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EU General Data Protection Regulations: Practical Considerations for Publication Professionals

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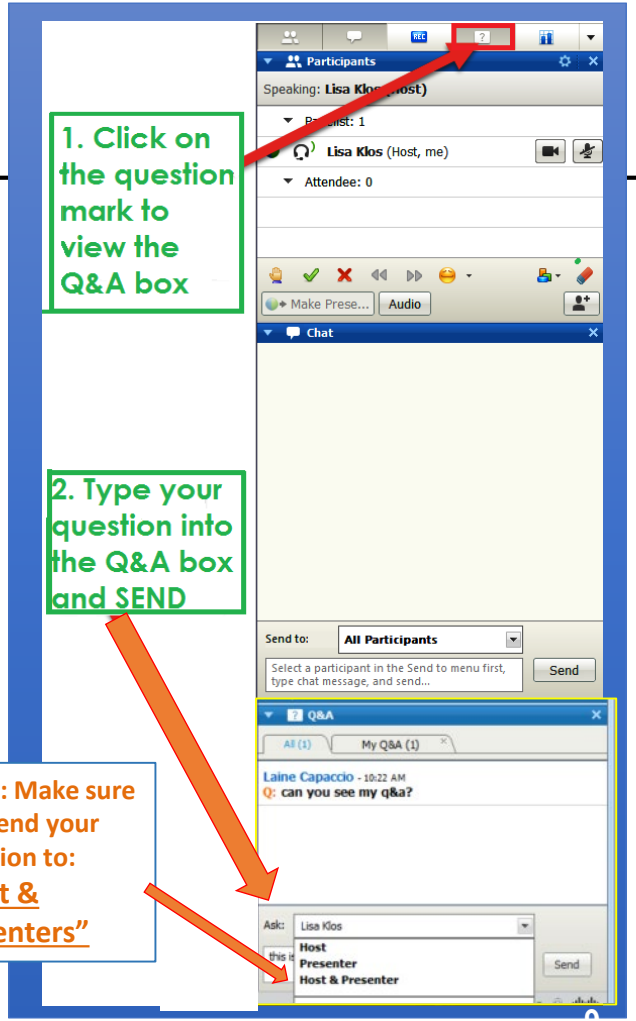

EU General Data Protection Regulations:

Practical Considerations for Publication Professionals

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Brian P. Sharkey, Esq

Brian Sharkey is a Principal of Porzio, Bromberg & Newman. He is a member of the firm's Life Sciences Practice Group and is a Vice President of Porzio Life Sciences, a subsidiary of the firm. He counsels life sciences companies on a variety of compliance-related issues, most significantly those relating to global marketing disclosure laws and industry codes. In particular, Brian focuses on helping companies understand and comply with global reporting requirements for transfers of value to healthcare professionals, healthcare organizations, and patient organizations. Brian also counsels clients with respect to data privacy laws and their obligations.

Marc I. Eida, Esq

Marc Eida is a Counsel of Porzio, Bromberg & Newman. He is a member of the firm's Life Sciences Practices Group and is an Associate of Porzio Life Sciences, LLC, a subsidiary of the firm. Marc counsels pharmaceutical, medical device and biotechnology companies on a variety of compliance-related issues, including data privacy, FDA promotional regulations, transparency and aggregate spend, industry standards regarding interactions with healthcare professionals, and sampling requirements. As a Compliance Associate with Porzio Life Sciences, Mr. Eida also assists in the creation, development and implementation of the subsidiary's products and services.

Joe Pierce

Joe Pierce has worked with pharmaceutical and biotech companies since 1995, specifically in the area of medical information and medical affairs. He was VP of Sales and Marketing for Online Business Applications, leading that company's core product IRMS, to become the most widely used medical information software solution in the industry. In 2014, Joe founded EndPoint Technologies, a business and technology consulting firm offering services in data privacy and validation, analytics and new and innovative technology solutions. EndPoint was acquired by Envision Pharma Group as a wholly owned subsidiary in 2017 and Joe continues to manage EndPoint with services across a broad spectrum of medical affairs.

Karen Mittleman, PhD

Karen Mittleman currently sits on the Board of Trustees of the International Society of Medical Publication Professionals (ISMPP) and serves as a member of the Global Transparency Committee of ISMPP. Prior to her retirement in June, Karen was the Head of Publications within Clinical Data Transparency, Medical Governance and Ethics in the Chief Medical Office at Sanofi. Karen has over 20 years of experience in medical publication planning and development.

Moderator:
Hajira Koeller, PhD, ISMPP CMPP™

Hajira Koeller is Global Publications Group Lead, Shire Pharmaceuticals, Inc. Hajira is a neuroscientist by training and has conducted basic and clinical research in CNS and oncology. She has previously worked as a journal Editor, Medical Writer and is now primarily focused on strategic medical communications, medical publication planning and development. Hajira is a member of the ISMPP-U Committee and is a Certified Medical Publication Profession (ISMPP CMPP™).

Disclaimer

The opinions expressed in this presentation are those of the presenters and do not necessarily reflect the views or policies of current or former employers, nor those of ISMPP

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Overview & Learning Objectives

At the end of this session, participants should be able to:

- List the most relevant aspects of GDPR for publication professionals (Brian & Marc)
- Identify gaps and devise plans to ensure that publications and publications-related information is in accordance with your organization's GDPR policies and processes (Joe Pierce)
- Use guiding principles of GDPR to address the practical scenarios that emerge as we manage data related to publications and contributing stakeholders (Karen)

EU GDPR: Essentials for Publication Professionals

Brian Sharkey

Marc Eida

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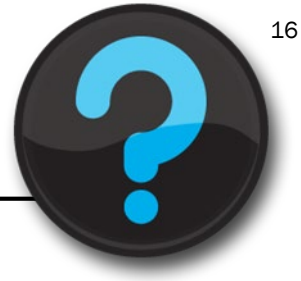
What is your level of understanding of the GDPR?



A. None
B. Basic – *aware of general principles, but not sure how it applies to publications*
C. Intermediate – *received general training*
D. Advanced – *received publications-specific training*

Who is responsible for data privacy compliance issues in your organization?

A. Legal

B. Compliance

C. IT

D. Data Privacy Office

E. No idea, but I know it's not me.

Why is this relevant to Pub Professionals?

- The GDPR is relevant to anyone in any industry that interacts with EU residents
- Potential for enormous sanctions
- Since Pub Professionals have access to personal data of EU residents, it's important to understand the principles of the GDPR and your own company's approach to avoid massive fines

Background - EU

4.5.2016 EN Official Journal of the European Union L 119/1

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 27 April 2016
on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 16 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

Having regard to the opinion of the Committee of the Regions (2),

Acting in accordance with the ordinary legislative procedure (3),

Whereas:

(1) The protection of natural persons in relation to the processing of personal data is a fundamental right. Article 8(1) of the Charter of Fundamental Rights of the European Union (the 'Charter') and Article 16(1) of the Treaty on the Functioning of the European Union (TFEU) provide that everyone has the right to the protection of personal data concerning him or her.

(2) The principles of, and rules on the protection of natural persons with regard to the processing of their personal data should, whatever their nationality or residence, respect their fundamental rights and freedoms, in particular their right to the protection of personal data. This Regulation is intended to contribute to the accomplishment of an area of freedom, security and justice and of an economic union, to economic and social progress, to the strengthening and the convergence of the economies within the internal market, and to the well-being of natural persons.

(3) Directive 95/46/EC of the European Parliament and of the Council (4) seeks to harmonise the protection of fundamental rights and freedoms of natural persons in respect of processing activities and to ensure the free flow of personal data between Member States.

(1) OJ C 229, 31.7.2012, p. 90.
(2) OJ C 391, 18.12.2012, p. 127.
(3) Position of the European Parliament of 12 March 2014 (not yet published in the Official Journal) and position of the Council at first reading of 8 April 2016 (not yet published in the Official Journal). Position of the European Parliament of 14 April 2016.
(4) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

- The Directive
  - Had been in place since 1995.
  - Precursor to the GDPR, May 25, 2018
- Directive v. Regulation
  - The Regulation establishes one single set of rules across the EU governing the processing of personal data
  - Some countries are permitted to legislate in certain areas
- Expanded scope
  - GDPR may still apply to a US-based company even if it has no employees or offices within the EU
- Stiff penalties
  - 4% of annual turnover or €20 million, whichever is greater

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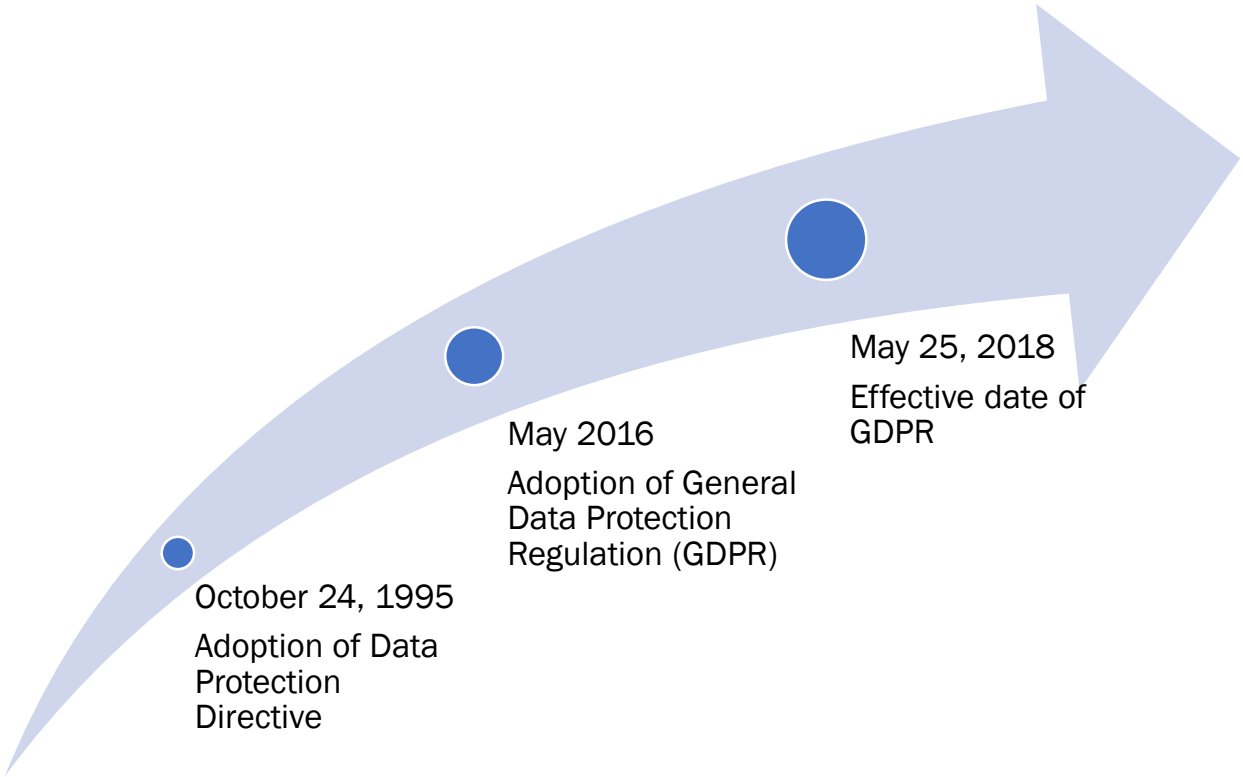
Data Protection Timeline



Key Terms

- **Personal Data**: Any information related to an identified or identifiable natural person ("data subject")
- **Process**: Any operation which is performed on personal data, including collection, storage, sharing or transfer
- **Controller**: The natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data
- **Processor**: A natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller

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Scope

- Territorial Scope – processing data by
  - EU businesses
  - businesses outside the EU if data processing relates to individuals in the EU
- Personal Data
  - Any information relating to an identified or identifiable natural person (a “data subject”)
  - Special categories of personal data which include biometric and genetic data, and data concerning health (e.g., patient data, employee data)
    - More stringent requirements associated with this data

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Key Concepts

- **Privacy by design** - organizations need to consider privacy at the initial design stages and throughout the complete development process of new products, processes or services that involve processing personal data
  - E.g., Pseudonomization, data security
- **Privacy by default** – By default, the highest levels of privacy, security, and data protection are provided to the end user.
  - E.g., data minimization (ensuring only the data that is necessary for a specific purpose is processed, used, transferred or stored)

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GDPR Guiding Principles

Transparency	• Provide clear and detailed notice and obtain consent when required
Data minimization	• Collect only as much data as necessary for that specific purpose
Purpose limitation	• Use data only for the original purpose
Access rights	• Enable individuals to exercise their right of access, right to rectify and right to be forgotten
Data Quality	• Keep data accurate and up-to-date
Data Retention	• Retain data only for as long as necessary for the specific purpose
Data Security	• Keep data secure through technical and organizational measures

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Cross-Border Data Transfers

- There are restrictions on how personal data of EU residents is transferred out of the EU to, for example, the United States

- In order for companies to lawfully transfer this type of data out of the EU, it must have in place a mechanism to ensure that the data leaving the EU is subject to an adequate level of protection and allow EU residents to exercise their rights as provided in the GDPR. Options include:

  - Standard Contractual Clauses
  - Privacy Shield
  - Binding Corporate Rules
  - Consent

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Processing Personal Data

- In order to process personal data in accordance with the GDPR, a valid “justification” must exist. Justifications include:
  - Performing a contract;
  - Legal duties of the controller (e.g., transparency laws);
  - Vital interests of the data subject (e.g., unconscious ER patient);
  - Public interest or the exercise of official authority;
  - Legitimate interests (e.g., fraud prevention); or
  - Obtaining consent of data subject

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Special Categories of Personal Data

- Special Categories of Personal Data include:
  - **Data revealing racial or ethnic origin**;
  - Political opinions;
  - Religious or philosophical beliefs;
  - Trade-union membership; or
  - **Data concerning health** or sex life and sexual orientation
- Sensitive personal data are subject to more stringent requirements

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Processing Special Categories of Personal Data

- In order to process special categories of personal data in accordance with the GDPR, there is a different set of valid “justifications” (non-exhaustive):
  - Explicit consent;
  - Public interest in the area of public health (e.g., AE reporting); or
  - Archiving purposes in the public interest, scientific or historical research purposes or statistical purposes

Consent

- Consent means offering individuals real choice and control over how their data is collected, used and disclosed
  - Individuals have the right to withdraw consent and need to be informed regarding how to exercise it
  - Withdrawing consent should be easy
- An indication of consent must be unambiguous and involve a clear affirmative action (an opt-in).
  - Pre-ticked opt-in boxes are prohibited
  - Requires distinct consent options for distinct data processing operations
- Consent should be separate from other terms and conditions and should not generally be a precondition of signing up to a service

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Consent – Scientific Research

- Recital 33
  - It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognized ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.

Individuals' Rights

- Right to Access - data subjects can ask the data controller whether personal data concerning them is being processed, where and for what purpose
  - E.g., Author contacts publication to request access
- Right of Erasure - allows data subjects to require the data controller to erase their personal data without undue delay in some instances (e.g., where consent is withdrawn and no other legal ground for processing applies), cease further dissemination of the data, and potentially have third parties stop processing the data
  - E.g. Investigator contacts publication requesting his/her address be deleted from their database
  - This right is limited in the context of processing for scientific research purposes

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Individuals' Rights

- Right of Data Portability - data subjects can ask to receive their personal data in a structured and commonly used format so that it can be easily transmitted to another data controller
- Right to Rectification - gives data subjects the right to request of the controller rectification of inaccurate data concerning him or her
  - E.g., After an Access request, Investigator asks for the correction of the spelling of his/her name in their records
- Right to Restriction of Processing – The data subject can restrict processing by the controller when disputes arise concerning the processing of data

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Breach and Notification

- Breach
  - “a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to personal data transmitted, stored or otherwise processed” GDPR, Art. 4(12)
- Under the GDPR, data controllers must notify Data Protection Authorities (DPAs) regarding most data breaches
  - Companies must report these breaches within 72 hours of first learning of the breach
  - Data subjects must be notified of breaches “without undue delay” in some instances

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Summary

- Know your company privacy policies
- Know who in your company is responsible for compliance with data privacy laws
- When dealing with the data of EU residents, be especially diligent
- Tell people what you're doing with their data, and do only what you tell them

GDPR and Publication Data Challenges

Joe Pierce

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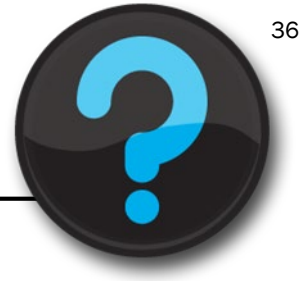
How much time is spent by you or your team on data privacy activities?



A. Minimal – Less than 5 hours a month

B. Moderate – 5 to 20 hours per month

C. Excessive – Over 20 hours per month

D. Not involved right now

Data Privacy Projects - Issues

- Data Protection Regulations are confusing
- Unprecedented activity in the development of data protection regulation around the world
- Businesses data is stored on vendor's server in the "cloud"
- Applications may not conform with new regulations
- Employees may not be aware of new regulation requirements
- Direct and indirect financial penalties are growing

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Data Privacy Projects – Two Paths

Legal or Process Project

- Identify and Document how PI is collected and stored
- Identify all locals of persons whose data you may collect
- Create SOPs around capturing / storing and purging data
- Build training and awareness around SOPs and technology
- Regular review of SOPs

Technology Project

- Define technology ‘gaps’ in existing systems
- Create requirements for system modification or new implementation
- Validate functionality of technology
- Train on new technology

Data Privacy Projects - Challenges

- Lack of Internal resources to maintain compliance with the evolving global privacy regulations
- Compliant 3rd party OOB applications can be configured or customized to be out of compliance
- Every country has different laws that are evolving quickly and may conflict with corporate privacy policies.
- Privacy Shield has not been challenged by European Court of Justice (ECJ)
- Systems and SOPs must be regularly reviewed and updated

Data Privacy Projects - Activity

- Create a Data Privacy Task Force
- Document all privacy regulations per country with applicable laws
- Document recommendations for each country including a risk matrix, assign risk level and organize countries by risk
- Document recommendations for business processes to adhere to the regulations

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Data Privacy Projects - Activity

- Document recommendations of system configuration or customizations necessary to enforce country specific data protection measures
- Create and execute validation test scripts to confirm the system enforces data protection measures as configured
- Proactively monitor laws and regulations for changes and address as needed

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Summary

- Changing data privacy rules impact all parts of the business
- Projects will impact business activities as well as technology
- Be prepared to participate in Data Privacy related tasks
- Stay informed of SOPs or changes in technology
- Network within the industry for insights or ideas

Valuable Resources

DLA Piper
https://www.dlapiperdataprotection.com/index.html
Global Data Protection Laws

https://www.privacyshield.gov/welcome
Privacy Shield Homepage

http://www.eugdpr.org/
GDPR Homepage

https://iapp.org/
International Association of Privacy Professionals

GDPR Implementation: Practical Scenarios for Publication Professionals

Karen Mittleman

ISMPP International Society for Medical Publication Professionals

“Know Before you Go”

https://www.cbp.gov/slide-show-image/know-you-go

Some Questions to Ask

1) Regarding Patients:
   - Was informed consent (IC) provided for all usage of data?
   - Are data to be shared or reported in public anonymized or in summary form?
2) Regarding Researchers:
   - Are they informed that their information will be shared with the public (eg, named in manuscripts, even if listed only in the acknowledgment)?
   - If raw data is shared, is it shared securely?
   - Are authors’ personal information and comments housed in a secure place?
3) Both
   - How long will data be retained?
   - Is this contained in the IC or agreement letter?

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What is your process for protocol submissions with a journal article?

A. Retrieve a copy of the final protocol and share with the author for submission

B. Request a colleague in another department to redact the protocol prior to sharing with the author for submission

C. After retrieving a copy of the final protocol, I am responsible for redaction of personal privacy information prior to sharing with the author for submission

D. Other

Practical Considerations - Data Sharing With Journals

- Supporting materials for journals
  - Protocols should be screened and redacted for personal and/or proprietary information
  - Supplemental data must go through the same screening process
- ISMPP resources for redacting protocols for journals:
  - https://ismpp.memberclicks.net/assets/docs/Education/AnnualMeeting/8thAM/OralPresentations/development and implications of a redacted clinical trial protocol ghildyal.pdf
  - http://ismpp-newsletter.com/2017/07/14/preparing-manuscript-submissions-plan-to-submit-supporting-documentation/

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Practical Considerations - Data Sharing With Authors

- Sharing of data with research authors
  - Must not be raw data and should not be sent by email (ie, use Dropbox, Sharepoint site) or, at the very least, should be encrypted before sharing
  - Agreements must be in place that include how that data will be used and for how long it must be retained
- Authors must be informed and provide consent for their personal information and comments to be stored (eg, Datavision)

https://www.advarra.com/the-gdpr-and-its-impact-on-the-clinical-research-community-including-non-eu-researchers/

Data Retention Schedules – A Gap Leading to Confusion

- No formal guidance for how long data or documents for publications must be retained
  - Varies across academic and research institutions
  - US Government:
    - Office of Management and Budget (Circular A-110) – retention period 3 years from the date the final financial report submitted (NIH)[1]
    - NSF (General Grant Conditions 2005) – retention period 3 years after the submission of all required reports (research and other special reports)[1]
    - HHS (45 CFR 46.115(b)) – research and IRB/EC records retained for at least 3 years after completion of the research[2]
    - Health Insurance Portability and Accountability Act (HIPAA) (45 CFR 164.530 (j)) – clinical records must be retained for 6 years from the date of creation or the date when the records were last in effect, whichever is later[2]

[1] https://ori.hhs.gov/education/products/rcradmin/topics/data/tutorial_11.shtml;
[2] https://www.niaid.nih.gov/sites/default/files/Record_Retention_policyVersion2%20Final.pdf

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Ongoing Publication Activity

- How might the new requirement impact publication of secondary data from a study that was conducted before GDPR came into effect?

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Ongoing Publication Activity

- How might the new requirement impact publication of secondary data from a study that was conducted before GDPR came into effect?
- Reconsent is not required for the use of data collected prior to May 25, 2018, provided that the way consent was previously given is in line with the conditions of the GDPR.
  - Older consents must meet the requirements for consent under the GDPR: freely given; informed; specific; unambiguous by a clear statement or affirmative action of consent (e.g., signing the consent form)

https://www.advarra.com/the-gdpr-and-its-impact-on-the-clinical-research-community-including-non-eu-researchers/

Conclusion

- Know your company policies on GDPR, data retention, etc.
- Perform a comprehensive audit[1] of your data:
  - Amount and type of personal information you have
  - Where it is kept
  - Who uses it
  - How it is used
  - How it is obtained
  - How secure it is

[1]Adapted from: http://www.pmlive.com/pmhub/healthcare_advertising/Apex_Conferences,_Events_and_Exhibition_Stands/white_papers_and_resources/gdpr_and_events._what_does_the_pharma_industry_need_to_know. Accessed September 25, 2018.

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- Due to the nature of this particular ISMPP U topic and the fact that it is an overview of many individual presentations, we may not be able to answer all questions. We are happy to follow up with specific faculty after the ISMPP U if needed

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DATE	TOPIC
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December 2018	*ISMPP West and AMWA Conference Highlights*

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