SUPPLEMENTAL MATERIAL

Table S1: Regional and National Documents Reviewed

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
North America										
Canada	Yes	Yes	(a) Yes (b) Yes	(a) No (b) No	(a) No (b) Yes – ICH GCP	Yes	(a) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018) (b) Guidance Document: Part C, Division 5 of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects" (2019)	(a) Informed by leading inter-national ethics norms (unspe-cified); DoH (2013), CIOMS (2016) and ICH GCP (2016) cited. (b) Provides guidance on imple-mentation of ICH GCP (2016), in accordance with Food and Drug Regulations; ICH GCP (2016) was fully adopted by Health Canada in 2019; local regu-lations apply where they exceed ICH GCP (2016).	Yes – ICH GCP (2016)	N/A
US	Yes	Yes	(a) Yes (b) Yes (c) No (d) Yes	(a) No (b) Yes (c) N/A (d) No	(a) No (b) No (c) N/A (d) No	Yes	(a) FDA 21 CFR 50 Protection of Human Subjects (current version)	(a) No (b) No (c) No (d) No	No	(a) The section on emergency research (s.24) was added in 1996.

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							(b) FDA 21 CFR 56 Institutional Review Boards (current version) (c) HHS 45 CFR 46 Protection of Human Subjects (2018) (d) HHS 45 CFR 46 Waiver of Informed Consent Requi-rements in Cer-tain Emergency Research (1996)			(d) Waiver enabled under s.101 of (c): "To what does this policy apply?" ICH GCP (2016) is provided as a guidance document on the FDA website here.
Europe										
EU/EEA (plus UK)	Yes	Yes	(a) Yes (b) No	(a) No (b) N/A	(a) No (b) N/A	Yes	(a) Regulation on Clinical Trials on Medicinal Products for Human Use (2014) (b) Directive on Good Clinical Practice in Clinical Trials (2001)	(a) The Regulation is in line with DoH (2008) and GCP; ICH GCP should be taken into account in applying the Regulation, where compatible. (b) States that GCP is a set of inter-nationally recog-nized ethical and scientific quality requirements; cites DoH (1996).	No	The Regulation is due to replace the Directive once the technological capacity is in place.

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Council of Europe	Yes	Yes	Yes	No	No	Yes	Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research (2005)	Takes into account international professional standards in the field of biomedical Research.	No	12 states have ratified the Additional Protocol (see below).
Armenia	Yes	No	Unknown	N/A	N/A	No	Order of the Ministry of Health on Adopting the Rules on Good Clinical Practice (2017)	Unknown	N/A	Document not compatible with GT. The Ministry of Health webpage includes a download of the ICH GCP (1996).
Belarus	Yes	No	(a) Yes (GT) (b) No (GT) (c) No (GT)	(a) No (GT) (b) N/A (c) N/A	(a) Yes – WIC (US) (GT) (b) N/A (c) N/A	No	(a) Procedure for the Organization and Work of the Ethics Committee (amended 2009) (b) Order of the Ministry of Health on Approval of the Rules for Conducting	(a) DoH (1996), CIOMS (2002) and ICH GCP (1996) were used in drafting; researchers must comply with DoH in obtaining consent (GT). (b) Based on ICH GCP (1996); clinical trials must be conducted in	Yes – DoH (no date)	(b) Lists patients in an emergency as vulnerable, but does not include guidance specific to emergency medical research (GT).

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							Clinical Trials of Medicines (amended 2009) (c) Resolution on Approval of the Regulations on the Ethics Committee (amended 2009)	strict accordance with DoH (GT). (c) The committee is guided by the basic international principles of clinical trials (unspecified) (GT).		
Mace-donia	Yes	No	(a) Yes (GT) (b) No (GT) (c) No (GT)	(a) No (GT) (b) N/A (c) N/A	(a) Yes – ICH GCP (GT) (b) N/A (c) N/A	No	(a) Guidelines for the Principles of Good Clinical Practice (2009) (b) Rulebook on the Manner and Procedure for Clinical Trials of Drugs and Content of the Documentation (2009) (c) Law on Medicinal Products and Medical Devices (2007)	(a) ICH GCP (1996) principles are prescribed by the Ministry of Health; clinical trials should be conducted in accordance with DoH principles (GT). (b) Ethics committees must assess whether clinical trials can be conducted in accordance with the principles in the 2009 GCP guidelines; principal investigators must state trials will adhere to GCP principles (GT).	Yes – ICH GCP (1996) and DoH principles	N/A

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								(c) Clinical trials must be conducted in accordance with DoH principles and international GCP (GT).		
Russia	Yes	(a) Yes (b) No (c) Yes (d) Yes	(a) Yes (b) Yes (GT) (c) No (d) No	(a) Yes (b) No (GT) (c) N/A (d) N/A	(a) Yes – ICH GCP (b) Yes – ICH GCP (GT) (c) N/A (d) N/A	No	(a) Order on Approval of Rules for Good Clinical Practice (2016) (b) National Standard: Good Clinical Practice (2005) (c) Federal Law on Circulation of Medicines (amended 2019) (d) Decree on Approval of Rules for Accreditation of Medical Institutions for the Right to Conduct Clinical Trials of Pharma-ceutical Drugs (amended 2011)	(a) No international documents are cited, but the wording on emergency situations mirrors ICH GCP. (b) The introduction states it is identical to ICH GCP (1996); clinical research should be conducted in accordance with DoH principles (GT). (c) Clinical trials must adhere to GCP. (d) No	Yes – ICH GCP (1996) and DoH principles	(a) Only includes part of the ICH GCP provisions for emergency situations. There are several further documents on the accreditation and functioning of ethics committees, but none of these address emergency medical research specifically or cite international documents.
San Marino	None found	N/A	N/A	N/A	N/A	No	N/A	N/A	N/A	N/A

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Serbia	Yes	No	(a) Yes (GT) (b) No (GT) (c) No (GT)	(a) No (GT) (b) N/A (c) N/A	(a) Yes – ICH GCP (GT) (b) N/A (c) N/A	No	(a) Good Clinical Practice Guidelines (2017) (b) Law on Medicines and Medical Devices (2017) (c) Regulation on Content of Requests and Documents for Approvals of Clinical Trials and Procedures for Conducting Clinical Trials (2018)	(a) An exact copy of ICH GCP (2016); clinical trials should be conducted in accordance with DoH principles (GT). (b) Clinical trials must be performed in accordance with the 2017 GCP guidelines (GT). (c) Clinical trials must be conducted in accordance with GCP guidelines (GT).	Yes – ICH GCP (2016) and DoH principles	N/A
Switzer-land	Yes	Yes	(a) Yes (b) Yes (c) No	(a) No (b) No (c) N/A	(a) No (b) No (c) N/A	Yes	(a) Federal Act on Research Involving Human Beings (2011) (b) Ordinance on Clinical Trials in Human Research (2013) (c) Swiss Clinical Trial Organisation Guidelines for Good Operational Practice	(a) Research with human beings must comply with internationally recognized good practice guidelines; the Federal Council will specify which international regulations must be complied with. (b) Applicable rules for clinical trials of medicinal products are ICH GCP (2016).	Yes – ICH GCP (2016) and DoH (no date)	(c) Mentions that special informed consent procedures apply in emergency situations, but refers readers to the relevant sections in (a) and (b) for details.

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							(version 3.0, 2017)	(c) Revised in response to ICH GCP (2016); protocols will be assessed on their adherence to ICH GCP; all research on humans must respect DoH.		
Ukraine	Yes	(a) No (b) Yes (c) No (d) No	(a) Yes (GT) (b) Yes (c) No (GT) (d) No (GT)	(a) No (GT) (b) No (c) N/A (d) N/A	(a) Yes – ICH GCP (GT) (b) No (c) N/A (d) N/A	No (see notes)	(a) Medicines: Good Clinical Practice (amended 2017) (b) Guideline on General Principles for Organizing the Activities of Ethics Committees in Medical and Preventive Institutions, Involved in Conducting Drug Clinical Trials (2017) (c) Statement of Procedure for Carrying Out Clinical Trials of Medicines and the Standard	(a) Complies with ICH GCP (2016) (exact copy plus local introduction); clinical trials should be conducted in accordance with DoH principles (GT). (b) Developed from ICH GCP (2016); investigators should adhere to DoH principles and GCP when obtaining informed consent; Council of Europe Additional Protocol referred to in section on emergency research; CIOMS (2016) cited. (c) Adopted in accordance with EU	Yes – ICH GCP (2016), DoH principles and EU Directive on GCP (2001)	(b) Stipulates that patients in emergency situations who cannot consent cannot be enrolled in a clinical trial unless their legal/close representative has discussed the trial with an investigator, so it would not be compatible with the consent substitute model.

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							Position about Commissions on Ethics (amended 2015) (d) Typical Regulations on Ethics Commissions at Treatment and Prevention Facilities Where Clinical Trials Are Conducted (amended 2012)	Directive GCP (2001) and to achieve harmonization with international rules for clinical trials (GT). (d) Developed taking into account EU Directive on GCP (2001) and ICH GCP (1996) (GT).		
Asia/Pacific										
Australia	Yes	Yes	(a) Yes (b) No	(a) No (b) N/A	(a) No (b) N/A	Yes	(a) National Statement on Ethical Conduct in Human Research (updated 2018) (b) Australian Clinical Trial Handbook (version 2.2, 2018)	(a) DoH is mentioned in the introduction; for relevant health research, researchers should show that the research meets ICH GCP requirements. (b) Clinical trials must be conducted in accordance with DoH principles and ICH GCP (2016).	Yes – ICH GCP (2016) and DoH principles	N/A
Bangla-desh	Yes	Yes	(a) Yes (b) No (c) No	(a) No (b) N/A (c) N/A	(a) Yes – ICH GCP (b) N/A (c) N/A	No	(a) Guidelines for Good Clinical Practice for Trials on	(a) Mostly adapted from ICH GCP (1996); clinical trials should be conducted in	Yes – DoH principles	N/A

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							Pharmaceutical Products (2015) (b) Ethical Guidelines for Conducting Research Studies Involving Human Subjects (no date) (c) Standard Operating Procedures: National Research Ethics Committee (no date)	accordance with DoH principles. (b) DoH (2000), CIOMS (2002) and ICH GCP (1996) are referenced; GCP common principles based on ICH GCP (1996) and WHO GCP (1995) should be strictly adhered to in clinical trials. (c) NREC should have copies of all relevant inter-national guidelines on research ethics.		
China	Yes	No	(a) No (GT) (b) No (GT) (c) No (GT)	N/A	N/A	No	(a) Measures for the Ethical Review of Biomedical Research Involving People (2016) (b) Measures for the Management of Clinical Research Projects Carried Out by Medical and Health Institutions (2014)	(a) No (GT) (b) Medical and health institutions shall follow international norms (unspecified) (GT). (c) Purpose is to ensure compliance with GCP (unspecified), DoH and CIOMS (2002); RECs should train in GCP (GT).	No (but see notes)	Google searches show that China released new GCP guidelines in April 2020, which largely adopt ICH GCP (2016), but links to the guidelines do not work and they could not be found online. They replaced the

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							(c) Guiding Principles for Ethical Review of Drug Clinical Trials (2010)			2003 GCP guidelines.
India	Yes	Yes	(a) No – only humanitarian emergencies (b) Yes	(a) N/A (b) Yes	(a) N/A (b) No	No	(a) National Ethical Guidelines For Biomedical and Health Research Involving Human Participants (2017) (b) New Drugs and Clinical Trials Rules (2019) (c) Drugs and Cosmetics Rules (amended 2016)	(a) The guidelines have adapted important guidance points from DoH (2013), CIOMS (2016), ICH GCP (2016) and several other documents; ethics committee members must be trained in GCP; clinical trials must be conducted in accordance with DoH (current). (b) Ethics committees must keep records of international guidelines followed in clinical trial reviews; trials must be conducted in accordance with DoH. (c) No	Yes – DoH (current)	All three documents refer to Indian GCP guidelines, which researchers must comply with, but these could not be found online.
Indo-nesia	Yes	No	(a) Yes (GT) (b) No (GT)	(a) No (GT) (b) N/A	(a) Yes – ICH GCP (GT)	No	(a) Guideline for Good Clinical Practice	(a) Exact copy of ICH GCP (1996); clinical trials must	Yes – ICH GCP (1996)	The 2020 compilation lists research

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					(b) N/A		(3rd edition, 2016) (b) Regulation about Clinic Test Approval Procedures (2015)	be conducted in accordance with DoH principles (GT). (b) Investigators must be trained in GCP (GT).	and DoH principles	ethics guidelines, but these could not be found online.
Japan	Yes	(a) Yes (b) Yes (c) No	(a) Yes (b) No (c) Yes (GT)	(a) No (b) N/A (c) No (GT)	(a) No (b) N/A (c) No (GT)	Yes	(a) Ethical Guidelines for Medical and Health Research Involving Human Subjects (2018) (b) Clinical Trials Act (2017) (c) Ministerial Ordinance on Standards for Conducting Clinical Trials of Pharma-ceuticals (amended 2009)	(a) No (b) No (c) No (GT)	No	The 2020 compilation also lists the "Pharma-ceuticals and Medical Devices Act" (2016), but this could not be found online.
Kazakh-stan	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	The 2020 compilation lists ethics and clinical trial guidelines, but these could not be found online.

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Korea (South)	Yes	(a) Yes (b) Yes (c) No	(a) No (b) No (c) No (GT)	N/A	N/A	No	(a) Bioethics and Safety Act (amended 2017) (b) Enforcement Decree of the Bioethics and Safety Act (2017) (c) Regulation on Education of Pharmaceutical Clinical Trial Workers and Designation of Educational Institutions (2017)	(a) No (b) No (c) No (GT)	No	N/A
Kyrgyz-stan	Yes	No	(a) No (GT) (b) No (GT)	N/A	N/A	No	(a) Medical Products: Rules for Conducting Clinical Trials (2010) (b) Law on Circulation of Medicines (2017)	(a) Clinical trials must comply with DoH (current) (GT). (b) Clinical trials must adhere strictly to GCP rules (unspecified) (GT).	Yes – DoH (current) (and unspecified GCP)	N/A
Malaysia	Yes	Yes	(a) Yes (b) No	(a) No (b) N/A	(a) Yes – ICH GCP (b) N/A	No	(a) Guideline for Good Clinical Practice (4th edition, 2018) (b) Guideline for Independent Ethics	(a) Adapted from ICH GCP (2016); should be read in tandem with DoH; clinical trials should be conducted in accordance with DoH principles.	Yes – DoH principles; also ICH GCP (1996) for RECs	The 2020 compilation lists "Guide-lines for Ethical Review of Clinical Research or Research

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							Committee Registration and Inspection (2016)	(b) Adapted from ICH GCP (1996) and other international documents; ethics committees must conform to DoH and ICH GCP.		Involving Human Subjects" (2006), but these could not be found online.
Myan-mar	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	The 2020 compilation lists the "Guideline for Submission to Ethics Review Committee" (2016), but this could not be found online. The "National Drug Law" (1992) is only partly compatible with GT – translatable parts contained no references to research or clinical trials.
Nepal	Yes	Yes	(a) No – only	N/A	N/A	No	(a) Final draft National Ethical Guidelines for	(a) Based on DoH (2013), CIOMS (2002), ICH GCP	Yes – DoH (current) and	(c) Lists patients in emergency

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			humanitarian emergencies (b) No (c) No				Health Research in Nepal (2019) (b) National Guidelines on Clinical Trials with the Use of Pharmaceutical Products (2005) (c) Guidelines for Institutional Review Committees for Health Research in Nepal (2016)	and other documents. (b) Informed consent principles from DoH (current) and CIOMS (1993) should be implemented; DoH (current) should be fully followed in clinical trials; based on WHO GCP (1995). (c) Cites DoH (2008), CIOMS (1993) and ICH GCP (1996).	CIOMS (1993)	situations as vulnerable, but does not include guidance specific to emergency medical research.
New Zealand	Yes	Yes	(a) Yes (b) No (c) No (d) No	(a) No (b) N/A (c) N/A (d) N/A	(a) No (b) N/A (c) N/A (d) N/A	Yes	(a) National Ethical Standards for Health and Disability Research and Quality Improvement (2019) (b) Clinical Trials – Regulatory Approval and Good Clinical Practice Requirements	(a) Informed by DoH (2013), CIOMS (2016) and other documents; standards assume researchers are familiar with relevant international guidelines. (b) Clinical trials must be conducted in accordance with ICH GCP (2016). (c) Ethics committees must operate in	Yes – ICH GCP (2016)	(c) Awaiting further updates to align with (a).

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							(2nd edition, 2018) (c) Standard Operating Procedures for Health and Disability Ethics Committees (version 3.0, 2019) (d) Health Research Council Research Ethics Guidelines (2017)	accordance with ICH GCP. (d) Ethics committees should ensure research involving human participants meets international best practice; clinical trials should observe ICH GCP; researchers should consult DoH.		
Pakistan	Yes	Yes	(a) Yes (b) No	(a) No (b) N/A	(a) Yes – ICH GCP (b) N/A	No	(a) Good Clinical Practice Guidelines (no date) (b) Research Ethics – Guidance Document to Help Researcher Fill the ERC Application Form (2015)	(a) Adopted from ICH GCP; clinical trials should be conducted in accordance with DoH principles. (b) Builds upon the most influential international guidelines (unspecified).	Yes – DoH principles	N/A
Phili-ppines	Yes	Yes	(a) Yes (b) No	(a) No (b) N/A	(a) No (b) N/A	Yes	(a) National Ethical Guidelines for Health and Health-Related Research (2017)	(a) Earlier guidelines revised in light of DoH (2013) and CIOMS (2016); researchers must comply with	Yes – ICH GCP (1996)	N/A

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							(b) Policies and Requirements for Accredi-tation of Research Ethics Committees (2020)	ICH GCP (1996); researchers and REC members must be trained in GCP. (b) RECs shall adhere to international research ethics guidelines (unspecified).		
Singa-pore	Yes	Yes	(a) Yes (b) No (c) Yes (d) Yes (e) No	(a) No (b) N/A (c) No (d) No (e) N/A	(a) No (b) N/A (c) No (d) No (e) N/A	Yes	(a) Human Biomedical Research Act (2015) (b) Human Biomedical Research Regulations (2017) (c) Health Products (Clinical Trials) Regulations (2016) (d) Medicines (Clinical Trials) Regulations (2016) (e) Guidance on GCP Compliance Inspection Framework (2017)	(a) No (b) No (c) Clinical trials must be conducted in accordance with DoH principles and GCP (unspecified). (d) Clinical trials must be conducted in accordance with DoH principles and GCP (unspecified). (e) Clinical trials must comply with ICH GCP (2016).	Yes – ICH GCP (2016) and DoH principles	N/A

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Sri Lanka	Yes	Yes	(a) No (b) No – only public health emergencies	N/A	N/A	No	(a) Guidelines for the Conduct of Clinical Trials in Sri Lanka (2019) (b) National Medicines (Clinical Trials) Regulations (2019)	(a) The guidelines are not intended as a comprehensive guide and should be read in conjunction with ICH GCP. (b) ICH GCP (2016) is applicable in addition to the regulations; DoH principles provide guidance on researcher responsibilities.	Yes – ICH GCP (2016)	The clinical trials guidelines do not include guidance on ethics and state that researchers should refer to ICH GCP.
Taiwan	Yes	Yes	(a) Yes (b) No (c) No (d) No	(a) Yes (b) N/A (c) N/A (d) N/A	(a) No (b) N/A (c) N/A (d) N/A	No	(a) Regulations for Good Clinical Practice (2014) (b) Regulations on Human Trials (2016) (c) Human Subjects Research Act (2019) (d) Regulations for Organization and Operation of Human Research Ethics Review Board (2018)	(a) Clinical trials should be conducted in accordance with DoH principles; much of the text mirrors ICH GCP. (b) No (c) No (d) No	Yes – DoH principles	N/A
Tajiki-stan	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
Thailand	Yes	(a) Yes (b) No	(a) No (b) No (GT)	N/A	N/A	No	(a) The Ethical Guidelines for Research on Human Subject in Thailand (2007) (b) Rules, Procedures and Conditions for Accepting Ethics Committee for Research Involving Human Subjects (2018)	(a) Developed considering DoH, CIOMS and other documents; RECs should review protocols in accordance with current international ethical guidelines. (b) RECs must consider research projects according to ICH GCP (GT).	No (but RECs must use ICH GCP in assessments)	N/A
Uzbeki-stan	Yes	(a) No (b) No	(a) Un-known (b) No (GT)	N/A	N/A	No	(a) Good Clinical Practice (2018) (b) Law on Drugs and Pharmaceutical Activity (amended 2016)	(a) Unknown (b) No (GT)		(a) Document not compatible with GT.
Vietnam	Yes	(a) No (b) Yes (c) No (d) Yes (e) No	(a) No (GT) (b) No – only health security emergencies (c) No (GT) (d) No (e) Un-known	N/A	N/A	No	(a) Regulations for Clinical Trials on Drugs (2018) (b) Guidelines for Clinical Trials on Drugs (2012) (c) Regulations on the	(a) Based on ICH GCP and WHO GCP; researchers and auditors must be trained in GCP; clinical trials must be conducted in accordance with DoH principles (GT).	Yes – GCP (ICH/WHO) and DoH principles	(b) Certain parts of the 2012 GCP guidelines were annulled by the 2018 GCP regulations.

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							Establishment, Functions, Duties and Rights of the Board of Ethics in Biological Research (2017) (d) Law on Pharmacy (2016) (e) Regulation on the Establishment of the Ethics Committee in National Biomedical Research of the Ministry of Health, Period 2018-2023 (2018)	(b) Health Ministry has recognized ICH GCP and WHO GCP; clinical trials shall be conducted in accordance with GCP. (c) REC members should be trained in ICH GCP (GT). (d) GCP (based on WHO instructions and other international bodies) must be applied strictly in clinical trials. (e) Unknown		(e) Document not compatible with GT.
Middle East/North Africa										
Egypt	None found	No	N/A	NA	NA	No	N/A	N/A	N/A	The 2020 compilation lists "Profes-sional Ethics Regulations: Conducting Medical Research on Human Beings" (2003), but these could not

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
										be found online.
Iran	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	The 2020 compilation lists the "Prot-ection Code for Human Sub-jects in Medical Research" (1999), but this could not be found online.
Israel	Yes	Yes	Yes	No	No	Yes	Guidelines for Clinical Trials in Human Subjects (2006)	Clinical trials must comply with DoH principles and ICH GCP (1996); in matters not covered by binding provisions in the national guidelines, ICH GCP should be followed.	Yes – ICH GCP (1996) and DoH principles	The 2020 compilation lists "Public Health Regulations (Clinical Studies in Human Subjects)" (amended 2005) and "Public Health Regulations (Medical Experiments Involving Human Subjects)" (1999), but these could not be found online.

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
Jordan	Yes	No	Unknown	N/A	N/A	No	(a) Law of Clinical Studies (2011) (b) Drugs and Pharmacy Law (2013)	Unknown	N/A	Documents not compatible with GT.
Kuwait	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	The 2020 compilation lists "Ethical Guidelines for Biomedical Research" (no date), but these could not be found online.
Qatar	Yes	Yes	(a) Yes (b) No	(a) No (b) N/A	(a) Yes – ICH GCP (b) N/A	No	(a) Standards of Good Clinical Practice (2018-19) (b) Guidelines, Regulations and Policies For Research Involving Human Subjects (2009)	(a) Adopts ICH GCP (2016); compliance by IRBs and researchers is required; clinical trials should be conducted in accordance with DoH principles. (b) DoH (2008), CIOMS (2002) and other documents consulted, adapted and modified.	Yes – ICH GCP (2016) and DoH principles	N/A
Saudi Arabia	Yes	Yes	No	N/A	N/A	No	Implementing Regulations of the Law of Ethics of	No	No	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							Research on Living Creatures (2nd Edition, 2016)			
Sudan	Yes	Yes	(a) Yes (b) No	(a) No (b) N/A	(a) Yes – CIOMS (2002) (b) N/A	No	(a) Guidelines for Ethical Conduct of Research Involving Human Subjects (2008) (b) Accredi-tation Guidelines for Research Ethics Committees in Sudan (2017)	(a) DoH (2002) and CIOMS (2002) are referenced. (b) Intended to ensure research in Sudan adheres to international commitments and guidelines; DoH (2008) and CIOMS (2002) are cited.	No	The "Medicines and Poisons Act" (2009) is incompatible with GT, so could not be assessed for relevance.
Tunisia	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	The 2020 compilation lists two docu-ments that may be relevant, but these could not be found online.
United Arab Emirates	Yes	Yes	No	N/A	N/A	No	Guidelines for Conducting Clinical Trials with Investigational Products and Medical Devices (2020)	Clinical testing in humans should be conducted in accordance with DoH; clinical trials should be conducted in accordance with	Yes – DoH (no date) (and unspecified GCP)	The guidelines list patients in emergency situations as vulnerable, but do not include guidance specific to

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
								GCP (unspecified) and other international documents.		emergency medical research. The 2020 compilation lists "Standard Operating Procedures for Research Ethics Committees" (2012), but these could not be found online.
Latin America and the Caribbean										
Argen-tina	Yes	(a) Yes (b) No	(a) No (b) Yes (GT)	(a) N/A (b) No (GT)	(a) N/A (b) No (GT)	No	(a) Regulatory Guideline for Good Clinical Practices in Clinical Pharmacology Studies (2010) (b) Resolution Approving the Guide for Investigations with Human Beings (2011)	(a) Clinical trials must comply with DoH (current); CIOMS (2002) cited; GCP defined as an international standard. (b) DoH (2008), CIOMS (2002), ICH GCP (1996) and other documents referred to in preparation of the guide (GT).	Yes – DoH (current)	N/A
Barbados	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	N/A
Bermuda	Yes	Yes	No	N/A	N/A	No	Department of Health Research	The Department of Health has adopted	Yes – CIOMS (2002)	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							Governance Framework (2008)	CIOMS (2002) in entirety; any research with humans must satisfy all the standards therein; the framework includes the guidelines in their brief form and readers are referred to the original for further details.		
Bolivia	Yes	No	No (GT)	N/A	N/A	No	Standard for Clinical Studies (2005)	ICH GCP (1996) must be complied with in all clinical studies with drugs; protocols must accept DoH (current) and other internationally recognized standards (GT).	Yes – ICH GCP (1996) and DoH (current)	The 2020 compilation lists "Rules and Regulations of the National Bioethics Committee" (no date), but these could not be found online.
Brazil	Yes	(a) Yes (b) No (c) Yes (d) Yes (e) Yes	(a) Yes (b) Yes (GT) (c) No (d) No (e) No	(a) Yes (b) Yes (GT) (c) N/A (d) N/A (e) N/A	(a) No (b) No (GT) (c) N/A (d) N/A (e) N/A	No	(a) Resolution: Norms of Research Involving Human Beings (1997) (b) Operational Manual for Research Ethics	(a) No (b) Cites DoH and CIOMS; REC members must be trained in international research ethics standards (GT). (c) DoH (2000) is cited.	Yes – ICH GCP (1996)	There are several further documents on the accreditation and functioning of ethics committees, but none of these address

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							Committees (4th edition, 2008) (c) Resolution: Guidelines and Standards Regu-lating Research Involving Human Beings (2012) (d) Resolution Regarding Regulation for Realization of Clinical Trials of Medication in Brazil (2015) (e) Guidance Manual: Frequent Pending Issues in Clinical Research Protocols (2015)	(d) Clinical trials must be conducted in accordance with ICH GCP (1996). (e) No		emergency medical research specifically or cite international documents (GT).
Chile	Yes	No	(a) No (GT) (b) No (GT)	N/A	N/A	No	(a) Law No. 20120 Regarding Scientific Research in the Human Being, its Genome, and Prohibits Human Cloning (2006)	(a) No (GT) (b) No (GT)	No	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							(b) Decree: Approves Regulation on Law No. 20120 (amended 2013)			
Colom-bia	Yes	No	(a) No (GT) (b) No (GT) (c) Yes (GT) (d) No (GT) (e) No (GT)	(a) N/A (b) N/A (c) No (GT) (d) N/A (e) N/A	(a) N/A (b) N/A (c) No (GT) (d) N/A (e) N/A	No	(a) Resolution Adopting Good Clinical Practices for Institutions that Conduct Research with Medicines in Human Beings (2008) (b) ABC Good Clinical Practice (2009) (c) Scientific, Technical, and Administrative Regulations for Health Research (1993) (d) Guide for Research Ethics Committees (2015) (e) Guide for the Evaluation and Follow-up of Research Protocols (2019)	(a) Refers to PAHO GCP (2005); researchers must know GCP standards, DoH and CIOMS (GT). (b) Refers to WHO (1995) and PAHO GCP (2005) (GT). (c) No (GT) (d) International GCP guidelines (unspecified) must be adhered to; ethical framework should be based on DoH and CIOMS; REC members and researchers must be trained and certified in GCP (GT). (e) Research will be conducted in accordance with DoH principles and the GCP guidelines; research teams must be trained in GCP (GT).	Yes – international GCP (unspecified) and DoH principles	(a) NB PAHO GCP (2005) is based on ICH GCP (1996).

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
Costa Rica	Yes	No	(a) Yes (GT) (b) No (GT) (c) No (GT)	(a) Yes (GT) (b) N/A (c) N/A	(a) No (GT) (b) N/A (c) N/A	No	(a) Biomedical Research Regulatory Law (2014) (b) Regulation to the Biomedical Research Regulatory Law (2015) (c) Reform of Regulations to the Biomedical Research Regulatory Law (2016)	(a) Researchers must conduct research in accordance with GCP (unspecified) (GT). (b) RECs and researchers must comply with GCP (unspecified) (GT). (c) No (GT)	Maybe – GCP (unspecified)	N/A
Cuba	Yes	No	(a) Yes (GT) (b) No (GT)	(a) No (GT) (b) N/A	(a) Yes – ICH GCP (GT) (b) N/A	No	(a) Good Clinical Practice in Cuba (2000) (b) Regulation of Clinical Trials in Cuba (2017)	(a) Exact copy of ICH GCP (1996); clinical trials must comply with DoH (1996) (GT). (b) Clinical trials must comply with (a), i.e. ICH GCP (1996) (GT).	Yes – ICH GCP (1996) and DoH (1996)	N/A
Domi-nica	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	The 2020 compilation lists "Guide-lines for the Conduct of Research on Human Subjects" (2005), but

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										these could not be found online.
Domi-nican Republic	Yes	No	(a) Un-known (b) Un-known (c) No (GT)	N/A	N/A	No	(a) Provision Creating the National Council on Health Bioethics (2000) (b) Resolution Establishing the Structure, Organization and Function of the National Council on Health Bioethics (2008) (c) General Health Law (2001)	(a) Unknown (b) Unknown (c) Research must adhere to internationally approved bioethical principles (GT).	Yes – international bioethical principles (unspecified)	(a) and (b) not compatible with GT.
Ecuador	Yes	No	(a) No (GT) (b) No (GT) (c) No (GT)	N/A	N/A	No	(a) Regulation on Health Research (2008) (b) Regulation for the Approval of Ethics Committees (2014) (c) Regulation for the Approval, Development Oversight, and	(a) Research must comply with internationally accepted ethical standards (unspecified) (GT). (b) RECs must make decisions in accordance with DoH, ICH GCP and other documents (GT).	Yes – international ethical standards (unspecified); DoH (undated) and ICH GCP (undated) for RECs.	(c) Lists patients in emergency situations as vulnerable, but does not include guidance specific to emergency medical research (GT).

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							Control of Clinical Trials (2017)	(c) RECs and the National Agency for Regulation, Control and Surveillance will be guided by CIOMS, DoH, ICH GCP and other documents (GT).		
El Salvador	Yes	No	(a) Yes (GT) (b) (No (GT) (c) No (GT)	(a) No (GT) (b) N/A (c) N/A	(a) Yes – ICH GCP (GT) (b) N/A (c) N/A	No	(a) Guide to Good Clinical Practices (2016) (b) Operating Manual of the National Health Research Ethics Committee (2017) (c) Standard Operating Procedures for the Ethical Evaluation of Health Research (2015)	(a) Adapted from ICH GCP (1996); clinical trials must be conducted in accordance with DoH principles (GT). (b) The National Committee must ensure that researchers comply with international ethical standards; DoH, CIOMS and ICH GCP are referenced (GT). (c) Intended to standardize opera-ting procedures of ethics committees to comply with international standards and GCP guidelines; adapted from ICH GCP	Yes – DoH principles and international ethical standards (unspecified)	(c) Lists patients in emergencies as vulnerable, but does not include guidance specific to emergency medical research (GT). (c) Includes a question on the self-evaluation checklist for RECs on whether they have written policies or procedures on exception from informed consent in

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
								(1996); CIOMS (2002) cited (GT).		emergency situations (GT).
Grenada	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	The 2020 compilation lists US regulation 45 CFR 46.
Guyana	Yes	Yes	(a) No (b) No	N/A	N/A	No	(a) Medical Research Involving Human Subjects Regulations (2008) (b) Medical Practitioners (Code of Conduct and Standards of Practice) Regulations (2008)	(a) No (b) Research protocols shall indicate compliance with DoH principles.	Yes – DoH principles	
Guate-mala	Yes	No	(a) Yes (GT) (b) Un-known	(a) No (GT) (b) N/A	(a) No (GT) (b) N/A	No	(a) Rules for the Regulation of Clinical Trials in Humans (2019) (b) Internal Regulations of the National Committee on Health Ethics (2018)	(a) Incorporates DoH (2013), CIOMS (2016) and ICH GCP (2016) at local level (GT). (b) Unknown	No	(b) Not compatible with GT. The 2020 com-pilation lists "Regulation on Clinical Research on Humans" (2015), but this could not be found online.

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
Haiti	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	The "National Policy of Health Research" (2020) outlines the need to streng-then the health research legal and regulatory framework, but does not contain guidance on ethical practice. RECs should be established in accordance with DoH and ICH GCP (GT).
Hon-duras	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	The "Regu-lation for the Health Control of Products, Services, and Health Estab-lishments" (2015) was not compatible with GT, so could not be assessed for relevance.

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
Jamaica	Yes	Yes	No	N/A	N/A	No	Guidelines for the Conduct of Research on Human Subjects (2010)	No	No	N/A
Mexico	Yes	No	(a) Yes (GT) (b) Yes (GT) (c) No (GT) (d) No (GT)	(a) No (GT) (b) Yes (GT) (c) N/A (d) N/A	(a) No (GT) (b) No (GT) (c) N/A (d) N/A	No	(a) Regulation of the General Health Law in Health Research (2014) (b) National guide for the integration and operation of the Research Ethics Committees (2018) (c) Standard which Establishes the Criteria for the Implementation of Projects of Research for Health in Humans (2012) (d) Guide for Submission for Research Protocol in Human Beings (2016)	(a) No (GT) (b) DoH (2013), ICH GCP (2016), CIOMS (2016) are cited; RECs should take international research ethics regulations into consideration; REC members should have ongoing training in GCP and international ethics regulations (GT). (c) Partly agrees with DoH (2008) (GT). (d) Protocols should describe the fulfilment of GCP (unspecified) (GT).	No	The ClinRegs website provides a link to national GCP guidelines (2012), but this does not work and the guidelines could not be found online. ClinRegs states that under these guidelines ICH GCP (1996) must be complied with. (But Good practice guidelines for other topics were available on the government website.)
Nica-ragua	Yes	No	No (GT)	N/A	N/A	No	General Health Law (2002)	States that health research must refer	No	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
								to internationally approved ethical principles (unspecified) (GT).		
Panama	Yes	No	Unknown	N/A	N/A	No	(a) Law that Regulates and Promotes Health Research and Establishes its Stewardship and Governance, and Dictates Other Provi-sions (2019) (b) Executive Decree on the National Research Ethics Committee of Panama (2015)	Unknown	N/A	Documents not compatible with GT.
Paraguay	Yes	No	(a) No (GT) (b) No (GT)	N/A	N/A	No	(a) National Institute of Health Research Ethics Committee Standard Operating Procedures (2017) (b) Law Regarding Health Products and Other Products (1997)	(a) The REC must comply with international ethical standards, including DoH (2013), CIOMS (2016) and ICH GCP (2016); researchers must adhere to international ethical standards (GT). (b) Clinical trials must be carried out in accordance with	Yes – DoH (no date) (and unspecified GCP); DoH (2013), CIOMS (2016) and ICH GCP (2016) for NIHR REC.	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
								DoH and GCP (unspecified) (GT).		
Peru	Yes	No	(a) No (GT) (b) No (GT) (c) Un-known (d) No (GT)	N/A	N/A	No	(a) Supreme Decree Approving the Regulation of Clinical Trials (2017) (b) Supreme Decree Approving the Guidelines to Guarantee the Exercise of Bioethics from the Recognition of Human Rights (2011) (c) Procedures Manual of Clinical Trials (2017) (d) General Health Law (1997)	(a) Clinical trials must adhere to DoH; aspects not provided for will be resolved within the framework of ICH GCP (GT). (b) No (based on UNESCO bioethics declaration) (GT). (c) Unknown (d) Research must adhere to DoH principles (current) (GT).	Yes – ICH GCP (2016) and DoH (current)	(c) Not compatible with GT.
St Lucia	Yes	Yes	No	N/A	N/A	No	Clinical Trials Act (2016)	In "Part 2: conditions and principles which apply to all clinical trials", the principles are based on ICH GCP.	No	The Act lists persons in emergency situations as vulnerable, but does not include guidance specific to emergency

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
										medical research.
Trinidad and Tobago	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	N/A
Uruguay	Yes	No	(a) No (GT) (b) Un-known	N/A	N/A	No	(a) Decree Regarding Research on Human Beings (2019) (b) Bioethics Commission Regulation (2020)	(a) Protocols conducted from abroad or with foreign cooperation must comply with international standards for research on human beings (unspecified); draws attention to DoH (2000) (GT). (b) Unknown	Yes – international standards (unspecified) for international research	(b) Not compatible with GT.
Vene-zuela	Yes	No	No – only humanitarian emergencies (GT)	N/A	N/A	No	Bioethics Code (2011)	DoH (1989), CIOMS (1982) and other international documents consulted (GT).	No	The 2020 compilation list includes further research ethics and health documents, but these could not be found online.
Africa										
Algeria	Yes	No	(a) Yes (GT) (b) No (GT) (c) No (GT)	(a) No (GT) (b) N/A (c) N/A	(a) No (GT) (b) N/A (c) N/A	No	(a) Order Relating to Clinical Trials (2006) (b) Order Setting the	(a) Clinical trial applications can be rejected if the protocol does not respect GCP prin-	Yes – international GCP (unspecified) and DoH (current)	(a) Specifies that patients in emergency situations cannot take part

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							Rules of Good Clinical Practices (2009) (c) Law on the Protection and Promotion of Health (2018)	ciples (unspecified) (GT). (b) DoH (current) must be known and followed by any person engaged in research with humans; investi-gators must confirm they will conduct trials in accordance with GCP; GCP is described as an international standard (GT). (c) No (GT)		in clinical trials (GT).
Benin	Yes	No	Yes (GT)	Yes (GT)	No (GT)	No	Law Regarding the Ethical Code and Duties in Health Research in the Republic of Benin (2010)	No (GT)	No	Research in emergency situations can only be conducted without prior consent of the participant if a family member has given consent (GT).
Bots-wana	Yes	Yes	No	N/A	N/A	No	Guideline for Regulating the Conduct of Clinical Trials Using Medicines in Human	Guideline prepared in accordance with ICH GCP (1996) and South African GCP (2000); it is not intended to be comprehensive and	Yes – DoH principles (and unspecified GCP)	The Guideline lists patients in emergency situations as vulnerable, but does not include guidance

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							Participants (2012)	should be read in conjunction with relevant international GCP guidelines; clinical trials and ethical evaluations thereof must be in accordance with GCP and DoH principles.		specific to emergency medical research. The 2020 compilation lists "Guidelines for the Review of Research Proposals" (2005), but these could not be found online.
Burkina Faso	Yes	No	Unknown	N/A	N/A	No	(a) Order on the Conditions for Granting Authorizations for Clinical Trials (2010) (b) Order on the Organisation and Functioning of the Ethics Committee for Health Research of Burkina Faso (2004)	Unknown	N/A	Documents not compatible with GT.
Came-roon	Yes	(a) Yes (b) No	(a) No (b) No (GT)	N/A	N/A	No	(a) Standard Operating Procedures for Research Ethics	(a) DoH (2008), CIOMS (2002), ICH GCP (1996) and other docu-	Yes – international guidelines	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							Committees in Cameroon (2012) (b) Good Practice Guide for the Creation, Organization and Functioning of Ethics Committees in Research for Human Health (2016)	ments consulted in drafting; RECs must review proto-cols in compliance with international guidelines; investigators must be familiar with international regulation; CIOMS and ICH GCP quoted extensively in glossary. (b) Inspired by international instruments and texts; DoH (2008), CIOMS (2002) and ICH GCP (1996) cited (GT).	(unspecified) for RECs	
Congo, Demo-cratic Republic of	Yes	No	(a) Yes (GT) (b) No (GT)	(a) Yes (GT) (b) N/A	(a) No (GT) (b) N/A	No	(a) Guidelines for the Ethical Evaluation of Research Invol-ving Human Subjects in DR Congo (2011) (b) Decree-Law Framework on Public Health, Title VII: Regarding the National Medical Ethics	(a) Guidelines are rooted in DoH (2008), ICH GCP (1996) and other documents; investigators must follow DoH, ICH GCP (1996) and CIOMS (1993) (GT). (b) No (GT)	Yes – DoH (no date), ICH GCP (1996) and CIOMS (1993)	(a) States that RECs should review arrangements if the patient is unable to give consent in emergencies, with reference to the details in DoH and ICH GCP (GT).

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							Committee, Biomedical Research etc (2001)			
Côte d'Ivoire	Yes	No	Unknown	N/A	N/A	No	Decree on Regulating Clinical Trials (2020)	Unknown	N/A	Document not compatible with GT.
Ethiopia	Yes	Yes	Yes	No	No	Yes	National Research Ethics Review Guideline (5th edition, 2014)	International docu-ments (unspecified) consulted in draf-ting; RECs have a duty to facilitate compliance with international regulations; GCP is an international ethical and scientific quality standard; RECs and researchers must be trained in GCP; CIOMS (2002) and DoH (2008) cited.	Yes – compliance with international regulations (unspecified) must be facilitated	N/A
Gambia	None found	No	N/A	N/A	N/A	No	N/A	N/A	N/A	N/A
Ghana	Yes	Yes	(a) No (b) No – only public health emergencies (c) No	N/A	N/A	No	(a) Guidelines for Good Clinical Practice in Ghana (2013) (b) Guidelines for Conduct of Clinical Trials during	(a) Derived from ICH GCP (1996) and CIOMS (2002); investigators are responsible for ensuring clinical trials are imple-mented according	Yes – ICH GCP (1996) and DoH (no date)	The 2020 compilation lists "Guidelines for Authorization of Clinical Trials" (2015), but these could

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							Emergencies (2015) (c) Public Health Act (2012)	to DoH and international GCP guidelines. (b) Only those specific to public health emergencies. (c) The Clinical Trials Technical Advisory Commit-tee will recommend educational programmesaimed at improving compliance with ICH GCP and DoH.		not be found online.
Guinea	Yes	No	(a) No (GT) (b) No (GT)	N/A	N/A	No	(a) Public Health Code Book Three: Ethics for Health Research (1997) (b) Decree on the Establish-ment, Functions and Organi-zation of the National Ethics Committee for Research in Health (1998)	(a) No (GT) (b) No (GT)		(a) States that the consent of a loved one is required when a participant cannot give consent in an emergency situation, but gives no further details (GT).
Kenya	Yes	Yes	(a) Yes (b) Yes	(a) No (b) Yes	(a) Yes – ICH GCP (b) No	No	(a) Guidelines for the Conduct of Clinical Trials in Kenya	(a) Clinical trials must comply with ICH GCP (2016) and be conducted in	Yes – ICH GCP (2016) and DoH	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							(2nd revision, 2020) (b) Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects (2004) (c) Guidelines For Accredi-tation Of Institution Ethics Review Committees in Kenya (2017)	accordance with DoH (current) principles. (b) Drafted using internationally recognized reference material; CIOMS (1993), DoH (2000) and WHO GCP (1995) are referenced. (c) No	(current) principles	
Liberia	Yes	Yes	(a) Yes (b) No	(a) No (b) N/A	(a) Yes – ICH GCP (b) N/A	No	(a) Guideline for Application to Conduct of Clinical Trials in Liberia (2014) (b) Operational Guidelines: National Research Ethics Board of Liberia (2019)	(a) The Liberia Medicines and Health Products Regulatory Authority has adopted ICH GCP (1996); investi-gators must conduct trials in accordance with ICH GCP (1996) and adhere to DoH principles in obtaining informed consent. (b) The NREB shall review research proposals in	Yes – ICH GCP (1996) and DoH principles	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
								keeping with DoH (2013), ICH GCP (2016) and CIOMS (2016).		
Mada-gascar	Yes	No	No	N/A	N/A	No	Law on the Health Code (2011) (GT)	Clinical trials must comply with WHO GCP guidelines and DoH principles (GT).	Yes – WHO GCP (no date) and DoH principles	The Law also states that trials must be conducted with the Ministry of Health's "Guide for Members of the Ethics Commit-tee" (no date), but this could not be found online (GT).
Malawi	Yes	Yes	(a) No (b) No (c) No	N/A	N/A	No	(a) The National Health Sciences Research Committee General Guidelines on Health Research (2007) (b) Procedures for Review/ Evaluation of Clinical Trial Applications for Vaccines and Biologicals in Malawi (no date)	(a) Guidelines based on CIOMS, WHO and UNESCO documents and other international ethical guidelines and regulations (unspecified). (b) Investigators must declare they have received suitable, recent training in GCP in the Malawi context and must name what GCP	No (but see notes)	The "Guidelines for Review/ Evaluation of Clinical Trial Applications for Vaccines and Biologicals in Malawi" (no date) make reference to "the regulation pertaining to the conduct of clinical trial in Malawi", but it is not clear

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							(c) Pharmacy, Medicines and Poisons Act (1998)	guidelines have been followed in compiling the protocol; reviewers of clinical trial applications should have received additional training in GCP. (c) No		what this regulation is and it could not be found online. The ClinRegs website states that Malawi is encouraging investigators to follow ICH GCP (2016).
Mali	Yes	Yes	Yes	No	No	No (see notes)	Law Governing Biomedical Research on Humans (2009)	No	No	The Law states that the consent of relatives, if present, can be sought in emergency situations. It does not state whether or not the research can take place with-out consent if relatives are not present. Thus it is not clear whether it would be com-patible with the consent substitute model.

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
Mozam-bique	Yes	No	No (GT)	N/A	N/A	No	Code of Ethics for Science and Technology (2007)	No (GT)	No	N/A
Nigeria	Yes	Yes	(a) Yes (b) No – only public health emergencies (c) No	(a) No (b) N/A (c) N/A (d) N/A	(a) Yes – ICH GCP (b) N/A (c) N/A (d) N/A	No	(a) Good Clinical Practice Guidelines (2020) (b) Guidelines for Conduct of Clinical Trials During Emergencies (2019) (c) National Code of Health Research Ethics (2007) (d) National Health Act (2014)	(a) Adapted from ICH GCP (2016); clinical trials must be conducted in accordance with DoH principles; objective of guidelines is to ensure clinical trials in Nigeria are conducted in accordance with international ethical standards. (b) Only those specific to public health emergencies. (c) Clinical trials must comply with ICH GCP (1996). (d) No	Yes – ICH GCP (1996) and DoH principles	N/A
Rwanda	Yes	Yes	(a) Yes (b) No (c) No	(a) Yes (b) N/A (c) N/A	(a) No (b) N/A (c) N/A	No	(a) National Ethics Committee Standard Operating Procedures (2009) (b) Clinical Trial Docu-	(a) The ethics committee must ensure research protocols adhere to the spirit of DoH (1964…2000), CIOMS and ICH GCP; investigators must comply with	Yes – applicable international guidelines	(a) States that the consent of the family members, if any, can be requested in emergency situations. It does not state

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							mentation Requirements (2020) (c) National Health Research Committee Operational Guidelines (2012)	applicable inter-national guidelines. (b) Investigators must declare that they are familiar with ICH GCP and will conduct trials in accordance with its principles. (c) The Scientific Review Committee must be satisfied that research proposals conform to the spirit of DoH (2008) and CIOMS (1993).		whether or not the research can take place without consent if there are no family members.
Senegal	Yes	No	Yes (GT)	No (GT)	No (GT)	No	Law on the Code of Ethics for Health Research (2009)	No (GT)	No	N/A
Sierra Leone	Yes	Yes	(a) Yes (b) No	(a) No (b) N/A	(a) Yes – ICH GCP (2016) and South African GCP (2006) (b) N/A	No	(a) Guidelines for Good Clinical Practice in Sierra Leone (2018) (b) Guidelines for Application and Authorisation of Clinical Trials (2019)	(a) Partly derived from ICH GCP (2016), CIOMS (2002) and other documents; investigators are responsible for ensuring that trials are based on and implemented according to DoH principles and	Yes – international GCP (unspecified) and DoH principles	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
								international GCP guidelines. (b) Special justi-fication is required for research with vulnerable persons, with reference to CIOMS (2002); investigators must comply with national GCP principles (see above for derivation).		
South Africa	Yes	Yes	(a) Yes (b) Yes	(a) No (b) No	(a) No (b) No	Yes	(a) Ethics in Health Research: Principles, Processes and Structures (2nd edition, 2015) (b) South African Good Clinical Practice Guidelines (2nd edition, 2006)	(a) Draws on and should be read in conjunction with DoH (2013), CIOMS (2002), ICH GCP (1996) and other docu-ments; researchers and REC members should be familiar with international research ethics guidelines and adhere to the principles therein; REC members should be trained in GCP and GCP training should be	Yes – ICH GCP (1996), DoH (2004), CIOMS (1993)	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
								accessible to researchers. (b) Guidelines are guided by and based on ICH GCP (1996), DoH (2004), CIOMS (1993) and other documents; investi-gators must fully follow these; RECs must ensure partici-pants are protected in accordance with international stan-dards and guide-lines; the national guidelines apply if they differ from the above texts.		
South Sudan	Yes	Yes	No	N/A	N/A	No	Drug and Food Control Act (2012)	No	No	N/A
Tanzania	Yes	Yes	(a) Yes (b) Yes (c) No (d) No	(a) No (b) No (c) N/A (d) N/A	(a) Yes – ICH GCP (b) Yes – WIC (US) (c) N/A (d) N/A	No	(a) Guidelines for Application to Conduct Clinical Trials in Tanzania (3rd edition, 2017) (b) Guidelines of Ethics for Health Research in Tanzania (2nd edition, 2009)	(a) Contains excerpts from ICH GCP and other documents; investi-gators must conduct trials in accordance with ICH GCP; informed consent must be sought in line with DoH (2013); DoH and	Yes – ICH GCP (no date) and DoH (2013)	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							(c) Tanzania Food, Drugs And Cosmetics Act (Clinical Trials Control) (2013) (d) Standard Operating Procedures for the National Health Research Ethics Committee (2nd edition, 2013)	CIOMS should be considered when conducting clinical trials with vulnerable persons. (b) Based on ICH GCP, CIOMS, and other documents; trials must be con-ducted in accor-dance with DoH. (c) Investigators must conduct trials in accordance with ICH GCP. (d) Committee is to be guided by DoH and CIOMS (2002); SOPs are based on ICH GCP; records of research that does not comply with national/ international guide-lines will be kept.		
Uganda	Yes	Yes	(a) Yes (b) Yes (c) No – only public health emergencies (d) No	(a) Yes (b) No (c) N/A (d) N/A	(a) No (b) Yes – ICH GCP (c) N/A (d) NA	No	(a) National Guidelines for Research involving Humans as Research Participants (2014)	(a) No (b) Adapted from ICH GCP (2016), CIOMS (2016) and DoH (2013); investigators must comply with these; RECs must ensure participants are	Yes – ICH GCP (2016), CIOMS (2016) and DoH (2013)	N/A

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
							(b) Guidelines on Good Clinical Practice in the Conduct of Clinical Trials Involving Human Participants (2019) (c) Guidelines for the Conduct of Clinical Trials in Uganda (2019) (d) Conduct of Clinical Trials Regulations (2014)	protected in accordance with international standards and guidelines. (c) Investigators are responsible for ensuring that trials are based on and implemented according to DoH principles and international GCP guidelines. (d) Principal investigators must declare that they have received recent training in internationally accepted GCP guidelines.		
Zambia	Yes	Yes	No	N/A	N/A	No	(a) National Health Research Act (2013) (b) Guidelines on Regulating the Conduct of Clinical Trial in Human Participants (2016)	(a) States that GCP (unspecified) shall be adhered to in research with human participants. (b) To be read in conjunction with international GCP guidelines; clinical trials must be implemented in accordance with	Yes – international GCP (unspecified) and DoH (no date)	(c) Lists patients in emergency situations as vulnerable, but does not include guidance specific to emergency medical research.

Region/ state*	Has research ethics and/or good clinical practice docu-ment/s?	Docu-ment/s available in English?	Include/s emergency medical research provisions?†	Emergency provisions only say to follow protocol/ guidelines and/or needs specific REC approval and/or consent must be sought ASAP?†	Emergency provisions only copy or para-phrase text from previously published docu-ments?†	Region/ state included in analysis?	Document/ website links	Include/s references to international documents? (Declaration of Helsinki/ CIOMS ethical guidelines/ ICH GCP)**	Is an obligation to comply with international documents specifically stated?	Notes
								DoH and international GCP guidelines; prepared in accordance with WHO guidelines.		
Zim-babwe	Yes	Yes	(a) No (b) No (c) No – only emergencies caused by disease outbreaks	N/A	N/A	No	(a) Medicines and Allied Substances Control Act (Chapter 15:03; amended 2015) (b) Medicines and Allied Substances Control (General) Regulations (Chapter 15:03; amended 2014) (c) Guidelines for Good Clinical Trial Practice in Zimbabwe (2020)	(a) No (b) No (c) Derived from ICH GCP (2016) and CIOMS (2002); Medical Research Council of Zimbabwe must ensure participants are protected in accordance with international standards and guidelines; DoH (current) informed consent principles should be imple-mented in clinical trials; investigators are responsible for ensuring trials are implemented according to DoH (current) and international GCP guidelines.	Yes – international GCP (unspecified) and DoH (current)	(a) Lists patients in emergency situations as vulnerable, but does not include guidance specific to emergency medical research (except in pandemics etc).

*EU/EEA states, the UK and signatories to the Council of Europe *Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research* are excluded.

The 27 EU states are Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary,Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden. The 3 EEA (but not EU) states are Iceland, Liechtenstein and Norway.

The 12 Council of Europe signatories are Bosnia and Herzegovina, Bulgaria, Czechia, Georgia, Hungary, Moldova, Montenegro, Norway, Portugal, Slovakia, Slovenia and Turkey.

† (GT) in these columns indicates that information was ascertained using Google Translate.

**Where dates are not given, it is because these are not specified in the text.

Note that a standard phrase in most GCP guidelines is: "Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki." In the table, for brevity, this has been noted as clinical trials needing to be conducted in accordance with Declaration of Helsinki principles.

Notes on the review process:

All documents were last accessed in the period September 24 to October 31, 2020. The International Compilation of Research Standards (2020) was used as a starting point. The information therein was supplemented with Google searches to try to ensure that the most up to date documents were being used and all potentially relevant documents were examined, e.g. "Belarus good clinical practice" or "Honduras ética salud". South Sudan has been added; it does not feature in the 2020 compilation, but a relevant document was found while searching for Sudanese documents.

In the column on references to international documents, only citations of the ICH GCP guidelines, the CIOMS ethical guidelines and the Declaration of Helsinki have been included for most states. Where a state has based its good clinical practice guidelines on WHO's Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products (1995), this has been noted. The WHO GCP guidelines were not included in the main analysis because although they list patients in emergency departments as vulnerable and state that consent in this context will need special consideration, they give no further details. Where international documents not included in the main analysis because they do not contain provisions on emergency research (e.g. UNESCO's Universal Declaration on Bioethics and Human Rights [2005]) have contributed to a national document, these have been noted simply as "other documents".