WHO guidelines for emergency research relevant to informed consent for clinical trials

International Ethical Guidelines for Health-related Research Involving Humans:

https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/ (accessed 15.04.2020)

WHO Templates for informed consent forms:

https://www.who.int/ethics/review-committee/informed_consent/en/ (accessed 15.04.2020)

Guideline reference	Quote relevant to informed consent
GUIDELINE 20: RESEARCH IN DISASTERS AND DISEASE OUTBREAKS	The individual informed consent of participants is obtained even in a situation of duress, unless the conditions for a waiver of informed consent are met (see Guideline 9 – Individuals capable of giving informed consent, and Guideline 10 – Modifications and waivers of informed consent); Informed consent. Even though most disaster victims are under duress, it is important to obtain their informed consent for study participation and especially to emphasize the difference between research and humanitarian aid. To explain the difference is especially important in the context of clinical trials that test experimental interventions in the early phases of development. The fact that potential participants are under duress does not prevent them from making a voluntary decision (Guideline 9 – Individuals capable of giving informed consent). The informed consent process must be designed in a way that is comprehensible and sensitive to persons who are under duress. Special protections for individuals incapable of giving informed consent may apply, as described in Guideline 16 – Research involving adults incapable of giving informed consent, in the section on Emergency care situations in which the researcher anticipates that many participants will be unable to consent.
Guideline 9: Individuals capable of giving informed consent	**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, or, where the individual lacks decisional capacity, a legal guardian or other duly authorized representative must do so (see Guideline 16 – Research involving individuals incapable of giving informed consent, and Guideline 17 – Research involving children and adolescents). The research ethics committee may approve a waiver of the requirement of a signed consent document under certain conditions (see Guideline 10 – Modifications and waivers of informed

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	consent). When consent has been obtained orally, researchers should provide to the research ethics committee documentation of consent, certified either by the person obtaining consent or by a witness at the time consent is obtained.
GUIDELINE 10: MODIFICATIONS AND WAIVERS OF INFORMED CONSENT	Researchers must not initiate research involving humans without obtaining each participant's individual informed consent or that of a legally authorized representative, unless researchers have received explicit approval to do so from a research ethics committee. Before a waiver of informed consent is granted, researchers and research ethics committees should first seek to establish whether informed consent could be modified in a way that would preserve the participant's ability to understand the general nature of the investigation and to decide whether to participate. **Waiving informed consent.** A research ethics committee may waive informed consent if it is convinced that the research would not be feasible or practicable to carry out without the waiver, the research has important social value, **and the research poses no more than minimal risks to participants.**
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); and - 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. If participants become capable of giving informed consent during the research, their consent to continued participation must be obtained. In general, a potential participant's refusal to enrol in the research must be respected, unless, in exceptional circumstances, research participation is considered the best available medical option for an individual who is incapable of giving informed consent. **Emergency care situations in which the researcher anticipates that many participants will be unable to consent.** Research protocols are sometimes designed to address conditions occurring suddenly and rendering the patients or participants incapable of giving informed consent. Examples are sepsis, head trauma, cardiopulmonary arrest and stroke. In such circumstances, it is often necessary to proceed with the research interventions very soon after the onset of the condition in order to evaluate an investigational treatment or develop the desired knowledge. **If possible, an attempt must be made to identify a population that is likely to develop the condition to be studied.** This can be done readily, for example, if the condition is one that recurs periodically in individuals, such as grand mal seizures and alcohol

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	binges. In such cases, researchers should ideally contact potential participants while fully capable of informed consent, and obtain their agreement to be involved in the research during future periods of incapacitation, for example in an advance directive. If there is no opportunity to solicit informed consent of participants while fully capable of informed consent, plans to conduct emergency care research with incapacitated persons must be publicized within the community in which it will be carried out, where feasible. In the design and conduct of the research, the research ethics committee, the researchers and the sponsors must be responsive to the concerns of the community. The research must not be carried out if it does not have substantial support in the community concerned. (See commentary on Guideline 4 – Potential individual benefits and risks of research, section on Risks to groups of persons, and Guideline 7 – Community engagement). Before proceeding without prior informed consent, the researcher must make reasonable efforts to locate a legally authorized representative to give permission on behalf of an incapacitated patient in need of emergency care. If such a person can be located and refuses to give permission, the patient may not be enrolled as a participant. The researcher and the research ethics committee should agree to a maximum time of involvement of an individual without obtaining either the individual's own informed consent or surrogate consent if the person continues to be unable to give consent. If, by that time, there is no individual or surrogate consent, the participant should be withdrawn from the study provided that withdrawal will not make the participant worse off. The participant or the surrogate should be offered an opportunity to object to the use of data derived from participation of the patient without consent or permission. When there are no advance directives for research participation for the period of incapacitation, permission of a legally authorized representative must be sought. This permission must take account of the participant's previously expressed preferences and values, if any. In all cases in which research has been approved to begin without prior consent of incapacitated persons because of suddenly occurring conditions, they must be given all relevant information as soon as they regain capacity, and their consent to remain in the study must be obtained as soon as reasonably possible. In addition, they must be given the opportunity to opt out of the study.

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