

IRB GUIDANCE: Rescinding COVID-19 Risk Mitigation Strategies

CONTENTS

Introduction..... 2

Access to or Collection of PHI is no Longer Permitted Effective on May 11, 2023. 2

Microsoft Teams and/or Doxy.Me Replaces Zoom for Access/Collection of PHI..... 2

Revision of Research Activities to Collect/Access Protected Health Information (PHI) with Microsoft Teams or with Doxy.Me Instead of Zoom, as Previously Approved by the Downstate IRB During the COVID-19 Pandemic. 2

Documentation of Amendment for the Research Record 3

Recommendations Related to the Amendment 4

Guidance Related to the Above Referenced Amendment..... 4

Precautions..... 4

Reminders 5

Examples of Applicability of Above Referenced Amendment 5

Applicability of Amendment to Use Microsoft Teams or DOxy.Me for Previously Approved ReseArch Using Zoom for PHI During the COVID-19 Emergency..... 5

General Examples of When Zoom Can be Used for Research with IRB Approval 6

Examples of When Zoom Cannot be Used for Research 6

Zoom for Healthcare with BAA 7

References 7

Authors 7

Review and Approval History..... 7

INTRODUCTION

During the COVID-19 emergency, the Downstate IRB followed federal guidance to mitigate the risk of COVID-19 exposure. One waiver pertained to a 'Notification of Enforcement Discretion' issued by the Office of Civil Rights (OCR) which allowed providers subject to HIPAA rules to communicate with patients and provide telehealth services through remote communication technologies even if they didn't fully comply with the requirements of the HIPAA rules. OCR stated that it would not impose penalties for noncompliance with HIPAA related to the good faith provision of telehealth during the COVID-19 nationwide public health emergency. It did encourage providers to notify patients that these applications potentially introduce privacy risks and advised providers to enable all available encryption and privacy modes when using such applications.

Based upon this notice, the IRB permitted the use of Zoom software to access Protected Healthcare Information (PHI) without executing a Business Associate Agreement (BAA). As this was only allowable for the temporary public health emergency period and the White House plans to end the COVID-19 Emergency Declaration on **May 11, 2023**, this enforcement discretion and the Downstate IRB Guidance for COVID-19 will, likewise, end on **May 11, 2023**.

ACCESS TO OR COLLECTION OF PHI IS NO LONGER PERMITTED EFFECTIVE ON MAY 11, 2023.

Given the above changes, access and collection of PHI via Zoom hosted by Downstate will no longer be permitted effective on **May 11, 2023**.

MICROSOFT TEAMS AND/OR DOXY.ME REPLACES ZOOM FOR ACCESS/COLLECTION OF PHI

Downstate has executed a BAA with Microsoft that is effective for accessing or collecting PHI using Microsoft Teams hosted at Downstate. Teams software is available through the Downstate Help Desk at no cost. Investigators may view the Microsoft Teams YouTube tutorial videos at:

<https://www.youtube.com/channel/UCTmtQNkwjkCXvLOSbWaFSbA>

Doxy.me and Microsoft Teams hosted at Downstate are HIPAA compliant and may be used for access or collection of PHI for research purposes with IRB approval.

REVISION OF RESEARCH ACTIVITIES TO COLLECT/ACCESS PROTECTED HEALTH INFORMATION (PHI) WITH MICROSOFT TEAMS OR WITH DOXY.ME INSTEAD OF ZOOM, AS PREVIOUSLY APPROVED BY THE DOWNSTATE IRB DURING THE COVID-19 PANDEMIC.

On **March 24, 2023**, the Downstate IRB and Privacy Board approved an amendment to all studies previously approved or activated by the Downstate IRB for the collection or access of Protected Health Information (PHI) with Zoom during the COVID-19 emergency. A copy of this amendment was e-mailed to all Principal Investigators/Local Principal Investigators/Project Leads on active human research studies/projects previously approved or activated by the Downstate IRB during the COVID-19 health emergency, using the e-mail addresses available in IRBNet for these studies. The information is also posted on the [Downstate IRB website](#), and may be shared with the other (external) Reviewing IRBs that reviewed research during this period, particularly if Zoom software hosted by Downstate without a BAA was specifically approved by the Reviewing IRB to be used for the collection of PHI during the healthcare emergency.

The following activities that were temporarily approved during the COVID-19 pandemic **must be discontinued prior to May 11, 2023**:

- All procedures previously approved or activated by the Downstate IRB using Zoom hosted by Downstate **for access or collection of PHI**.

For procedures previously approved or activated by the Downstate IRB that used Zoom hosted by Downstate for the access or collection of PHI, during the COVID-19 pandemic, the following methods may be immediately implemented without an additional amendment approval or activation by the Downstate IRB:

- Convert over to the collection or access of PHI via Microsoft Teams hosted at Downstate.
- Convert over to the collection or access of PHI via Doxy.me hosted at Downstate.

Note: The use of Zoom may continue when there is no health information associated with individuals during the zoom session because by definition, PHI is not involved.

This amendment approved by the Downstate IRB represents a minor change to previously approved or activated research.

DOCUMENTATION OF AMENDMENT FOR THE RESEARCH RECORD

If the above amendment pertains to your study, previously approved by the Downstate IRB, save a copy of the amendment approval in your research records. No additional action is required for research or determinations previously approved by the Downstate IRB.

For studies that were previously approved by reliance (oversight) by a Reviewing (external) IRB, and subsequently activated by the Downstate IRB Office, this amendment

represents activation of Downstate requirements of a Downstate study approved by the Reviewing IRB. Information security administrative review is generally conducted by the Downstate IRB Office to confirm all local requirements are met; however, if the use of Zoom was specifically approved by the Reviewing IRB, please consult with the reviewing IRB to determine if an amendment to the Reviewing IRB is required.

RECOMMENDATIONS RELATED TO THE AMENDMENT

If the Downstate IRB previously approved or activated a research study that involved informed consent language related to COVID-19 or a remote consent process as part of the COVID-19 risk mitigation strategies, it is recommended the consent form(s), application, and protocol be reviewed by Principal Investigator to determine if any updates are needed.

Any NEW changes or modifications of previously approved research (including beyond the above referenced amendment) by the Downstate IRB must be submitted to the Downstate IRB for review and approval, using Form 20-B2A: Application for Amendment.

Any NEW changes or modifications of previously approved research by reliance (oversight) by a Reviewing (external) IRB, must be submitted to the Reviewing IRB for review and approval. Upon approval by the Reviewing IRB, submit to the Downstate IRB for activation and acknowledgement using Form 20-B1: Application for Acknowledgement.

GUIDANCE RELATED TO THE ABOVE REFERENCED AMENDMENT

PRECAUTIONS

The above solutions with Microsoft Teams and Doxy.me may be used for conducting interviews and remote study visits or for obtaining remote consent if previously approved by the Downstate IRB with Zoom; however, the following precautions are noted:

- If the written consent document includes PHI (e.g., HIPAA Identifiers PLUS health information, such as participant name and diagnosis), the software system used to obtain electronic signatures must be HIPAA compliant (e.g., REDCap hosted by Downstate) and approved by the IRB.
- The Qualtrics and DocuSign software that are hosted at Downstate may only be used for obtaining electronic signatures on documents which do not contain PHI, because there is no BAA in place for these software programs.
- Presently, remote consent CANNOT be used to obtain electronic signatures for FDA regulated Clinical Investigations, using any software hosted by Downstate as

they are not yet validated for electronic signatures, as described in 21 CFR part 11.

REMINDERS

The following reminders are provided:

- The Zoom, SharePoint, OneDrive, Qualtrics, and DocuSign software hosted by Downstate are not considered to be HIPAA compliant at the present time. They cannot be used to access, collect, store, or share PHI nor sensitive information.
- Software available at collaborating sites or sponsors might be considered HIPAA compliant for PHI and/or 21 CFR part 11 compliant for electronic signatures. These software solutions may be used by Investigators approved by the Downstate IRB (or approved by an External IRB with Downstate IRB Activation); however, may require additional review by the Privacy Officer or Information Security Officer or may require additional agreements (e.g., BAA, Data Sharing Agreements, DUA, MTA).

EXAMPLES OF APPLICABILITY OF ABOVE REFERENCED AMENDMENT

APPLICABILITY OF AMENDMENT TO USE MICROSOFT TEAMS OR DOXY.ME FOR PREVIOUSLY APPROVED RESEARCH USING ZOOM FOR PHI DURING THE COVID-19 EMERGENCY

The above referenced amendment approved by the Downstate IRB allows for immediate conversion to Microsoft Teams or Doxy.me, when the IRB previously approved the use of Zoom software involving PHI during the COVID19 emergency.

Detailed **examples** on the applicability of this amendment are provided below:

- If the Downstate IRB previously approved a research **focus group** that included questions about research participants' past, current, or future health or other PHI with Zoom software during the COVID-19 emergency, the study may immediately convert over to **Microsoft Teams** and **must** be convert **prior to May 11, 2023**.
- If the Downstate IRB previously approved **one on one interviews, remote study visits, or remote consent visits** that included questions about research participants' past, current, or future health or other PHI with Zoom software during the COVID-19 emergency, the study may immediately convert over to **Microsoft Teams or DOXY.ME** and **must** be convert **prior to May 11, 2023**.

GENERAL EXAMPLES OF WHEN ZOOM CAN BE USED FOR RESEARCH WITH IRB APPROVAL

The following **examples** illustrate when **Zoom CAN be used** with IRB approval:

- Research participants and their family members are invited to participate in a Focus Group to answer questions about diabetes. There are no inclusion/exclusion criteria based on their health information that is required of all participants in the Zoom Focus group session. Because every participant in the group is **not** required to have a specific diagnosis their diagnosis is not associated with them during the session. The research participants are reminded not to share any health information about themselves and/or other individuals that can be identified. The participants are asked a series of questions about the general quality-of-care that diabetic patients should expect to receive. No PHI is involved; therefore, the discussions can take place during a Zoom session.
- Research participants in a Zoom Focus Group session are reminded to never share any health information about themselves or other individuals that can be identified, while participating in the session. During this Zoom Focus Group session, research participants are asked whether they are aware of any friends who are HIV-positive and how their status has impacted their friends' lives. They are not asked to identify anyone who is HIV-positive.
- Zoom is used for a remote study visit when no PHI is shared.
- Zoom is used for the process of obtaining remote consent, when no PHI is shared, and the appropriate software system is used for obtaining electronic signature.

EXAMPLES OF WHEN ZOOM **CANNOT** BE USED FOR RESEARCH

The following **examples** illustrate when **Zoom CANNOT be used**:

As a reminder, HIPAA identifiers (e.g., video or still image of participant, name, a distinctive voice identifiable to the study team or others, IP address, other HIPAA identifier) of an individual **PLUS** any past, current, or future health information about the individual for whom the identifier pertains, is considered PHI. The following examples illustrate when Zoom hosted at Downstate (without a BAA) **CANNOT** be used when **PHI is involved in a study on or after May 11, 2023, and therefore if such activities were to occur, they would need to be reported to the IRB as non-compliance**:

- All research participants in a Zoom Focus Group are known to have diabetes based on the enrollment criteria for their participation.
- A research participant is asked “What is your HIV status?”
- A research participant is asked “What is the HIV status of Ms. Jackie Smith?”
- Health information needs to be discussed or disclosed via Zoom.

ZOOM FOR HEALTHCARE WITH BAA

Please note that the SUNY Downstate IRB has recommended Downstate implement Zoom for Healthcare and execute a BAA with Zoom. It is not known at this time if a BAA can be established with Zoom for Healthcare nor whether this software may be hosted by Downstate. However, if Zoom for Healthcare can be hosted by Downstate with a BAA in the future, this guidance may be rescinded or updated, and/or the IRB Guidance on Data Security can be updated.

REFERENCES

This document was created based on discussion at the Downstate IRB meeting on March 1, 2023, and subsequent follow up discussions with the Downstate Privacy Officer and Data Security Officer.

AUTHORS

Kevin Nellis

REVIEW AND APPROVAL HISTORY

Original Issue Date: 03/24/2023

Supersedes: N/A

Revision Date: N/A

Date Reviewed & Approved	Revision Required		Responsible Staff Name and Title	
	Yes	No		
3/24/2023		X	Clinton D. Brown, MD, FASN, FAHA, FNLA Chair, Downstate IRB & Privacy Board	Based on information to rescind COVID-19 risk mitigation strategies with input from the IRB, OCAS, SPA, Information Security Officer, Privacy Officer.