The Impact of the General Data Protection Regulation (GDPR) on U.S. Researchers

Thursday, November 18th, 2021

UC Health

UC Health Reminder: Annual Flu Campaign

This year UC Health's annual flu campaign began the week of October 4th. The flu vaccine is a mandatory requirement and of utmost importance this year with the continued challenge of COVID-19.

UC Health Employee Health will be providing the flu vaccine, free of charge, to our employees and affiliates but also willingly accept documentation of the vaccine received elsewhere.

UCH Employee Health will be loading your survey (consent form) into Readyset. This survey must be filled out prior to receiving your vaccine, and also if you receive the vaccine elsewhere, for you to be considered compliant.

This is due November 19th, 2021

TOMORROW

UC Health

November 2021 Study of the Month

Obesity Research Study

For Participants That Do Not Have Binge Eating Disorder

What
The purpose of this research study is to learn more about the role of the circadian system in binge eating disorder (BED). Participants will be asked to come in for 4 visits over approximately 4 weeks, and will wear an activity monitor and provide saliva samples.

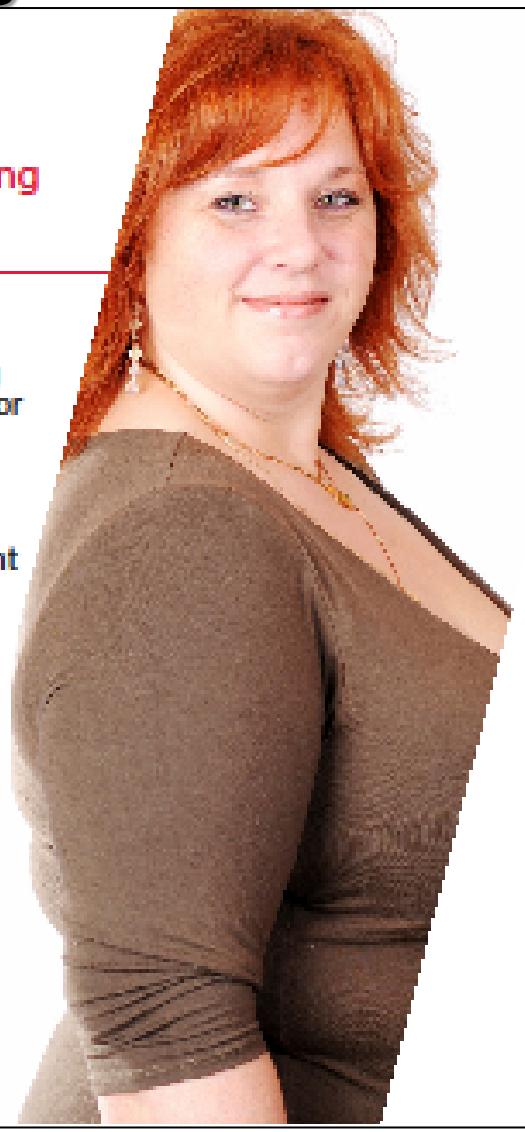
Who
Adults age 18-50 with obesity that do not have current or lifetime history of BED or bulimia nervosa. Not currently experiencing other psychiatric disorders.

Pay
Eligible participants will be paid up to $215.

Details
For more information, contact Brian or George at (513) 536-0707 or visit LCOH.info and fill out a pre-screen questionnaire. Located at the Lindner Center of HOPE in Mason, Ohio.
in Mason, Ohio.

UC Health. / UC Health. Lindner Center of HOPE

14-21 IRB # 2020-0345



Westchester Hospital (WCH) Study review and approval

Reminder:

Clinical research studies at West Chester Hospital (WCH), including hospital-based clinics, must go through WCH senior leadership for approval before research begins. WCH approval is usually the last step in the UCH Research Approval Process, allowing all ancillary services to review feasibility and approve prior to WCH approval. Please note: WCH Executive Leadership meets on Mondays and Fridays. Depending on when the ancillary services approve the research impacts when it is scheduled for WCH review. The research can be approved without WCH review and approval and this site approval comes at a later date, or the WCH site can be added to the REDCap submission at a later time.

CRP Collaborations:
CCHMC SOCRA EXAMINATION
Friday, December 3rd, 2021

Contact Nate Harris or Email CRP@cchmc.org with any questions or for information.

Friday, December 3rd, 2021

Understanding and Utilizing Umbrella Protocols

Hilary Perez, PhD, CCRP

Mike Linke, PhD

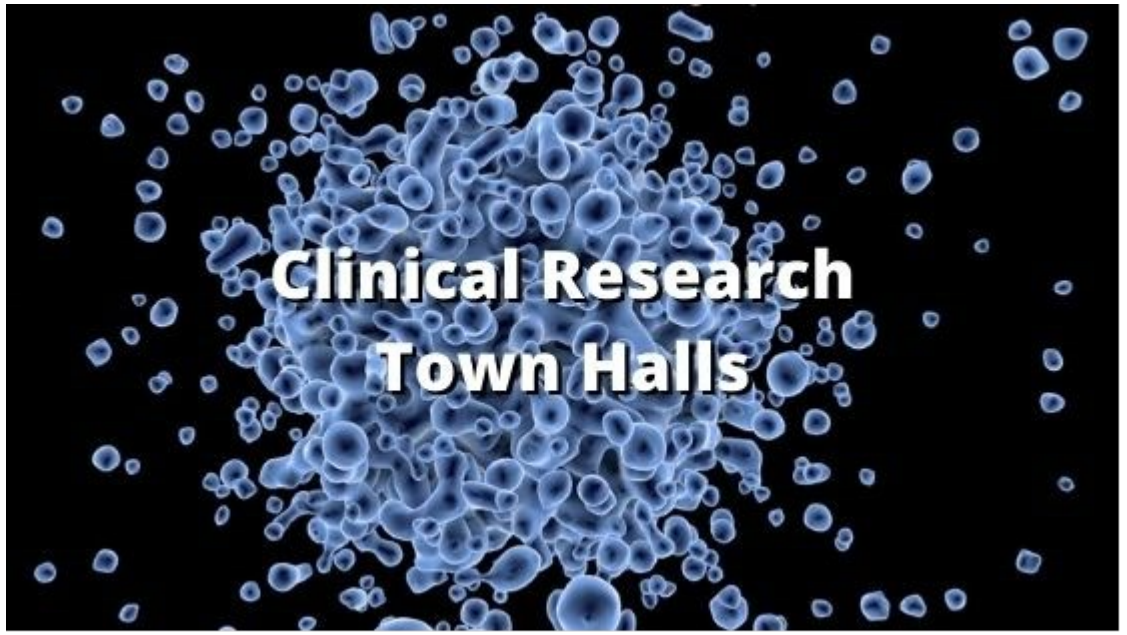
UC Health

UC Health Clinical Research Orientation and Training (CRO&T)

Thursday, December 9th, 2021
9:00 am - 3:00 pm
Virtual presentation

The last day of registration is EOB Friday, December 3rd, 2021

Special OCR Town Hall Lunch & Learn Sessions



December 16, 2021: General Clinical Research Q&A

January 20, 2022: Clinical Research Finance, Accounting, Post-Award, and Invoicing Q&A

UC Health

Today's Presentation:

The Impact of the General Data Protection Regulation (GDPR) on U.S. Researchers

An overview of The General Data Protection Regulation (GDPR), and how it affects clinical research in the United States

Lorren Ratley

Director of Privacy

University of Cincinnati

UC Health

General Data Protection Regulation and Research

Lorren Ratley, Director of Privacy

11/2021

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This training will address:

- What the GDPR is and how it impacts research
- To whom it applies, and where
- Rights of subjects
- What kinds of data are protected
- Determining who is a controller and a processor
- Data collection on the basis of consent
- Data collection without consent
- Cross border data transfers

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GDPR

- The European Union's General Data Protection Regulation applies to natural persons located in the EU.
- Protects any information relating to a natural person ('data subject') who can be identified, directly or indirectly.
- Aims to ensure personal data is processed in a transparent manner, only for specific purposes, kept no longer than necessary, and in a secure manner that is protected from accidental loss, destruction or damage.
- Processing always has a defined legal basis
- When processing is based on consent, the consent is freely given and can be withdrawn.

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Data Subjects

People who are in the Union

Data belonging to subjects is protected where the processing activities are related to:

- Offering of goods or services to data subjects in the Union; or
- Monitoring of their behavior as far as their behavior takes place within the Union.

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Data…and special categories of data

Any identifier, direct or indirect is covered.

Special categories or sensitive data is personal data revealing:

- racial or ethnic origin,
- political opinions,
- religious or philosophical beliefs,
- trade union membership,
- the processing of genetic data,
- biometric data for the purpose of uniquely identifying a natural person,
- data concerning health
- data concerning a natural person's sex life or sexual orientation

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De-identifying Data

- **Pseudonymisation**
  - Data can be reidentified using a key.
  - Helps meet security requirements, but regulation still applies
- **Anonymization**
  - Regulation does not apply

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Is it anonymized?

Pseudonymized data which could be attributed to an individual using additional information is considered to be information on an identifiable individual.

To determine whether an individual is identifiable, consider all means reasonably likely to be used to identify the individual directly or indirectly.

GDPR Recital 26

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Rights of Data Subjects

- Right of access
- Right to rectification
- Right to erasure/Right to be forgotten
- Right to restriction of processing
- Right to data portability
- Right to object

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Exceptions for Research

- Right to Erasure
  - GDPR provides an exception to the right to be forgotten if exercise of the right is "likely to render impossible or seriously impair the achievement of the objectives of the research." https://gdpr-info.eu/art-17-gdpr/

- Right of Access
- Right to Rectification
- Right to Restriction of Processing
- Right to Object
  - Each country's supervisory authority *may* authorize an exception to each of the other rights listed above, if exercise of the right is "likely to render impossible or seriously impair the achievement of the objectives of the research." https://gdpr-info.eu/art-89-gdpr/

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Controllers

If you make any of these decisions determining the purposes and means of the processing, you are a controller:

- If processing will take place
- On what legal basis
- What types
- Purpose
- From whom
- Whether to disclose the data, and if so, to whom;
- What to tell individuals about the processing;
- How to respond to requests to exercise rights; and
- How long to retain the data

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Sponsors are Controllers

The sponsor determines what data is collected for the research study through the protocol, case report form and/or structured data fields in a database.

The sponsor therefore acts as a controller in relation to the research data. If the sponsor and Principal Investigator develop the protocol together, they may be joint controllers.

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Joint Controllers

Where two or more controllers jointly determine the purposes and means of processing, they are joint controllers.

They determine, in a transparent manner, their respective responsibilities for compliance, specifically for the rights of the data subject.

Processors

A processor may decide:

- The IT systems or other methods to use to collect personal data;
- How to store the personal data;
- The details of the data security measures;
- How it will transfer the personal data from one organization to another;
- How it will retrieve personal data about certain individuals;
- How it will adhere to a retention schedule; and
- How it will delete or dispose of the data.

Contracting with Processors

- Agreements with processors need to include GDPR language if data from EU subjects is involved.
- A data processing addendum can be provided to you.

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Legal Bases

To collect data covered by the GDPR, there must be a legal basis for doing so.

1. Consent

2. Public interest in the area of **public health**, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medical products or devices, subject to appropriate conditions and safeguards set out in Union or Member State law.

3. Processing is necessary for archiving purposes in the public interest, **scientific or historical research** purposes or statistical purposes subject to appropriate conditions and safeguards set out in Union or Member State law.

   See Recital 156: https://gdprinfo.eu/recitals/no-156/

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Consent

- Clear and plain language
- Specific
- Freely given
- Right to withdraw his or her consent at any time, as easy to withdraw as it is to give

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Transparency: Data Protection Notice Provided to Subject

- Identity and contact details of controller
- Purposes of the processing
- Legal basis for the processing
- Where the processing is based
- Legitimate interests pursued by the controller
- Recipients of the personal data, if any
- Where applicable, the fact that the controller intends to transfer personal data to a third country
- Period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period
- Existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability
- Right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal
- Right to lodge a complaint with a supervisory authority
- Where the controller intends to further process the personal data for a purpose other than that for which the personal data were collected, the controller shall provide the data subject prior to that further processing with information on that other purpose

Legal Basis: Legitimate Interest

- Legitimate interests gives you the job of explaining your purpose and justifying why this is in your legitimate interests in addition to you having to demonstrate the necessity of the processing. The onus is also on you to ensure – and demonstrate – that your interests are balanced with the individual rights.

- You need to be able to clearly justify your decision that the balancing test actually favors you processing the data.

- If you intend to rely on legitimate interests you need to be confident about taking on the responsibility of protecting the interests of the individual.

- More work to be transparent when you are relying on legitimate interests. You need to clearly explain in your privacy policy what the legitimate interests of the processing are.

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Secondary Use of Data

- Data that was obtained for a specific research use may be processed again for additional research.

- Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes.

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Data Transfers Outside the EU

- Appropriate safeguards may be provided for by contractual clauses between the controller and processor

-OR-

- The data subject has explicitly consented to the proposed transfer, after having been informed of the possible risks of such transfers due to the absence of appropriate safeguards such as contractual clauses

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UC Process for GDPR Research

- If protocol is submitted to UC IRB, Director of Privacy will be notified.
- A GDPR ancillary review form will be sent to you.
- Through the review you will document all elements in today's presentation: role of controller or processor, legal basis, consent elements, and more.

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EU Ethics Committees

Approval by the Ethics Committee in the member state does not equal a GDPR review or assurance that all GDPR requirements have been met.

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UC Legal Advice

If legal guidance is needed, contact Office of General Counsel (OGC) early in the process to avoid delays.

OGC has previously engaged outside counsel and received guidance from EU counsel.

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Breach Response

Processor shall notify the controller without undue delay after becoming aware of a personal data breach.

Controller shall notify the personal data breach to the supervisory authority of the member state not later than 72 hours after having become aware of it.

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Fines

- Organizations can be fined up to 4% of annual global turnover for breaching GDPR
- Apply to both controllers and processors

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Summary

- The EU GDPR aims to strengthen protections for personal data and to ensure consistency of such protections across the EU.

- The EU GDPR provides new ways people can protect their personal data, and by extension their privacy and other human rights. It gives everyone more control and requires private and public organizations to disclose more about their data practices, and regulates the way they collect, process, and store people's data.

References

- https://gdpr-info.eu/
- https://iapp.org/news/a/how-gdpr-changes-the-rules-for-research/
- https://www.mwe.com/insights/does-gdpr-regulate-research-studies-united-states/
- https://www.jhsph.edu/offices-and-services/institutional-review-board/_pdfs-and-docs/GDPR_Application%20in%20Research%20Settings.pdf

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