

HCCA Orange County Regional Year In Review – Key Developments in Research Compliance and Regulation

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▶ I have no relevant personal/professional/
financial relationship(s) with respect to this
educational activity



Agenda / Topics – Year in Review!

- ▶ COVID
- ▶ Common Rule - All Sections Now in Effect
- ▶ GDPR, California Consumer Protection Act, and Other International Privacy Laws

3

About Advarra

- ▶ The research community’s most collaborative single source to optimize compliance and clinical trials



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Research
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4



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COVID

Impacts and Considerations for Research
Some Key Points, but certainly not all points...



General Considerations in an Unprecedented Time

- ▶ Ensure participant safety
- ▶ Pivot to changes in study procedures that reduce risk to participants
- ▶ Ensure minimal impact to data integrity
- ▶ Identify any changes to the risk/benefit ratio of the study

DOCUMENT, DOCUMENT, DOCUMENT!

7



Approving New Research Not Related to COVID-19

Consider the changing landscape and the impact on newly approved research:

- ▶ Does the investigator have adequate study staff and resources to conduct the study?
 - Is it likely that this will change over the course of the study?
- ▶ Are the facilities where the research will be conducted likely to be impacted by the pandemic ?
 - E.g., facility closures, space pre-empted for overflow hospital patients
- ▶ Will the investigator be able to enroll on the study without increasing risk to participants?
- ▶ Will any study procedures be impacted by the pandemic; should study procedures be re-evaluated?

Note: Screening questions relating to COVID-19 are not considered research questions unless the researchers will be collecting data on COVID-19 infections

8



Public Health Surveillance Activities

Under [45 CFR 46.102\(l\)](#), public surveillance activities would not need IRB review:

“(l) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, **the following activities are deemed not to be research:**

“(1) Scholarly and journalistic activities (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

“(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).”

9



Consent Form: Additional Language

For COVID-19 research, the newly passed [Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19](#) may impact participant injury language in consent forms. The PREP Act provides that:

“[S]ubject to other provisions of [the PREP Act], a covered person shall be immune from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a Declaration has been issued with respect to such countermeasure.”

10



Consent From COVID-19 Patients in a Containment Unit or Quarantined Space or From a Physically Unavailable LAR

Documenting That a Patient/LAR Signed the Consent Form

- ▶ If imaging technology is available, provide a digital image of the signed consent form to the study team
 - The consent form can then be destroyed if necessary
- ▶ If no imaging technology is available, **document the following:**
 - An unsigned consent form was provided and received by the prospective participant
 - No imaging technology was available to capture the signed consent form
 - How consent was obtained (e.g., a telephone call or video conference with the prospective participant, investigator, and witness [at minimum])
 - There is a record of all parties who participated in the consent process
 - There is a record that the informed consent was reviewed and questions answered
 - The witness confirmed questions were answered
 - Investigator confirmed the patient/LAR is willing to participate
 - Investigator confirmed that the patient/LAR stated they signed the consent form
 - Witness confirmed that the witness heard the patient/LAR confirm that they signed/dated the consent form
- ▶ A copy of the informed consent form (ICF) signed by the investigator and witness should be placed in the study record, including a statement of why the ICF signed by the participant was not retained (e.g., due to contamination of the document by infectious material)

11



Consenting Research Participants in Isolation



Investigator Communicates:

- With patient, family members, impartial witness, healthcare workers, study team
- Describes the research study objectives, risks, benefits, alternatives
- Using a paper ICF or electronic ICF or audio recording of ICF or read full ICF over phone



Healthcare Workers and Patient Communicates:

- With investigator, family members, impartial witness, study team
- Questions about the research, understanding of the research
- Agreement to participate:
 - Takes a picture of the fully signed ICF or electronic ICF captures signature or audio recording documents agreement or "verbal" agreement is documented after listening to a full reading of the ICF



Document, Document, Document:

- *What:* The research was described, questions were answered and agreement to participate
- *When & Where:* Date, time, isolation unit, medical intensive care unit, emergency room
- *Why:* Pandemic, declared state of emergency, disaster declaration, limited resources (e.g., PPE)
- *How:* Phone, videoconference, secure radio, two-way baby monitor
- *Who:* Investigator, healthcare workers, study team

12



Consent From COVID-19 Patients Who Are Unable to Sign the Consent Form

COVID- 19 patients who have capacity to consent but are not able to sign the consent form (e.g., physical impairment prevents them from signing; monitoring and medical equipment prevent signing):

- ▶ A request for participants to not sign a consent form, is not a waiver of documentation
- ▶ The FDA draft guidance below allows for obtaining consent from the participant, and we also require a witness (and documentation as previously described)
 - “Section V. D. Physically Challenged Subjects: A person who is physically challenged (for example, physically unable to talk or write or has hearing or visual loss) can enroll in a clinical investigation if competent and able to signal consent when consistent with applicable State law. The records relating to the clinical investigation must include **documentation** of the informed consent process (21 CFR 50.27) unless excepted under 21 CFR 56.109(c). FDA recommends that the subject’s case history include a description of the specific **means by which the prospective subject communicated** agreement to take part in the clinical investigation and **how questions were answered**. **FDA recommends that investigators accommodate the specific needs of the study population.**
 - “For example, the investigator **could use an audio tape of the contents of the consent form** or a form with enlarged font, depending on the level of impairment of the visually impaired subjects.”

Source: [FDA Information Sheet Informed Consent](#)

13



HIPAA Compliance and Telemedicine

Telemedicine is an acceptable option where it can adequately replace an in-person physical examination

- ▶ “For the purpose of HIPAA, HHS has issued a notice waiving penalties for non-compliance with HIPAA. OCR will exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the **good faith provision of telehealth** during the COVID-19 nationwide public health emergency. This notification is effective immediately.”

Source: [OCR Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency](#)

14



Remote Visits to Substitute for In-Office/Hospital/Clinic Visits

- ▶ The Office of Civil Rights (OCR) Guidance identified popular applications that allow for video chats and may be used to help provide telehealth visits during the COVID-19 nationwide public health emergency, including:
 - Apple FaceTime; Facebook Messenger video chat; Google Hangouts video; Skype
 - Providers are encouraged to notify patients that these third-party applications potentially introduce privacy risks, and providers should enable all available encryption and privacy modes when using such applications
- ▶ The following applications **should not be used** in the provision of telehealth by covered health care providers:
 - Facebook Live; Twitch; TikTok; similar video communication applications that are public facing
- ▶ Vendors who represent that they provide HIPAA-compliant video communication products and that they will enter into a HIPAA Business Associates Agreement (BAA) include:
 - Skype for Business; Updox; Vsee; Zoom for Healthcare; Doxy.me; Google G Suite Hangouts Meet

Source: [OCR Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency](#)

15



Regulatory Guidance Relating to the COVID-19 Pandemic

The following government guidance documents impact research

16



FDA Guidance Documents

- ▶ [Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency \(March 2020\)](#)
- ▶ [Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic \(March 2020\)](#)
- ▶ [Digital Health Policies and Public Health Solutions for COVID-19 \(March 2020\)](#)

17



FDA Guidance Documents

[Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic \(March 2020, updated April 2020\)](#)

- ▶ “Contingency measures implemented to manage study conduct during disruption of the study as a result of COVID-19 control measures.
- ▶ “A listing of all participants affected by the COVID-19 related study disruption by unique participant number identifier and by investigational site, and a description of how the individual’s participation was altered.
- ▶ “Analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., trial participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study.”

18



CTEP Guidance

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- ▶ [Interim Guidance for Patients on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program \(NCORP\) \(March 13, 2020\)](#)
 - Some topics covered:
 - Transfer of participant’s care to a different participating study site
 - Continuity of care provided by non-research staff
 - Administration of oral investigational agents
 - On a protocol-by-protocol basis, the CTEP Pharmaceutical Management Branch (PMB) will consider requests from Responsible Investigators at participating sites to allow shipment of oral IND agents on NCI/CTEP sponsored trials directly to patients enrolled on a clinical trial
 - ▶ [Additional Guidance Regarding Alternative Procedures for Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program\(CTEP\) and NCI Community Oncology Research Program \(NCORP\) Affected by the Spread of the Novel Coronavirus \(March 23, 2020\)](#)

19



HIPAA Temporary Waiver

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- ▶ [OCR Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency \(March 2020\)](#)
 - Waives sanctions and penalties against a covered hospital that does not comply with the following provisions of the HIPAA Privacy Rule:
 - The requirements to obtain a patient's agreement to speak with family members or friends involved in the patient’s care [45 CFR 164.510\(b\)](#)
 - The requirement to honor a request to opt out of the facility directory [45 CFR 164.510\(a\)](#)
 - The requirement to distribute a notice of privacy practices [45 CFR 164.520](#)
 - The patient's right to request privacy restrictions [45 CFR 164.522\(a\)](#)
 - The patient's right to request confidential communications [45 CFR 164.522\(b\)](#)

20



PREP Act



- ▶ [Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 \(March 2020\)](#)



New “Common Rule”

The entire new regulation is now in effect - 45 CFR 46

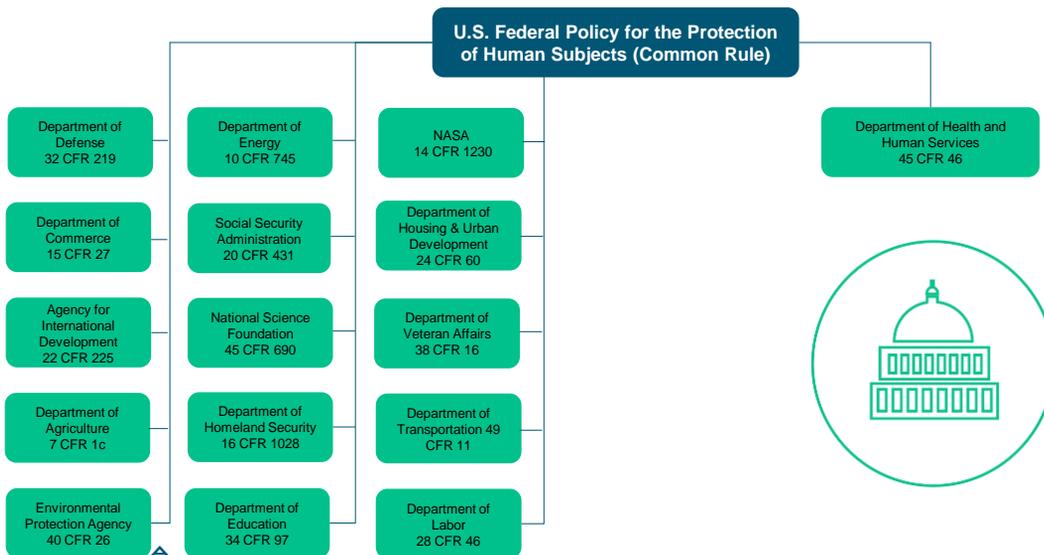
Applicability of Common Rule

- > Only federally funded research
- > Non-exempt “human subjects” research
- > FDA has separate rules



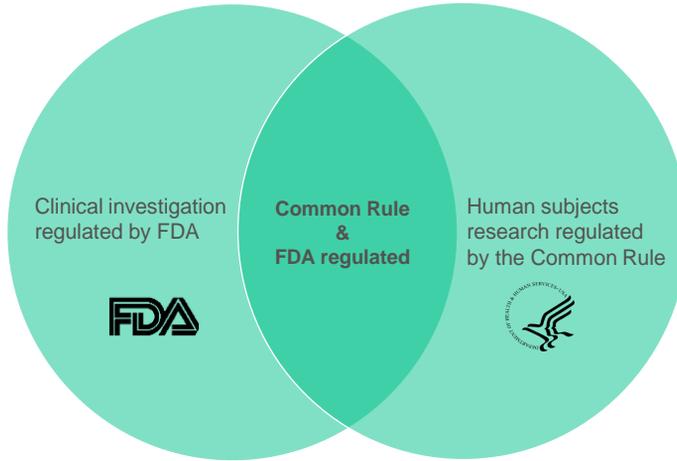
23

What Are the Common Rule Agencies?



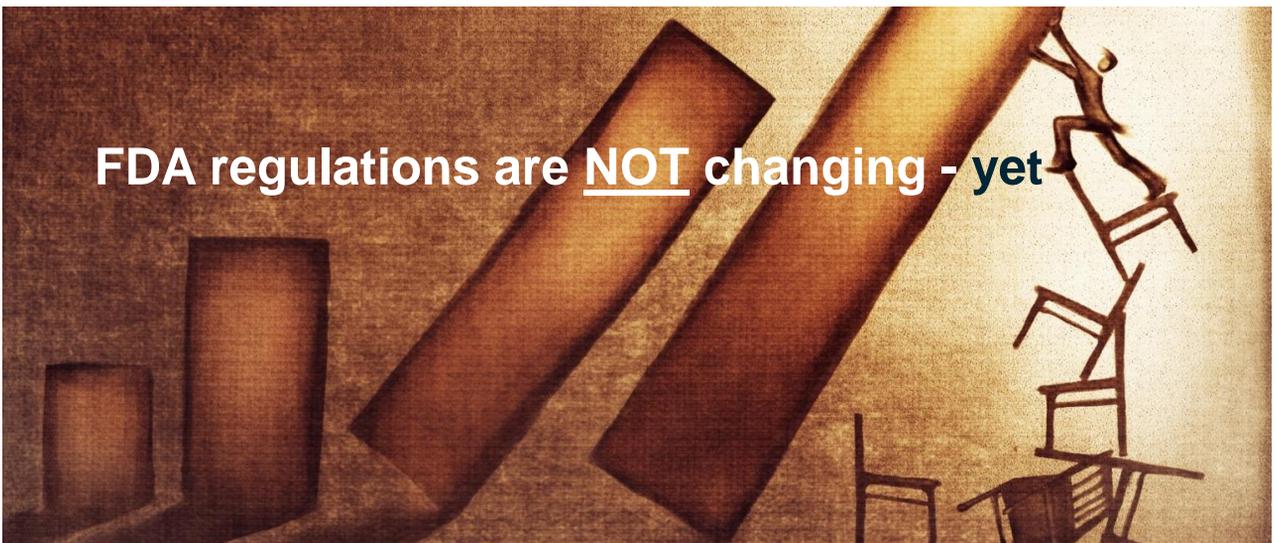
24

FDA Is Not a Common Rule Agency (cont.)



25

FDA Is Not a Common Rule Agency



26

Important Dates – All of Common Rule Is Now In Effect



Key Common Rule Changes Impacting Research Compliance Programs

Changes: New 46.116 Informed Consent Requirements

- > Concise summary of “key information”
- > “Reasonable person” standard
- > Present in “sufficient detail”
- > Organize in a way that “facilitates comprehension”
- > Future use of biospecimens disclosure
- > Commercial use disclosure
- > Whole genome sequencing disclosure
- > New waiver criteria
- > Posting Consent Forms
- > And more...



29

The Consent Rules – New General Requirements

- > .116(a)(4) subjects must be provided with the information that a “reasonable person” would want to have in order to make an informed decision and subjects must be provided an opportunity to discuss that information
- > .116(a)(5)(i) the informed consent process must begin with a concise and focused presentation of the “key information” that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subsection also requires that this part of the informed consent be “organized and presented in a way that facilitates comprehension
- > .116(a)(5)(ii) informed consent as a whole must present information in sufficient detail and organized in such a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s ... understanding of the reasons why one might or might not want to participate



30

So what does this new consent form that must “Begin With” a “Concise Summary” of “Key Information” containing “Sufficient Detail” and “Organized .. To Facilitate Understanding” of a “Reasonable Person” look like?



31



Guidance Coming Soon...



32

New Consent Requirements: Implications

- > IRB Determination of “Reasonable Person”, “Succinct Summary”, etc.?
- > Maintain separate templates?
- > Update pre-negotiated language with central IRBs, NCI CIRB, others?
- > Industry sponsors push back if applying Common Rule standards to them?
- > Template consent language need legal review?
- > IRB forms ask questions about future use and whole genome testing?



33

Posting Consent Forms: A New Mandate

- > Who is going to post?
- > How will they know research is complete?
- > Who will track compliance?
- > Who will determine if redactions are necessary?
- > Which version will you post?
- > Multi-site?



OHRP has identified the site for posting – clinicaltrials.gov



34

Changes: New Expanded Exemptions from IRB Review

- > New exemption for “benign behavioral interventions”
- > Exemption 4 no longer restricted to “existing” data
- > Updated exemption 2 for surveys etc.
- > New exemption 7 & 8 for use of identifiable information and biospecimens with Broad Consent and Limited IRB Review
- > Lots of other minor changes – review carefully



**Exemptions have moved
46.101(b) is now at 46.104(d)**



35

Changes: Continuing Review Reduction

- > Continuing Review no longer required for:
 - Any projects originally approved through expedited or limited review 45.109(f)(1)(i)&(ii)
 - Projects where remaining activity is data analysis or data collection only 45.109(f)(1)(iii)
- > IRB maintains authority to require continuing review for these studies *with* documented justification 45.109(f)(1)



OHRP’s stated goal is to reduce regulatory burden for minimal risk studies



36

Changes: Institutional Matters

- > No more **check the box** option
- > FWA holders no longer need to submit IRB member information to OHRP or identify an IRB



IRBs are no longer required to review grant applications. Current requirement at 46.103(f) does not appear as written in the new Common Rule.



- > OHRP now has direct regulatory jurisdiction over external IRBs
- > New specific requirement to document reliance agreements between IRBs *46.103(e)*



37

Now In Effect – sIRB Requirement!

- > NIH already mandates sIRB
- > All other Common Rule agencies now required to follow suit effective in January 2020



DoD funded research will require an sIRB plan in new grant applications per Common Rule requirements. New DoD Directive 3216.02 issued last month.

- > May designate independent IRBs
- > Applies only to domestic performance sites



38



Information Privacy Laws

More GDPR-like Laws Seem To Be Coming Every Year

39

Then vs. Now

- > The General Data Protection Regulation ("**GDPR**") took effect May 25, 2018, replacing the 1995 European Union ("**EU**") Data Protection Directive.
- > GDPR applies in the 28 member states of the EU and three additional countries (**Iceland, Liechtenstein, and Norway**) that together with the EU make up the European Economic Area ("**EEA**").



40

Where Does GDPR Apply?



41

Personal Data

- > Any information relating to an identified or identifiable natural person (“**data subject**”).
- > **Special categories of personal data, include:**
 - “...data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health, or data concerning a natural person's sex life or sexual orientation...”*

The collection of special categories of personal data is prohibited by the GDPR, unless an exception condition is met, which includes the data subject giving their explicit consent for the collection of these categories of data.



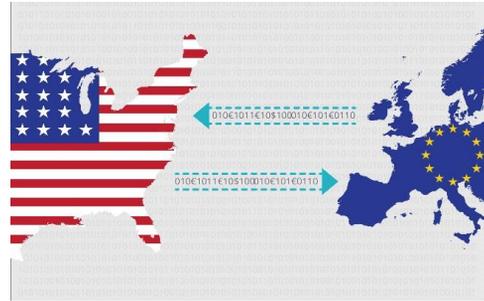
42

Authority to Transfer Personal Data

GDPR requires a legal basis for the transfer of personal data from the EEA to jurisdictions that do not have commensurate level of data protection.

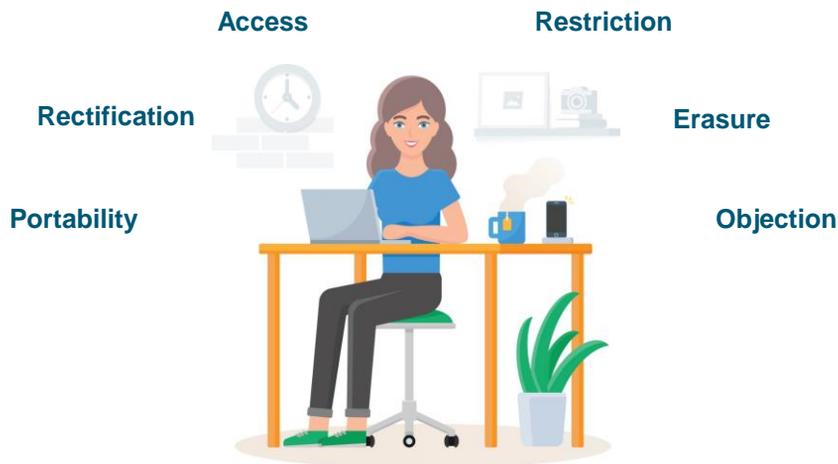
Transfer requirements apply even if GDPR does not apply directly to receiving party!

- > Explicit consent
- > Performance of a contract between data subject and controller...
- > Important reasons of public interest
- > Establishment, exercise, or defense of legal claims
- > Protection of vital interests
- > Standard contractual clauses, binding corporate rules, codes of conduct



43

Data Subjects Rights



44

Other International Regulations Impacting Research - China

technode

TOPICS ▾

SECTIONS ▾

NEWSLETTERS ▾

CHINA TECH CALENDAR

One year after GDPR, China strengthens personal data regulations, welcoming dedicated law

China's National Information Security Standardization Technical Committee (TC260) – Effective March 2018

Similar to GDPR, but without the same individual data subject right to be forgotten.

<https://www.tc260.org.cn/upload/2018-01-24/1516799764389090333.pdf>



45

Other International Regulations Impacting Research - China



ENGLISH.GOV.CN
THE STATE COUNCIL
THE PEOPLE'S REPUBLIC OF CHINA

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Regulations on management of human genetic resources

Updated: Jun 10, 2019 5:02 PM english.gov.cn

National regulations on the management of human genetic resources recently released by the State Council, which was approved at the 41st executive meeting on March 20, will go into effect on July 1, in a bid to effectively protect and reasonably utilize human genetic resources and safeguard public health, national security, and public interests.

State approval required for export of genetic material from the country!

Regulation of Human Genetic Resources
Effective July 1, 2019

http://english.gov.cn/policies/latest_releases/2019/06/10/content_281476708945462.htm (translated)



46

Other International Regulations Impacting Research - Thailand

Thailand Personal Data Protection Act (PDPA)
BE 2562
Compliance Effective May 27, 2020

Similar to provisions in GDPR

- Applicable ex-Thailand
- Broad Scope
- Thai specific provisions beyond GDPR
- Compliance with GDPR does not mean compliance with PDPA



<https://canchamthailand.org/thailands-personal-data-protection-act-passes-law/>



47

Other International Regulations Impacting Research - Nigeria

National Data Protection Regulation 2019
National Information Technology
Development Agency (NITDA)
Compliance Effective January 25, 2019

Similar to provisions in GDPR

- Applicable ex-Nigeria
- Broad Scope
- Requires Data Protection Officer similar to GDPR
- Hefty Nigeria specific fines
- Requires Organizations to conduct an audit of their practices within 6 months *section 4.1(5)* with copy submitted to NITDA

HUNTON
ANDREWS KURTH



<https://nitda.gov.ng/wp-content/uploads/2019/01/NigeriaDataProtectionRegulation.pdf>



48

Other International Regulations Impacting Research - Israel

Protection of Privacy Regulations 5777-2017 & Protection of Privacy Law (PPL) Effective May 8, 2018

- Applicable ex-Israel
- Requires registration of databases over 10k individuals *PLL section 8.c*
- Failure to register punishable by up to year in prison
- Organizations with 5 or more databases must appoint Data Protection Officer *PLL section 17b*
- New inspection unit activated in August 2018



https://www.gov.il/en/Departments/the_privacy_protection_authority



49

Other International Regulations Impacting Research – USA!!

California Consumer Privacy Act of 2018, Cal. Civ. Code §§ 1798.100 et seq. (CCPA) Effective January 1, 2020 Enforcement begins July 1, 2020



- Applicable to all organizations of certain characteristics
 - Businesses that earn \$25,000,000 or more a year in revenue
 - Businesses that annually buy, receive, sell or share personal information of 50,000 or more consumers, households or devices for commercial purposes
 - Business that derive 50% or more of its annual revenue from selling consumer personal information
- Similar rules and privacy protection concepts as GDPR
- Failure to comply could bring fines of up to \$2500 per user per “*piece*” of data [emphasis added]
- Similar to GDPR – Protects any California resident and is applicable ex-CA to any business conducting activity in California regardless of where company is headquartered



<https://www.wired.com/story/ccpa-guide-california-privacy-law-takes-effect>

50



Questions?

51



Thank you!

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52