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Bio-Streams – Report on Data Management Policy

Challenges and solutions

WLC is collaborating in Bio-Streams, an innovative research project supported by the European Commission

BIO-STREAMS

Bio-Streams aims to combat childhood obesity and is working towards establishing the first EU-wide virtual biobank focused on obesity among young people.

White Label Consultancy

WLC provides continuous support to the Project Coordinator and the Project Partners, ensuring that Bio-Streams activities align with the applicable legal and ethical standards.

WLC guides Bio-Streams research throughout its entire lifecycle with informative reports addressing ethical and legal challenges.

Start of the project

End of the project

Report on Data Management Policy

WLC is nearing the release of a comprehensive report designed to provide an extensive overview and analysis of the first challenges encountered by the Project and its Partners in managing legal and ethical aspects related to data in the context of research on childhood obesity.

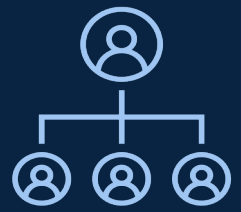
This report represents an iterative process and will be updated with subsequent findings in M32.

Key challenges in the Report

- One of the key challenges at this initial stage of the Project revolved around **establishing a clear framework for the lawful and ethical use of retrospective data by Technical and Clinical Partners**.
- Retrospective data, often collected for other purposes than the project's objectives, is a valuable source of information for research endeavours. Nonetheless, they bring about significant challenges, such as the risk of unauthorized repurposing of personal data and the necessity to establish a suitable legal basis.
- Consequently, it is crucial to address the legal and ethical considerations associated with the use of retrospective data to ensure both the project's success and its adherence to regulatory norms.
- The use of retrospective data in research context is challenged in three main ways in the GDPR:

The identification of a suitable legal basis for the processing

The applicability of the research exemption



The division of the roles and responsibilities between the Project Partners

Legal Bases

Articles 6 and 9 GDPR

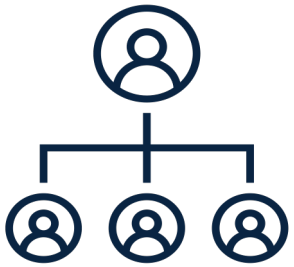
- While obtaining **consent** is typically the preferred legal basis for data collected directly from patients, utilising retrospective datasets can pose challenges under the GDPR, specifically for compliance with the principle of purpose limitation and the requirement for specific consent.
- Other viable legal bases for personal data processing in scientific research contexts could be:
  - **Public interest** in Article 6(1)(e) for the processing ordinary personal data and Article 9(2)(j) for sensitive data, which must align with the research exemption in Article 89.
  - **Legitimate interest** in Article 6(1)(f) for ordinary data. However, there is no equivalent legal basis for sensitive data in Article 9.

Research Exemption

Article 89 GDPR

- Article 5(1)(b) provides an exemption to the purpose limitation principle: '*...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...*'
- Article 89 GDPR provides a framework for balancing data protection principles with research activities. It addresses: **archiving in the public interest, scientific or historical research, and statistical analysis**.
- The application of Article 89 **does not** exempt researchers from complying with GDPR's requirements, nor does it provide a legal basis for the processing of personal data.
- Article 89 allows for exceptions to certain rights established by the GDPR, on the condition that appropriate technical and organizational measures are implemented to safeguard the rights and freedoms of data subjects.

Roles & Responsibilities



Controllership and processorship

- Defining the role of each Project Partner within the Project (as **controllers, joint controllers, or processors**) is crucial as it delineates their respective responsibilities and accountabilities regarding personal data processing. This is essential for compliance with the accountability principle outlined in Article 5(1)(d) GDPR.
- Determining the role of each Project Partner depends on the specific context of the processing operation in question.
- In light of the challenges associated with processing retrospective data, four alternative controller/processor options have been identified to ensure the clear division of roles in the processing of retrospective data in Bio-Streams research activities. These options are presented in the next slide, with a brief overview of each option's strengths and weaknesses.

Roles & Responsibilities

	Option 1: Data Collectors as Sole Controllers; Technical Partners Use Anonymous Data	Option 2: Clinical Partners Transfer to Central Organising Partner	Option 3: Joint Controllership with Technical Partners	Option 4: Technical Partners Process on Behalf of Clinical Partners
Roles	• Clinical Partners process personal data. • Technical Partners analyse anonymous data.	• Clinical Partners and the Organising Partner are joint controllers. • The Organising Partner engages Technical Partners as processors.	• Clinical and Technical Partners are joint controllers.	• Clinical Partners are the sole controllers. • Technical Partners process data on behalf of the controllers.
Strengths	• Least ethical and legal challenges.	• Project can use personal data in its virtual biobank.	• Agency of Technical Partners maximised.	• Clinical Partners maintain control over the personal data.
Weaknesses	• Data quality significantly reduced. • Key project target might not be fulfilled.	• Reduced agency of Technical Partners. • More ethical and legal challenges compared to Option 1.	• Most problematic legally, ethically and organisationally.	• Reduced agency of Technical Partners. • Project coordination becomes cumbersome.
Opportunities	• Reduced ethical approval time and legal risks.	• Simplified joint controllership arrangement.	• Increased insight into project data.	• Increased chance of ethical approval. compared to Option 2 and 3.
Threats	• Risk of difficulties in proper anonymisation.	• Technical Partners may act as controllers, not processors.	• Time and difficulty of obtaining ethical approval from Clinical Partners' ethics review boards.	• Technical and other Partners might be deemed controllers factually. • Potential for controllership dispute.
Preference	• Unsatisfactory, considered a 'last resort.'	• Preferred unless Technical Partners need to be controllers or if ethical approval is not obtained.	• Unsatisfactory, to be considered only if Technical Partners must be controllers to undertake their roles in the Project.	• Unsatisfactory compared to Option 2 but is more likely to gain ethical approval.

For any further inquiries or to explore our services in detail, please reach out to us at:

hello@whitellabelconsultancy.com

Or on our website:

www.whitelabelconsultancy.com

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