IRB GUIDANCE: INFORMATION SECURITY

TABLE OF CONTENTS:

Introduction .................................................................................................................................................. 2

Downstate Information Security Officer .................................................................................................. 2

Contacts ..................................................................................................................................................... 2

Suspected Breach ...................................................................................................................................... 3

Information Security Requirements ........................................................................................................ 3

Physical Safeguards ................................................................................................................................ 3

Technical Safeguards ............................................................................................................................... 4

General ..................................................................................................................................................... 4

Downstate E-Mail ...................................................................................................................................... 5

Storage and Data Back-up ......................................................................................................................... 5

Virtual, Internet & Telehealth Platforms ................................................................................................. 5

Remote Consent ....................................................................................................................................... 6

Electronic Consent; Electronic Signatures ............................................................................................... 7

Administrative Safeguards ....................................................................................................................... 7

General ..................................................................................................................................................... 7

Protocol Specific Safeguards .................................................................................................................. 8

Agreements ............................................................................................................................................... 8
INTRODUCTION

Investigators must follow the standards outlined in the Downstate and RF policies, when using Downstate or RF resources or data.

All Research must meet the institutional requirements for electronic data and information security, including any data security plans involving the use, storage or transmission of Electronic Protected Health Information (EPHI), Electronic Confidential Information (ECI), or Electronic Sensitive Information (ESI).

This guidance applies to investigators and others approved by the Downstate IRB, including any affected Business Associate with access to EPHI, ECI, ESI or confidential information.

DOWNSTATE INFORMATION SECURITY OFFICER

The Downstate Information Security Officer provides guidance to the IRB, reviews information security incidents. (S)he makes determinations of information security breach and reporting requirements to the HHS Office of Civil Rights. (S)he assists the IRB’s review of non-compliance, when applicable and is permitted to be appointed as an IRB Member.

CONTACTS

For information on data security as it relates to SUNY Downstate specific policies, please contact the Information Security Officer, Igor Gorelik at igor.gorelik@downstate.edu.

For informed consent disclosures related to EU GDPR requirements, contact Alexandra Bliss, Compliance Coordinator, Office of Compliance & Audit Services at Alexandra.Bliss@downstate.edu.
For questions for the Downstate Privacy Officer, contact Shoshana Milstein, Assistant Vice President, Compliance and Audit at shoshana.milstein@downstate.edu

For any contractual agreements related to research data security, contact Ethan Denny, Assistant Director, Contracts, RF SUNY at Ethan.Denny@downstate.edu.

For SUNY RF policies, related to RF business applications, see: Acceptable Use and Security of RF Data and Information Technology or contact: Gerard Drahos, Vice President Chief Information Officer, Corporate Information Security Officer; Gerard.Drahos@rfsuny.org; Phone: (518) 434-7205.

For more general information or questions, please contact the Downstate IRB at IRB@downstate.edu.

SUSPECTED BREACH

In the event of a suspected breach, immediately contact the Downstate IRB, Downstate Information Security Officer, and Downstate Privacy Officer, and report the event to the IRB in writing in accordance with Policy IRB-01.

In addition to notifying the above individuals and IRB for a suspected breach involving an RF business management system, notify the Downstate RF Operations Manager who will then notify the RF Information Security Officer.

INFORMATION SECURITY REQUIREMENTS

Safeguards can be physical, technical, or administrative and are described below.

The IRB, Privacy Officer, or Information Security Officer may consider or require additional safeguards.

PHYSICAL SAFEGUARDS

- Physical security measures must be in place. As applicable, these may include controlled access, locks, fire suppression, alarms, etc.
- Do not leave sensitive documents in plain view on your desk, computer, or on fax machines or copiers.
- Use simulated data for training purposes.
- Discard confidential and secure information in accordance with Downstate policy (e.g., Shred-It program, computer/electronic waste procedures, etc.). Do not discard any confidential and secure information in a waste receptacle or recycling bin.
- Enable a password protection/screen lock and establish automatic security timeout or auto lock after no more than 15 minutes of inactivity.
• When available, enable the application or feature to remotely trace, wipe or clear lost or stolen devices.
• Mobile devices must not be “jail broken” or “rooted” by the user.

TECHNICAL SAFEGUARDS

GENERAL

• When transmitting EPHI, ECI, or ESI over an electronic network, utilize technical security controls (such as encryption) to guard against unauthorized access.
• Research projects that contain EPHI, ECI, or ESI must reside in a centralized secure location (i.e., network file share, server database, secure system approved by the DMC Information Security Officer).
• OneDrive is the only cloud drive approved for use at Downstate; however, cannot be used for EPHI.
• Downstate hosts REDCap on a Downstate server with a web interface. It can be used to store EPHI. For more information, see: http://guides.downstate.edu/redcap
• EPHI, ECI, or ESI must not be stored on a local computer hard drive, non-encrypted laptop, or non-encrypted mobile device. All mobile devices intended for Downstate business/research use must be provided to IT for enrollment into the Mobile Device Management (MDM) platform.
• Messages sent within Downstate’s network (from one Downstate.edu account to another) are automatically secured. Emails containing EPHI, ECI, or ESI that are sent outside of Downstate’s network (including forwarding or replying to external emails) MUST be encrypted. The simplest way to encrypt an email message using the Downstate MS Outlook program is to enter “Confidential” without quote anywhere in the message subject.
• Encrypt any mobile device connected to a Downstate network. Call extension 4357 (HELP) for additional information.
• Downstate and Non-Downstate owned mobile devices (e.g., laptops, notebook, tablets, cell phones, smart phones, USB connected thumb drives, portable storage device, etc.) may be used for research; however, they cannot contain EPHI, ECI, or ESI, unless encrypted with a validated Federal Information Processing Standard (FIPS 140-2) or other encryption algorithms or protocols approved by Downstate policy (see HIS-13).
• Any data repository, data warehouse, file server and/or database that stores research data must comply with Downstate policies.
• To ensure data security when in transit, data entry or file transfers containing EPHI, EPHI and ECI or ESI may be sent to an external site via a HTTPS secured website, encrypted e-mail, or via a secure file transfer, Secure File Transfer (SFTP), Virtual Private Networks (VPN), or via other methods approved by the DMC Information Security Officer.
• Do not use USB drives or other removable storage devices for long-term storage or confidential or EPHI, ECI, or ESI data.
DOWNSTATE E-MAIL

All Downstate business must be conducted using a downstate.edu e-mail address.

All members of the Downstate workforce MUST use their Downstate e-mail address when communicating with the Downstate IRB and when setting up accounts to use IRB systems (e.g., such as IRBNet, Huron Click, Downstate MyResearch, etc.).

STORAGE AND DATA BACK-UP

Take all reasonable precautions to mitigate the risk of loss, which may include storing work-related data on a Downstate approved network drive to ensure appropriate back up.

Back-Up the research data to a Downstate approved server or other alternative secure location. If the data is sensitive or includes PHI, use the technical safeguards noted above.

VIRTUAL, INTERNET & TELEHEALTH PLATFORMS

When approved by the Downstate IRB, the following platforms may be used for interviews, focus groups or obtaining informed consent/HIPAA authorizations, remote communications, data collection, and data storage that involve PHI:

- Applications through software available through the Downstate HELP Desk:
  - Zoom (temporary):
    - Note: May be used during the COVID-19 health crisis during discretion period of the COVID-19 health crisis as outlined by the Office of Civil Rights (OCR) Notification of Enforcement Discretion for Telehealth.
  - Zoom for Healthcare (tentative):
    - Note: This information is provided for planning purposes. Zoom for Healthcare may be used once SUNY campuses establish a SUNY-wide BAA, which is currently under negotiation. The plan is to convert all existing Downstate Zoom Accounts to Zoom for Healthcare once the BAA is executed.
  - Docu-Sign (tentative):
    - Note: This information is provided for planning purposes. Docu-Sign may be used once Downstate has executed a BAA, which is currently under negotiation.
  - Doxy.Me
  - REDCap hosted by Downstate.
    - Note: The REDCap system used at Downstate is HIPAA compliant; however, there is no documentation in place for 21 CFR Part 11 certification (therefore e-consent cannot be used for FDA regulated clinical investigations)
• **FDA COVID MyStudies Application (App)** for e-consent for FDA regulated clinical investigations that occur during the COVID public health emergency.

• Other platforms described in the OCR Notification of Enforcement Discretion for Telehealth may be used during the discretion period of the COVID-19 health crisis, when approved by the Downstate IRB, Privacy Officer, and Information Security Officer.

• Applications used in collaboration with external sites:
  - When PHI is shared from Downstate in an Electronic Data Capture system, the EDC must be HIPAA compliant.
  - When PHI is included in REDCap platforms hosted at other sites, written documentation about the system must be approved by the Downstate Information Security Officer to demonstrate that it is fully compliant with privacy and security guidelines defined by HIPAA and the Federal Information Security Management Act (FISMA). It is highly recommended that sites use MS SQL server version 2016 or newer to support strong encryption. The REDCap database should also be encrypted.
    - When REDCap from an external site is used to obtain e-signatures for informed consent for FDA regulated clinical trials, REDCap must be compliant with HIPAA and 21 CFR Part 11 (electronic records regulations).

• When applicable the platform must be approved by Information Security and compliant as follows:
  - 21 CFR Part 11 compliant for FDA regulated clinical investigations,
  - ICH GCP compliant when the study follows GCP guidelines,
  - ISO certified when required,
  - California Privacy Rights and Enforcement Act (CPRA)/ California, Consumer Privacy Act (CCPA) compliance when California regulations apply,
  - GDPR compliant, when GDPR regulations apply, and/or
  - Compliant for foreign regulations as applicable to the research.

**WARNING: DO NOT USE** One Drive, MS Forms, SharePoint, Qualtrics, or Google Forms for research activities involving PHI, as there are no BAAs in place with Downstate for these platforms.

**REMOTE CONSENT**

With IRB approval, research participants may participate in studies in which they do not have to meet directly with the investigator. In general, informed consent and authorization may be initiated and obtained through the following methods as recruitment policy allows (i.e., telephone contact, email, letter, fax).

Fax transmissions from Downstate should use the approved [HIPAA Facsimile Cover Page](#).
When a consent document contains PHI, electronic communications containing PHI for research purposes must be encrypted to Downstate standards.

ELECTRONIC CONSENT; ELECTRONIC SIGNATURES

With IRB approval, an investigator may obtain electronic consent and obtain electronic signatures, when the IRB waives documentation of informed consent or when all applicable regulatory requirements for an electronic signature are met. For more information on regulatory requirements refer to:

- FDA Regulations (21 CFR 11): Electronic Records; Electronic Signatures
- New York State Technology Law Article 1- Electronic Signatures & Records Act (ESRA), September 28, 1999 and amended August 6, 2002
- 9 NYCCR Part 540- ESRA Amended Regulations, May 7, 2003
- NYS Office for Technology- ESRA Guidelines, May 26, 2004
- National Archives & Records Administration- Records Management Guidelines for Agencies Implementing Electronic Signature Technologies, October 18, 2000
- 10 NYCRR Part 405.10- Medical Records, February 25, 1998
- 42 CFR Section 482.24- CMS Conditions of Participation for Hospitals, Medical Record Services
- Joint Commission Hospital Accreditation Standards- IM.2.20

Additional guidance documents for remote consent related to the COVID-19 public health emergency and for data security requirements are available on the IRB website.

ADMINISTRATIVE SAFEGUARDS

GENERAL

- Principal Investigators are responsible for enforcing Downstate and RF policies related to data security.
- Principal Investigators are responsible for ensuring that all study personnel have received appropriate training in accordance with Downstate Policies.
- Passwords must comply with HIS-04, Password Policy.
- Do not share user credentials (i.e., logon and/or password) with anyone, including supervisors, immediate colleagues, or administrative support staff.
• Do not re-use the same passwords across different media.
• Do not use someone else’s logon and/or password.
• Change temporary passwords assigned by an administrator.
• When study personnel are no longer part of the Research team, the PI should remove their access to any identifiable research study data.
• Unauthorized access, manipulation, or disclosure of confidential data may constitute a security breach and may be grounds for disciplinary action up to and including termination of employment by the Department or School or an external institution.
• Report suspected violations to the appropriate person (e.g., Supervisor, Manager, Information Security Officer, Privacy Officer, Compliance Line, IRB, etc.).
• General reports or concerns related to privacy or misuse of data should be reported to the IRB Office, the HIPAA Privacy Officer or to the Downstate Compliance Line at 1-877-349-SUNY or by making a report on the “Compliance Line” on the bottom of DMC’s webpage or https://www.compliance-helpline.com/downstate.jsp
• Downstate and the RF will not tolerate retaliation toward or harassment of employees who in good faith report a suspected or knowing violation of policy.
• Investigators must immediately report lost or stolen mobile devices to the SUNY Downstate Data Safety Office by contacting the HELP desk (X4357).
• Investigators must follow Policy HIS-12, Mobile Device Usage, when using mobile devices in a research project.

PROTOCOL SPECIFIC SAFEGUARDS

• Within the study protocol or other IRB application materials, include a description of the methods to destroy data at the end of its life cycle or security measures used for data retention.
• Do not release or disclose data other than what is required to perform the research as approved by the IRB.
• Implement Confidentiality or Non-Disclosure Agreements, Data Use Agreements, Business Associate Agreements, when needed or required.
• The user of a mobile device that has been approved for use in research must provide reasonable safeguards and manage the location of the device to prevent unauthorized access. All Bring Your Own Devices (BYOD) should be approved and enrolled in the MDM platform to ensure the appropriate level of security controls over data and have ability to selectively lock or wipe Downstate data only, without affecting the user’s personal data.

AGREEMENTS

When applicable to the research, appropriate agreements must be established prior to conducting the research. These may include any of the following:

• Data Agreements
• Data Use Agreements (DUA) for research involving limited data sets
• Business Associate Agreements (BAA)
• Material Transfer Agreements (MTA)
• Confidentiality agreements
• Confidentiality and Non-Disclosure Agreements (CDA/NDAs)

DUA OR BAA RELATED TO DATA SECURITY

When a limited data set is released outside the institution where the research takes place or obtained from an external source, a Data Use Agreement (DUA) is generally required; however, the Privacy Officer or IRB may consider the approval of a HIPAA authorization or waiver to release the data.

A Business Associate Agreement (BAA) is required when providing a vendor (e.g., transcription service, data center, etc.) with PHI information for the purposes of the research.

Agreements for unfunded studies must be reviewed and approved by General Counsel and the Hospital Privacy Officer, before being presented to the individual with signatory authority.

Documents for funded studies must be reviewed Sponsored Research Programs for review and signature.

All original signed and dated forms must be retained in the investigator's research files, secure but readily retrievable.

When a human research project is determined to be exempt and involves PHI, a HIPAA Waiver, a HIPAA Authorization, a Data Use Agreement (DUA), or a Business Associate Agreement (BAA) is usually still required.

For more information and for Downstate templates, please see Step 5G on the IRB Electronic Submission Process website.

Note: If informed consent is obtained from a research participant when a limited data set is released outside the institution where the research takes place, a HIPAA authorization should be obtained, indicating the disclosure. A “limited data set” is a data set that is stripped of certain direct identifiers that are specified in the Privacy Rule.

SOCIAL MEDIA

Social media platforms may be considered for recruitment of potential research participants if approved by the Downstate IRB.

Any Downstate representation on social media must be approved by the Downstate Office of Communications and Marketing.
EUROPEAN UNION GENERAL DATA PROTECTION REGULATION (EU GDPR)

If the European Union (EU) General Data Protection Regulation (GDPR) or California Privacy Rights and Enforcement Act (CPRA)/ California Consumer Privacy Act (CCPA) are applicable to a study, please work with the sponsor, Privacy Officer, or the Office of Compliance and Audit Services (OCAS) to include the appropriate stipulations within consent documents or addendums. The IRB will work with OCAS to confirm all required provisions are included.

Examples for when GDPR applies to the research include the following:
1) The study includes outreach and recruitment of individuals who are located in the European Economic Area (EEA), which is 28 EU member states and three additional countries (Liechtenstein, Iceland, and Norway).
2) Downstate or a site approved by the Downstate IRB is the site for a study involving the EEA and has the role of primary research site and/or lead investigator, or
3) Downstate or a site approved by the Downstate IRB collects and/or processes Personal Data (as defined by GDPR) in the EEA in connection with the study (including incidental collection of personal data on a mobile app while a research participant is travelling in the EEA).

CALIFORNIA PRIVACY RIGHTS AND ENFORCEMENT ACT (CPRA)/ CALIFORNIA CONSUMER PRIVACY ACT (CCPA)

In general, the California Privacy Rights and Enforcement Act (CPRA)/ California Consumer Privacy Act (CCPA) regulations do not apply to non-profit organizations or government agencies; however, when applicable to a multi-site study, these requirements should be reviewed by the external site to ensure compliance.

REFERENCES

- California Privacy Rights and Enforcement Act (CPRA)
- California Consumer Privacy Act (CCPA) regulations
- European Union General Data Protection Regulation (EU GDPR)
- Office of Civil Rights Notification of Enforcement Discretion for Telehealth
- SUNY Downstate Information Services Policies and Procedures (Downstate Intranet link)
- SUNY RF Acceptable Use and Security of RF Data and Information Technology

AUTHORS

Alexandra Bliss, Compliance Coordinator, Office of Compliance & Audit Services
Ethan Denny, Contract Manager, Research Administration
Igor Gorelik, Information Security Officer,
Kevin L. Nellis, Executive Director Human Research Protections and Quality Assurance
**REVIEW AND APPROVAL HISTORY**

Original Issue Date: 12.27.2016


Revision Date: 01.20.2021

<table>
<thead>
<tr>
<th>Date Reviewed &amp; Approved</th>
<th>Revision Required</th>
<th>Responsible Staff Name and Title</th>
<th>Responsible Staff Name and Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Kevin Nellis, Executive Director Human Research Protections and Quality Assurance</td>
<td>Kevin Nellis, Executive Director Human Research Protections and Quality Assurance</td>
</tr>
<tr>
<td>12.27.2016</td>
<td>X</td>
<td>Kevin Nellis, Executive Director Human Research Protections and Quality Assurance</td>
<td>Guidance updated with input from Dr. David Lowey.</td>
</tr>
<tr>
<td>12.28.2016</td>
<td>X</td>
<td>Kevin Nellis, Executive Director Human Research Protections and Quality Assurance</td>
<td>Guidance updated with input from Lin Wang, PhD, PMO. GDPR section updated.</td>
</tr>
<tr>
<td>01.23.2019</td>
<td>X</td>
<td>Kevin Nellis, Executive Director Human Research Protections and Quality Assurance, David Loewy, PhD, SUNY Downstate Information Security Officer</td>
<td>Guidance updated with input from Lin Wang, PhD, PMO. GDPR section updated.</td>
</tr>
<tr>
<td>09.05.2019</td>
<td>X</td>
<td>Kevin Nellis, Executive Director Human Research Protections and Quality Assurance, Lin Wang, PhD, PMO, Interim SUNY Downstate Information Security Officer</td>
<td>Guidance updated with input from Lin Wang, PhD, PMO. GDPR section updated.</td>
</tr>
<tr>
<td>01.20.2021</td>
<td>X</td>
<td>Kevin Nellis, Executive Director Human Research</td>
<td>Updated or added information for new</td>
</tr>
<tr>
<td>Date</td>
<td>Action</td>
<td>Name</td>
<td>Changes</td>
</tr>
<tr>
<td>------------</td>
<td>--------</td>
<td>-------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>01.20.2021</td>
<td></td>
<td>Igor Gorelik, Information Security Officer</td>
<td>Information Security Officer, revised IT policies, references to RF policies, CA regulations, agreements, social media, virtual and internet platforms, remote consent, DUA, BAA, reporting suspected breach. Reorganized based on categories of safeguards. Changed the term Electronic Personal Information to Electronic Confidential Information to be in alignment with IT and OCAS policies.</td>
</tr>
<tr>
<td>01.21.2021</td>
<td>X</td>
<td>Kevin Nellis, Executive Director Human Research Protections and Quality Assurance</td>
<td>Minor edits and formatting changes made.</td>
</tr>
</tbody>
</table>