Challenges for Secondary Research Uses of Data Under GDPR

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MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

ROPES & GRAY

November 2019

Agenda

1. **Basis for Processing Special Categories of Personal Data in Secondary Research**
2. Basis for Transfer of Personal Data to U.S. for Secondary Research

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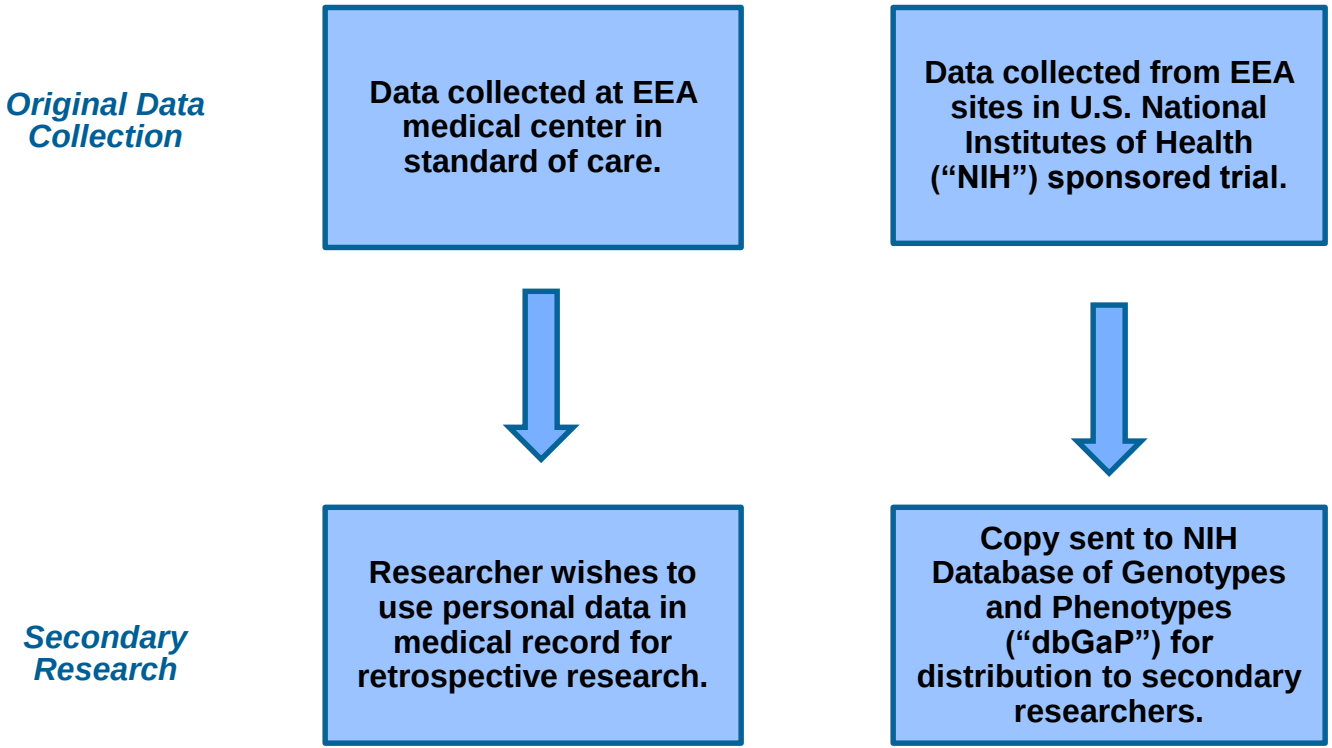
Issue: Secondary Research

- What basis can be used for processing special categories of personal data for secondary research, including research use of personal data in databanks, use of biospecimens in biobanks, and clinical care data for real world evidence (RWE)?
  - Compatibility?
  - Consent?
  - Scientific Research?
  - Public Interest in the Area of Public Health?

Flows of Data in Secondary Research: Examples



Compatibility

- GDPR also provides that scientific research shall not be considered incompatible with prior purposes for processing.
  - "The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is **compatible with the purposes for which the personal data were initially collected. In such a case, no legal basis separate from that which allowed the collection of the personal data is required**." (GDPR, Recital 50).
  - "Personal data shall be . . . collected for specified, explicit and legitimate purposes and **not further processed in a manner that is incompatible with those purposes;** further processing for archiving purposes in the public interest, **scientific or historical research purposes** or statistical purposes shall, **in accordance with Article 89(1), not be considered to be incompatible with the initial purposes.**" (GDPR, Art. 5(1)(b)).

Compatibility

- The EDPB briefly addressed compatibility in its January 2019 guidance on the intersection of GDPR and the EU Clinical Trials Regulation, but the EDPB highlighted the need for future guidance on this question.
  - The EDPB's guidance states that "[compatibility] due to [its] horizontal and complex nature, **will require specific attention and guidance from the EDPB in the future**."
- Accordingly, the research community's has remained reluctant to rely upon "compatibility" as a basis for the processing of personal data for secondary research.

Consent for Secondary Research

- **Consent**
  - GDPR recitals recognize that "[i]t 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. . . .**" (GDPR, Recital 33).
  - However, the Working Party guidance on consent limits the application of this recital:
    - "Recital 33 **does not disapply the obligations with regard to the requirement of specific consent.**"

    (WP259 Guidelines on Consent Under Regulation 2016/679).

Working Party Guidance on Consent

- The Working Party Proposal: Obtain additional consent as research advances and more details are known about future research activities.
  - If details of research are not known with specificity at outset, **updates regarding details of the research should be provided to subjects as the information becomes known** so that subject can determine whether to exercise right to withdraw.
  - Suggests making available a "**comprehensive research plan**" to subjects at the outset of the research.

Working Party Guidance on Consent

- Working Party's "rolling consent" approach poses particular **challenges for research, including database and biobanking studies**, and could impede future research in several ways:
  - Obtaining **subsequent consents could prove infeasible** in biobanking and databanking studies.
  - Data **subjects may feel pestered** by repeated requests for additional consent and cease responding to such requests.
  - Requirement to obtain consent from subjects **would fall on controller that holds the personal data**, often a databank or biobank controller, or a commercial clinical trial sponsor, which have not historically had direct contact with study subjects.
    - Inconsistent with current practice and **could confuse subjects**, who likely have not been contacted directly by the sponsor or databank/biobank before.

Consent for Secondary Research

- CTR **expressly contemplates that consent would be a basis for processing for secondary research purposes under the GDPR,** but the Working Party Guidance appears contrary to this position.
  - "It is appropriate that universities and other research institutions, under certain circumstances that are in accordance with the applicable law on data protection, be able to **collect data from clinical trials to be used for future scientific research**, for example for medical, natural or social sciences research purposes. **In order to collect data for such purposes it is necessary that the subject gives consent to use his or her data outside the protocol of the clinical trial** and has the right to withdraw that consent at any time. It is also necessary that research projects based on such data be made subject to reviews that are appropriate for research on human data, for example on ethical aspects, before being conducted." (CTR, Recital 29).

Scientific Research & Public Health Bases

- Alternate bases for processing personal data for secondary research include:
  - Necessary for **scientific or historical research** purposes in accordance with Article 89 **based on Union or Member State law**.
    - Regarded as requiring an affirmative act of the Union or EEA member states to become operative.
  - **Public interest** in the area of public health
    - Most directly relates to processing by health professionals to protect public health in the event of epidemics or pandemics, or reporting of adverse events by life sciences companies to regulatory authorities.
    - Not clear that the life sciences community could/should rely on this basis without a direct link between the research and public health.

(*See* GDPR Art. 9(2)(h), (i)).

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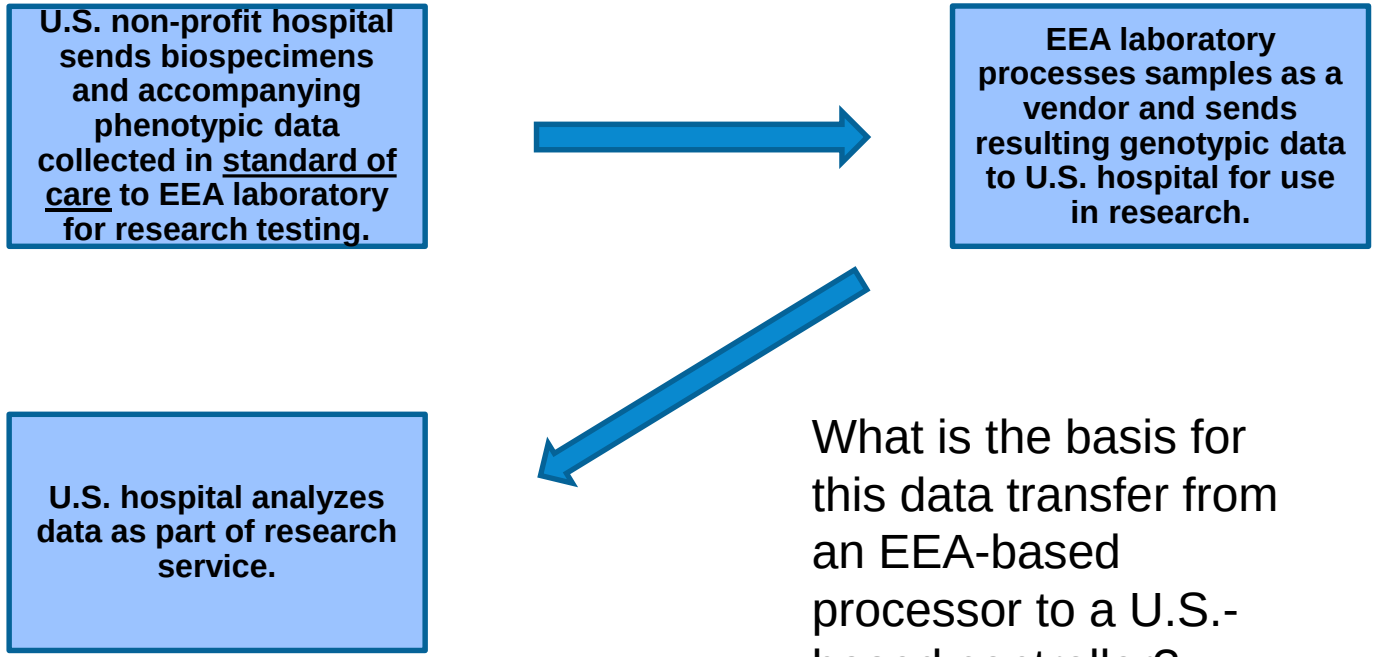
Issue: Basis for Transfer of Personal Data to U.S.

- For secondary research uses of personal data, what will be the legal basis for transferring personal data from the EEA to the U.S. or other jurisdictions outside of the EEA that lack an “adequacy decision”?
- What can be done when model contracts and Privacy Shield are not options?

Potential Flows of Data in Secondary Research



What is the basis for this data transfer from an EEA-based processor to a U.S.-based controller?

Basis for Transfer for Secondary Research

- Obtaining the **explicit consent** of the data subject to the transfer of personal data to the U.S. for processing.
  - Requires **advising the data subject of the risks** of the transfer resulting from the absence of adequate data protection legislation in the recipient jurisdiction. (GDPR, Art. 49(1)(a)).
  - Not possible for most secondary research.
- Entering into **model contractual clauses** approved by the European Commission with the EEA entity transferring personal data.
  - Two sets of controller-controller clauses.
  - One set of controller-processor clauses.
  - ***No processor-controller clauses available.***

Basis for Transfer for Secondary Research

- Transfer **necessary for performance of a contract between the data subject and the controller**, implementation of pre-contractual measures taken at the data subject's request, or contract concluded in the interest of the data subject.
  - In *prospective* research, consent form is often seen as contract between subject and *institution*. Subject has no contract with *sponsor*, so this basis does not help with transfers to the sponsor.
  - In *secondary* research, no contract with subject or contract in the interest of the subject. Research is in interest of institutions.

  (GDPR, Art. 49(1)).

Basis for Transfer for Secondary Research

- Transfer necessary for **important reasons of public interest**.
- Transfer necessary for **establishment, exercise or defense of legal claims**.
- Data transfers necessary to protect the "**vital interests**" of the data subject. Generally, "life and death" situations.

Basis for Transfer for Secondary Research

- U.S.-based companies that are **for-profit entities** may have an additional option of applying for certification under the **EU-U.S. Privacy Shield**, a program administered by the U.S. Department of Commerce.
- Associations may create **codes of conduct** setting forth rules on data processing. Such codes must be approved by the supervisory authority in the relevant EEA jurisdiction or the European Data Protection Board, if operable in multiple jurisdictions. (GDPR, Art. 46(2)(e)).

Basis for Transfer for Secondary Research

- **Binding corporate rules** for **intra-company** transfers.
  - Must be approved by competent supervisory authorities.
  - Lengthy list of requirements, including:
    - Categories of personal data and type of processing
    - Application of general data protection principles
    - Rights of data subjects and means to exercise rights
    - Complaint procedures
    - Description of how notice of binding corporate rules provided to data subjects
    - Cooperation mechanism with supervisory authorities
    - Data protection training for persons who have permanent or regular access to personal data

  (GDPR, Art. 47).

Basis for Transfer for Secondary Research

- GDPR provides that the European Commission could adopt an adequacy decision for "**one of more specified sectors within [a] third country** . . . ." (GDPR, Art. 45(1)).
  - "The adoption of an adequacy decision with regard to a territory of a specified sector in a third country should take into account clear and objective criteria, such as specific processing activities and the scope of applicable legal standards and legislation in force in the third country. The third country should offer guarantees ensuring **an adequate level of protection essentially equivalent to that ensured within the Union**, in particular where personal data are processed in one or several specific sectors." (GDPR, Recital 104).
  - Canada has a sector-specific adequacy decision for organizations subject to the Personal Information Protection and Electronic Documents Act ("PIPEDA"), *i.e.*, most commercial organizations.
- ***Could the European Commission issue an adequacy decision covering U.S. HIPAA covered entities?***

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