementing Regulations of the Law of Ethics of Research on Living Creatures (the Implementing Regulations), Kingdom of Saudi Arabia
		2005	2003	2014	2022
Disclosure to participants	The fact that this is a scientific research	Yes: (Article 13)-Information for research participants. (2) The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee. Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research.	Yes: (Sec. 50.25) Elements of informed consent. (a) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject: (1) "A statement that the study involves research."	Yes: (Art. 16) Informed consent (2) The persons concerned must receive comprehensible oral and written information on: a. the nature, purpose and duration of, and procedure for, the research project."	Yes: (Article 11.2) The informed Consent" form shall include the following: (1)-A clear statement at the top of the first page that reads «You are invited by (Name of. Principal investigator) to participate in a scientific research.
	Aims of the study	Yes: (Article 13)-Information for research participants. (2) The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project,....according to the nature and purpose of the research.	Yes: (Sec. 50.25) Elements of informed consent. (a) Basic elements of informed consent. (1) "An explanation of the purposes of the research and the expected duration of the subject's participation."	Yes: (Art. 16) Informed consent (2) The persons concerned must receive comprehensible oral and written information on: a. the nature, purpose and duration of, and procedure for, the research project."	Yes: (Article 11.2) The "Informed Consent" form shall include the following: (4)-Research objectives.
	Possible benefit and risks of the study intervention	Yes: (Article 13)-Information for research participants. (2) The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project... Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research.	Yes: (Sec. 50.25) Elements of informed consent. (a) Basic elements of informed consent. (2) A description of any reasonably foreseeable risks or discomforts to the subject. (3) A description of any benefits to the subject or to others which may reasonable be expected from the research.	Yes: (Art. 16) Informed consent (2) The persons concerned must receive comprehensible oral and written information on: ... b. the foreseeable risks and burdens; c. the expected benefits of the research project, in particular for themselves or for other people;"	Yes: (Article 11.2) The "Informed Consent" form shall include the following: (5)- A description of any expected benefit for the human subject. (6)- A description of any expected risk or harm that may affect the human subject or society.

	Trial-related injury treatment and/ or compensation	Yes: (Article 13)-Information for research participants. (2)....Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research: (vi) of the arrangements for fair compensation in the case of damage;	Yes: (Sec. 50.25) Elements of informed consent. (a) Basic elements of informed consent. (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.	Yes: (Art. 19) (1) Any person who carries out a research project involving persons shall be liable for damage suffered by them in connection with the project. The Federal Council may specify exemptions from liability. (2) Compensation claims become time-barred three years after the injured party has become aware of the damage and of the liable party, but no later than ten years after the completion of the research project.	Yes: (Article 11.2) The Informed Consent" form shall include the following: (19)-Method of compensating of the human subject in case he sustains any harm resulting from the research.
	Right of the participant to withdraw the consent at any time without receiving any drawbacks	Yes: (Article 13)-Information for research participants. (3)... the persons being asked to participate in a research project shall be informed of the rights and safeguards prescribed by law for their protection, and specifically of their right to refuse consent or to withdraw consent at any time without being subject to any form of discrimination, in particular regarding the right to medical care.	Yes: (Sec. 50.25) Elements of informed consent. (a) Basic elements of informed consent. (8) A statement that participation.... and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.	Yes: (Art. 7) Consent. (2). The persons concerned may withhold or revoke their consent at any time, without stating their reasons.	Yes: (Article 11.2) The Informed Consent" form shall include the following: (13)- A statement which explicitly reads as follows: «Participation in the research..... The human subject may withdraw from the research at any phase without loss of benefits to which he is otherwise entitled.
	Record confidentiality for identifying information	Yes: (Article 13)-Information for research participants. (2)....Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research: (iv) of arrangements to ensure respect for private life and ensure the confidentiality of personal data;	Yes: (Sec. 50.25) Elements of informed consent. (a) Basic elements of informed consent. (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.	Yes: (Art. 16) Informed consent (2) d. the measures taken to protect the personal data collected;	Yes: (Article 11.2): The Informed Consent" form shall include the following: (8). "A statement of the level of respect accorded to the confidentiality of information that may reveal the identity of the subject, along with a commitment by the investigator to secure such confidentiality";

	Research participation invitation	Yes: (Article 13)-Information for research participants. (1) The persons being asked to participate in a research project shall be given adequate information in a comprehensible form. This information shall be documented. (2) The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee. Before being asked to consent to participate in a research project.	Yes: (Sec. 50.25) Elements of informed consent. (c) When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282 (j) (1) (A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph.	not explicitly	Yes: (Article 11.2): The "Informed Consent" form shall include the following: (1). A clear statement at the top of the first page that reads "You are invited by (Name of principal investigator) to participate in a scientific research.
	Research title	not explicitly	not explicitly	not explicitly	Yes: (Article 11.2): The "Informed Consent" form shall include the following: (2). Research title
	Methods of the study e.g. randomization	not explicitly	not explicitly	not explicitly	not explicitly
	Duties and functions of the participants connected to the study including follow-up appointments	not explicitly	not explicitly	not explicitly	Yes: (Article 11.2): The Informed Consent" form shall include the following: (9) A description of all medical procedures and treatments related to the research or carried out only as a result of conducting the research, if any. (11) A description of requirements to be fulfilled by the human subject.
	Possible discomfort or burden	Yes: (Article 13)-Information for research participants. (2) Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpos of the research: (i) of the nature, extent and duration of the procedures involved, in particular, details of any burden imposed by the research project;	Yes: (Sec. 50.25) Elements of informed consent. (a) Basic elements of informed consent. (2) A description of any reasonably foreseeable risks or discomforts to the subject.	Yes: (Art. 16) Informed consent (2) The persons concerned must receive comprehensible oral and written information on: b. the foreseeable risks and burdens; c. the expected benefits of the research project, in particular for themselves or for other people;"	Not explicitly

	Alternative interventions, that are available outside the study and its potential benefit and risks	not explicitly	Yes: (Sec. 50.25) Elements of informed consent. (a) Basic elements of informed consent. (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.	not explicitly	Yes: (Article 11.2) The "Informed Consent" form shall include the following: (7)- A description of alternative treatments available outside the scope of the research, if any.
	Different interventions of the study arms	not explicitly	not explicitly	not explicitly	not explicitly
	Trial participation payment as prorated (if any)	not explicitly	not explicitly	not explicitly	not explicitly
	The chance to receive a placebo intervention or no intervention	not explicitly	not explicitly	not explicitly	not explicitly
	Blinding of the participant or the physician	not explicitly	not explicitly	not explicitly	not explicitly
	Ethics committee approval	not explicitly	not explicitly	not explicitly	not explicitly
	The existence of another study group that may receive a seemingly more attractive intervention in the case the participant was allocated to the control group	not explicitly	not explicitly	not explicitly	not explicitly
	The fact that a new treatment can cause unwanted effects that one cannot reliably predict and, which can harm the participant	not explicitly	Yes: (Sec. 50.25) Elements of informed consent. (b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject: (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.	not explicitly	not explicitly
	Source of funding of the study	Yes: (Article 13): Information for research participants. (2) Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpos of the research: (viii) of the source of funding of the research project.	not explicitly	not explicitly	not explicitly

	Potential conflicts of interest	not explicitly	not explicitly	not explicitly	not explicitly
	Researches' institutional affiliations	not explicitly	not explicitly	not explicitly	not explicitly
	The name of the institution approving the research (that is, IRB)	not explicitly	not explicitly	not explicitly	Yes: (Article 11.2): The "Informed Consent" form shall include the following: (3). Name of institution approving the research;
	The contact person(s) for further information	not explicitly	Yes: (Sec. 50.25) Elements of informed consent. (a) Basic elements of informed consent. (7) "An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights"	not explicitly	Yes: (Article 11.2): The "Informed Consent" form shall include the following: (16). "Contact numbers and addresses to enable the human subject to obtain information related to the research or to his rights"
	Informing participants of new findings that might affect their willingness to participate in the research	Yes: (Article 24)-New developments. (3). Any new information relevant to their participation shall be conveyed to the research participants, or, if applicable, to their representatives, in a timely manner.	Yes: (Sec. 50.25) Elements of informed consent. (b) Additional elements of informed consent. (5) "A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject."	not explicitly	Yes: (Article 11.2): The "Informed Consent" form shall include the following: (15)."The investigator's pledge that the human subject (participant or volunteer) shall be notified of all information that may emerge during the research period, the knowledge of which may affect his decision for continued participation in the research"
	Receiving the results of the study	Yes: (Article 13) ➢ Information for research participants. (2) Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpos of the research: (v) of arrangements for access to information relevant to the participant arising from the research and to its overall results;	Yes: (Sec. 50.25): Elements of informed consent. (c). "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."	Yes: (Art. 8) Right to receive information 1. The persons concerned are entitled to be informed of results relating to their health. The information is to be communicated in an appropriate manner. The persons concerned may choose to forgo such information. 2. They are entitled to be informed about all the personal data held in relation to them.	not explicitly
	Termination of participation without the subject's consent for foreseeable reasons and/ or circumstances	not explicitly	Yes: (Sec. 50.25) Elements of informed consent. (b) Additional elements of informed consent. (2) "Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent."	not explicitly	not explicitly

	The approximate number of subjects involved in the trial	not explicitly	Yes: (Sec. 50.25) Elements of informed consent. (b) Additional elements of informed consent. (6) "The approximate number of subjects involved in the study."	not explicitly	not explicitly
	The trial participation duration	Yes: (Article 13) Information for research participants (2) Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research: (i) of the nature, extent and duration of the procedures involved, in particular.	Yes: (Sec. 50.25) Elements of informed consent. (a) Basic elements of informed consent. (1) "A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation."	Yes: (Art. 16) Informed consent (2) a. the nature, purpose and duration of, and procedure for, the research project.	Yes: (Article 11.2): The "Informed Consent" form shall include the following: (10). "Duration of the research project"
	The need for further details in the case of genetic research and the possible future use of biological materials collected during the research	Yes: (Article 13)-Information for research participants. (2) The information shall cover the purpose, the overall plan and the possible risks and benefits of the research project, and include the opinion of the ethics committee. Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research: (vii) of any foreseen potential further uses, including commercial uses, of the research results, data or biological materials;	not explicitly	Yes: (Art. 32) Further use of biological material and genetic data 1. Further use may be made of biological material and genetic data in uncoded form for a research project if informed consent has been given by the person concerned, or by the legal representative or next of kin. For consent, Articles 16 and 22–24 apply mutatis mutandis. 2. Further use may be made of biological material and genetic data in coded form for research purposes if informed consent has been given by the person concerned, or by the legal representative or next of kin. For consent, Articles 16 and 22–24 apply mutatis mutandis. (Chapter 4): Further Use of Biological Material and Health-Related Personal Data for Research)	not explicitly
Comprehension	The information should be given in a language and at a level of understanding appropriate to the research subject (The informed consent document should be simplified as much as possible)	not explicitly	not explicitly	not explicitly	Yes: (Article 12.1) (a) He shall, in a clear and simple manner, explain in person the information stated in the “Informed Consent” form to the human subject (or his guardian if the subject is incompetent); (b). The explanation shall be appropriate to the educational level, culture and understanding of the human subject (or guardian if the subject is incompetent)

	Comprehension verification through questions and clarifications	not explicitly	not explicitly	not explicitly	Yes: (Article 12.1): (f) He shall ensure via suitable methods that the human subject (or guardian if the subject is incompetent) has understood all the information provided to him prior to signing the "Informed Consent" form. (c). He shall, if required, explain any additional information not stated in the "Informed Consent" form; (d). He shall answer any question raised by the human subject (or guardian if the subject is incompetent);
Voluntariness	Voluntariness of the participation/ right of the participant to refuse participation	Yes: (Article 14)-Consent (1) No research on a person may be carried out, subject to the provisions of both Chapter V and Article 19, without the informed, free, express, specific and documented consent of the person. Such consent may be freely withdrawn by the person at any phase of the research. (2) Refusal to give consent or the withdrawal of consent to participation in research shall not lead to any form of discrimination against the person concerned, in particular regarding the right to medical care.	Yes: (Sec. 50.25) Elements of informed consent. (a) Basic elements of informed consent. (8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled."	not explicitly	Yes: (Article 11.2) The "Informed Consent" form shall include the following: (13) A statement which explicitly reads as follows: Participation in the research is voluntary. Refusal to participate shall not entail penalty or loss of benefits to which the human subject would otherwise be entitled.
	The physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress	not explicitly	not explicitly	not explicitly	Yes: (Article 12.1): (2) If the human subject is a patient, a person other than his attending physician shall obtain his "Informed Consent," provided said person is well-informed about the research and able to answer all the patient's questions.

Competence	Potential research subjects who are incapable of giving informed consent (incompetent/ vulnerable subjects and minors): the physician must seek informed consent from the legally authorized representative	Yes: (Article 15): Protection of persons not able to consent to research. (1) Research on a person without the capacity to consent to research may be undertaken only if all the following specific conditions are met: (iv) the necessary authorisation has been given specifically and in writing by the legal representative or an authority, person or body provided for by law, and after having received the information required by Article 16, taking into account the person's previously expressed wishes or objections. An adult not able to consent shall as far as possible take part in the authorisation procedure. The opinion of a minor shall be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity;	not explicitly	Yes: (Art. 21): Involvement of persons lacking capacity in the consent procedure. (1). Children, adolescents and adults lacking capacity must be involved as far as possible in the consent procedure. (2). Increasing weight must be accorded to the views of children and adolescents lacking capacity the older and more mature they are. (Art. 22), (Art. 23), (Art. 24) Research projects involving adults lacking capacity (1) A research project with an expected direct benefit may only be carried out in adults who lack capacity if:.....a,b,c (2) A research project with no expected direct benefit may only to be carried out in adults who lack capacity if, in addition to the requirements specified in paragraph 1: a,b.	Yes: (Article 25.1) 1. Research may not be conducted on minors, incompetent or mentally disabled persons without obtaining the "Informed Consent" from parents or the legal guardians in accordance with conditions set forth in the Law and Regulations, provided they are informed of the level of risk and its probability as well as the person's assent.
Formal requirements of consent	The informed consent in written format	Yes: (Article 14): Consent: (1) No research on a person may be carried out, subject to the provisions of both Chapter V and Article 19, without the informed, free, express, specific and documented consent of the person. (Article 15): (iv) "the necessary authorisation has been given specifically and in writing by the legal representative or an authority."	Yes: (Sec. 50.27) Documentation of informed consent. (a) Except as provided in 56.109 (c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form."	Yes: (Art.16) Informed consent (1). Persons may only be involved in a research project if they have given their in- formed consent. Consent must be given in writing; the Federal Council may specify exemptions. (2). The persons concerned must receive comprehensible oral and written information on.	Yes: (Article 11.2): The "Informed Consent" form shall include the following: (1). A clear statement at the top of the first page that reads.

	Signature of the human subject	not explicitly	Yes: (Sec. 50.27) Documentation of informed consent. (a) Except as provided in 56.109 (c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form."	not explicitly	Yes: (Article 11.2): "The "Informed Consent" form shall include the following: (17). Signature of the human subject"
	Before a decision on consent is made by the persons concerned, they must be allowed an appropriate period for reflection	not explicitly	not explicitly	Yes: (Art. 16) Informed consent (3). Before a decision on consent is made by the persons concerned, they must be allowed an appropriate period for reflection.	Yes: Article (12.1) 1 When obtaining the "Informed Consent", the investigator shall in all cases observe the following: (e) "He shall not obtain the consent in haste or use coercion or undue inducement to obtain it."
	Reassurance by the physician that the participant understood the information	not explicitly	not explicitly	Yes: (Art. 7) Consent (1). Research involving human beings may only be carried out if, in accordance with the provisions of this Act, the persons concerned have given their informed consent or, after being duly informed, have not exercised their right to dissent.	Yes: (Article 12.1) (f). "He shall ensure via suitable methods that the human subject (or
	guardian if the subject is incompetent) has understood all the information provided to him prior to signing the "Informed Consent."	28	28	28	28
	Providing a copy of the informed consent form and explanations about the study	not explicitly	Yes: (Sec. 50.27): Documentation of informed consent. (a) Except as provided in 56.109 (c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form."	not explicitly	Yes: (Article 13.4): (1). The principal investigator or his duly appointed designee shall issue the "Informed Consent" form in three copies, one for the principal investigator, one for the human subject of the research to be conducted.

	Date and place of the "Informed Consent"	not explicitly	not explicitly	not explicitly	Yes: (Article 11.2) "The Informed Consent" form shall include the following: (18). Date and place of the "Informed Consent.
	The study is conducted by experts according to ethics guidelines	not explicitly	not explicitly	Yes: (Art. 10) Scientific requirements. (1) Research involving human beings may only be carried out if. (d) the persons responsible have appropriate professional qualifications.	not explicitly
	The principal investigator obtains the informed consent or assignes a delegate	not explicitly	not explicitly	not explicitly	Yes: (Article 13.3) (1) The principal investigator shall be responsible for obtaining the "Informed Consent" but he may delegate one of his assistants to obtain such consent provided said assistant is fully aware of the research project and able to answer questions raised by the human subject.
	Consent renewal when needed	Yes: (Article 24): New developments (1) Parties to this Protocol shall take measures to ensure that the research project is re-examined if this is justified in the light of scientific developments or events arising in the course of the research. (2) The purpose of the re-examination is to establish whether: (i) the research needs to be discontinued or if changes to the research project are necessary for the research to continue; (ii) research participants, or if applicable their representatives, need to be informed of the developments or events; (iii) additional consent or authorisation for participation is required.	not explicitly	not explicitly	not explicitly
Total items	44	17	20	15	26