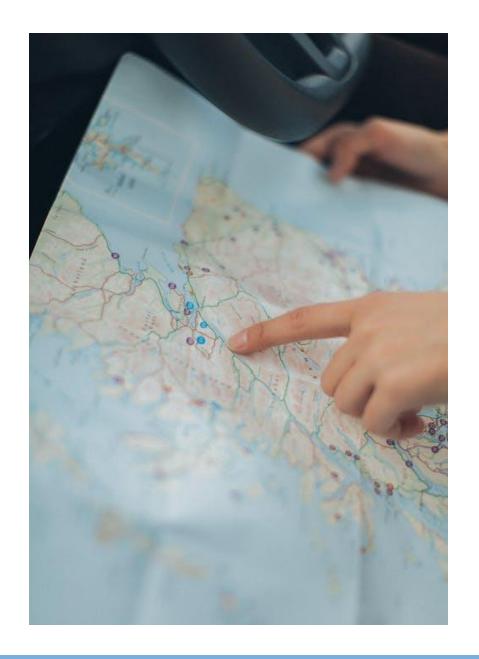
Confidentiality Laws and Emergencies

APRIL 10, 2024

KIRSTEN E. LELOUDIS, MPH, JD

UNC SCHOOL OF GOVERNMENT

The information provided in this presentation is for educational purposes only and does not constitute legal advice or establish an attorney-client relationship.



Presentation Roadmap

Federal Law: HIPAA

• 45 C.F.R. Parts 160, 162, and 164

State Law: NC Communicable Disease Confidentiality

• N.C.G.S. 130A-143

Using and Disclosing Confidential Info in an Emergency

Questions + Answers

Let's Level Set!

This presentation will...

- Provide you with an overview of two confidentiality laws that frequently apply to NC public health work and that may be implicated during an emergency
- Teach you the basics so that you can identify which law(s) apply to certain information and know where to go for more information about the law

This presentation will not...

- Provide an in-depth look at both laws and how they interact with one another (that could take us *days!*)
- Teach you about every confidentiality law that may apply in the public health field

For each of the confidentiality laws, we will discuss:

Introduction: what is this law?

Who must comply with this law?

What information does this law protect?

What are permitted uses and disclosures of information under this law?

Considerations in an emergency



What Do We Mean by "Confidentiality?"

Confidentiality laws protect specific types of information by establishing requirements for how the information can be...

- Used or shared
 - Ex: use by the entity that holds the information
 - Ex: sharing the information with the person who the information is about, a family member, law enforcement, another health care provider, a third-party research team, etc.
- Securely stored and transmitted
 - Ex: firewalls, VPNs, encrypted emails, locked file cabinets, etc.
- And more



Why Does Confidentiality Matter?

What do you think?



Why Does Confidentiality Matter?

What do you think?

Possible reasons:

- Protects individuals' privacy
- Helps prevent fraud (misuse of someone else's information)
- Violating confidentiality can result in loss of an individual's and/or the public's trust in your organization
- Violating confidentiality can result in civil, criminal, and other penalties
- And more





What Do We Mean by "Emergency?"

For this presentation, "emergency" refers to an emergency that impacts entire groups or communities of people- e.g., a hurricane, a disease outbreak, mass casualty event, etc.

We are not talking about other types of emergencies, such as situations where information may need to be disclosed to prevent child abuse or to avoid imminent injury or death



The Law Still Applies During an Emergency (Usually*)

Confidentiality laws don't cease to apply just because there is an emergency and an urgent need to share information

- But there are many lawful ways to share info in a crisis!
- Familiarizing yourself with options for sharing information now makes it easier to implement information sharing when disaster strikes

*Why *usually*? In limited circumstances, regulations may sometimes be waived or enforcement discretion may be exercised.

Federal Law: HIPAA



What is HIPAA?

<u>H</u>ealth <u>Insurance</u> <u>P</u>ortability and <u>A</u>ccountability <u>A</u>ct of 1996

- A federal law that required US DHHS to create regulations governing the security and use of protected health information (PHI)
- The resulting regulations are what people colloquially refer to as "HIPAA"
- Includes the Privacy Rule, Security Rule, Breach Notification Rule, and more

Found at 45 CFR 160, 162, and 164

Who Must Comply with HIPAA?



PCP: John Doe Co-Pay: \$25/\$50 Deductible: \$1000 Coinsurance: 20%



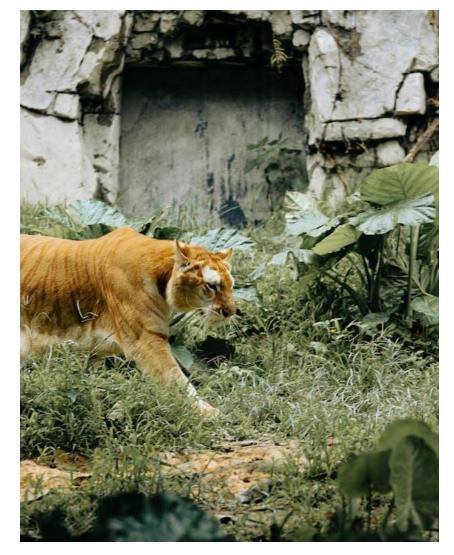


A covered entity (CE) is the name for entities that are regulated- or "covered"- by HIPAA and must comply with HIPAA's requirements. A CE's "business associate" (BA) must also comply with HIPAA.

There are 3 types of CEs:

- Health plan
- Covered health care provider
- Health care clearinghouse

Note: most LHDs are subject to HIPAA because they have/are "covered health care providers"



Like the majestic liger (lion + tiger), a HIPAA hybrid entity is one organization made up of two parts: covered and non-covered components.

HIPAA Hybrid Entities

"Hybrid entity" is defined at 45 CFR 164.103

- A single legal entity
- Whose business activities include HIPAA covered and non-covered functions
- That designates itself as a hybrid entity by identifying its health care components (aka, the components that perform covered functions under HIPAA)
 - This is important! Your organization is not a hybrid entity until you go through the hybrid entity designation process.

In a hybrid entity, only the parts of the organization that are "health care components" must comply with HIPAA



HIPAA Protects...

... protected health information (PHI)

PHI is any individually identifiable information or records in any form (electronic, paper, spoken) created or maintained by a CE that relates to any of the following:

- An individual's physical or mental health status or condition,
- Provision of health care to an individual, or
- Payment for the provision of health care to the individual.

PHI must not be used or disclosed except as permitted by HIPAA

PHI: Exceptions to the Definition

School records covered by FERPA

Individually identifiable health information in school records that are covered by the Family Educational Rights and Privacy Act (FERPA) is not PHI under HIPAA.

Employment records

Individually identifiable health information in employment records that are held by a covered entity *in its capacity as an employer* is not PHI under HIPAA.

Deceased individuals

Individually identifiable health information that pertains to a person who has been deceased for more than 50 years is not PHI under HIPAA.

Permitted Uses and Disclosures

- 1. Disclosures required by HIPAA
 - To the individual (patient or their representative), to US DHHS for compliance investigations or enforcement
- 2. Treatment, payment, or health care operations (TPO)
- 3. Disclosures where individual must have the opportunity to agree/object to the disclosure
 - E.g., hospital directories
- 4. Disclosure with the individual's written authorization (permission)
- 5. "Public interest" disclosures
 - Reporting abuse/neglect, organ donation purposes, judicial proceedings, workers' compensation claims, etc.

Note: Each type of permitted use or disclosure has specific requirements set forth in HIPAA. Reviewing the law before you make a disclosure is recommended- don't just assume it is allowed!

Permitted Uses and Disclosures

- 1. Disclosures required by HIPAA
 - To the individual (patient or their representative), to US DHHS for compliance investigations or enforcement
- 2. Treatment, payment, or health care operations (TPO)
- 3. Disclosures where individual must have the opportunity to agree/object to the disclosure
 - E.g., hospital directories
- 4. Disclosure with the individual's written authorization (permission)
- 5. "Public interest" disclosures
 - Reporting abuse/neglect, organ donation purposes, judicial proceedings, workers' compensation claims, etc.

Note: Each type of permitted use or disclosure has specific requirements set forth in HIPAA. Reviewing the law before you make a disclosure is recommended- don't just assume it is allowed!

HIPAA Permitted Disclosures: Select Examples for Emergencies

As required by other law 45 CFR 164.512(a)	 HIPAA allows for sharing of information when it is <u>required</u> by another law. Does not apply to situations where another law only permits (but does not require) sharing information. Examples: G.S. 130A-144- requires providing information to the state or local health director upon request and as necessary to investigate or control a communicable disease outbreak. 10A NCAC 41A .0200- may require disclosure of communicable disease information to enforce control measures and protect the public's health.
To prevent	If, in a HIPAA covered health provider's good faith judgment, it is necessary to share
serious, imminent	PHI to prevent a "serious and imminent" threat to the patient or others, the provider
threat to health	can share PHI without written authorization (consent). The PHI can be shared with
and safety	anyone who is in a position to prevent or lessen the threatened harm, including family,
45 CFR 164.512(j)	friends, caregivers, and law enforcement.

HIPAA Permitted Disclosures: Select Examples for Emergencies (cont.)

National security and intelligence activities 45 CFR 164.512(k)(2)	HIPAA allows disclosure of PHI to certain federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized under the National Security Act.
Public health activities 45 CFR 164.512(b)	HIPAA allows disclosure of PHI for certain public health activities, including to a "public health authority" (as defined under HIPAA) that is authorized by another law to collect the info for the purpose or preventing/controlling disease, injury, or disability (need that other authorizing law, though!) Examples of public health authorities include CDC and the Division of Public Health within NCDHHS.



HIPAA + NEDs

The Office of Civil Rights (OCR) within federal HHS has enforcement authority for violations of HIPAA

In emergencies, OCR can issue a "Notification of Enforcement Discretion," or an "NED"

HIPAA + NEDs (cont.)

An NED is how OCR lets the public know that it is exercising its enforcement discretion and will not impose penalties for noncompliance with the HIPAA Rules when covered entities are carrying out specific actions covered by the NED

- NEDs are typically narrowly tailored and limited in scope- the details of a NED are important!
- Usually tied to an emergency declaration-typically expire when declaration expires
- NEDs only address HIPAA- do not waive or change other applicable state or federal law
- \rightarrow How would you learn about an NED?
 - CDC or federal HHS websites/emails
 - NCDHHS websites/emails
 - Your health department's HIPAA Privacy Officer

Example NEDs: COVID-19

Notice of Expiration of Certain Notifications of Enforcement Discretion Issued in Response to the COVID-19 Nationwide Public Health Emergency

A Rule by the Health and Human Services Department on 04/13/2023

PUBLISHED DOCUMENT

AGENCY:

:=

1

Ū

 \square

 \geq

Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION:

Expiration of Notifications of Enforcement Discretion and transition period for telehealth.

SUMMARY:

This document is to inform the public that four Notifications of Enforcement
Discretion ("Notifications") issued by the U.S. Department of Health and Human
Services (HHS), Office for Civil Rights (OCR) regarding how the Privacy,
Security, and Breach Notification Rules ("HIPAA Rules") promulgated under the
Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the
Health Information Technology for Economic and Clinical Health (HITECH) Act
will be applied to certain violations during the COVID–19 nationwide public
health emergency ("COVID–19 PHE"), will expire upon expiration of the
COVID–19 PHE, which is currently scheduled for 11:59 p.m. on May 11, 2023.
Accordingly, upon expiration of the COVID–19 PHE, the Notifications will not

DOCUMENT DETAILS

Printed version: PDF

Publication Date: 04/13/2023

Agencies:

Department of Health and Human Services Office of the Secretary

Dates:

The Notifications of Enforcement Discretion addressed in this document expire at 11:59 p.m. on May 11, 2023. The 90calendar day transition period with respect to telehealth will expire at 11:59 p.m. on August 9, 2023.

Document Type: Rule

Document Citation: 88 FR 22380 Page:



Limited Waiver of HIPAA Sanctions and Penalties During a Declared Emergency: 2023 Public Health Emergency for Georgia in Response to Hurricane Idalia

Severe disasters impose additional challenges on health care providers. Often questions arise about the ability of entities covered by the HIPAA regulations to share individuals' health information, including with friends and family, public health officials, and emergency personnel. As summarized in more detail below, the HIPAA Privacy Rule allows patient information to be shared to assist in disaster relief efforts, and to assist patients in receiving the care they need. In addition, while the HIPAA Privacy Rule is not suspended during a public health or other emergency, the Secretary of HHS may waive certain provisions of the Privacy Rule under section 1135(b)(7) of the Social Security Act.

President Joseph R. Biden, Jr. has declared that an emergency exists in the state of Georgia and Secretary Xavier Becerra has declared a public health emergency to address the health impacts caused by Hurricane Idalia. Under these circumstances, the Secretary has also exercised the authority to waive sanctions and penalties against a covered hospital that does not comply with the following provisions of the HIPAA Privacy Rule:

- the requirements to obtain a patient's agreement to speak with family members or friends involved in the patient's care. See 45 CFR 164.510(b).
- the requirement to honor a request to opt out of the facility directory. See 45 CFR 164.510(a).
- the requirement to distribute a notice of privacy practices. See 45 CFR 164.520.
- the patient's right to request privacy restrictions. See 45 CFR 164.522(a).
- the patient's right to request confidential communications. See 45 CFR 164.522(b).

When the Secretary issues such a waiver, it <u>only</u> applies: (1) in the emergency area and for the emergency period identified in the public health emergency declaration; (2) to hospitals that have instituted a disaster protocol; and (3) for up to 72 hours from the time the hospital implements its disaster protocol. When the Presidential or Secretarial declaration terminates, a hospital must then comply with all the requirements of the Privacy Rule for any patient still under its care, even if 72 hours has not elapsed since implementation of its disaster protocol.

HIPAA + Limited Waivers

Limited waivers of HIPAA sanctions and penalties may also be issued by HHS Secretary

- Like NEDs, typically limited in scope, time limited, and tied to a specific emergency declaration
- More often used when an emergency impacts a discrete geographic area- e.g., one state (rather than a nationwide emergency)

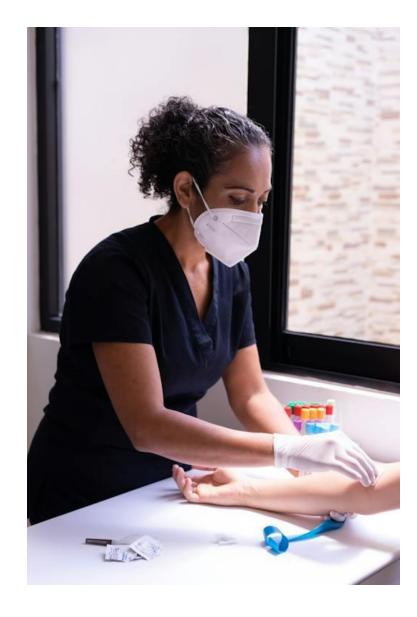
Would likely learn about a waiver the same way you would learn about an NED

State Law: G.S. 130A-143



What is G.S. 130A-143?

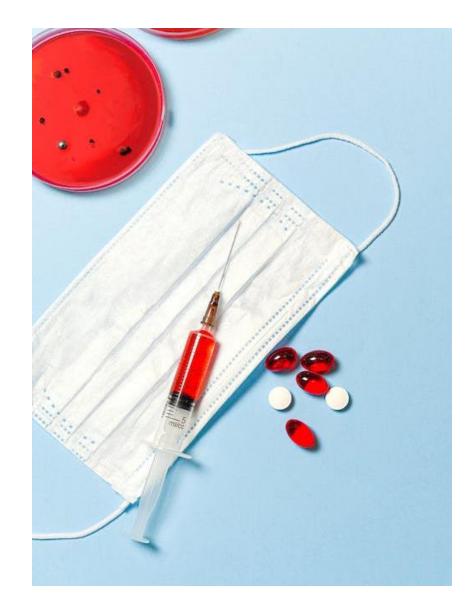
A North Carolina statute governing the confidentiality of information about someone who has (or may have) a reportable communicable disease or condition



Who Must Comply with G.S. 130A-143?

The law applies to "all information and records, whether publicly or privately maintained, that identify a person who has or may have a disease or condition required to be reported" under NC law

- Includes individuals/entities that regularly hold communicable disease information- e.g., health care providers, local health departments, laboratories, school employees, etc.
- ... but also, others who might hold this data: jails/prisons, schools, employers, insurance companies, etc.



What Information is Protected?

The law applies to "all information and records, whether publicly or privately maintained, **that identify a person who has or may have a disease or condition required to be reported**" under NC law



What Information is Protected? (cont.)

- Must be individually identifying- the law does not provide a deidentification standard, but NCDHHS has guidance on deidentification and small cell suppression
- Not limited to confirmed cases- includes information about someone who "may have" a disease or condition, such as someone who was exposed but has not yet been diagnosed
- Only applies to reportable diseases and conditions; see 10A NCAC 41A .0101 for a list of reportable diseases and conditions for NC

List of reportable diseases and conditions is found at **10A NCAC 41A .0101**

CHAPTER 41 - EPIDEMIOLOGY HEALTH

SUBCHAPTER 41A - COMMUNICABLE DISEASE CONTROL

SECTION .0100 - COMMUNICABLE DISEASE CONTROL

10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS

(a) The following named diseases and conditions are declared to be dangerous to the public health and are hereby made reportable within the time period specified after the disease or condition is reasonably suspected to exist:

- (1) acquired immune deficiency syndrome (AIDS) 24 hours;
- (2) acute flaccid myelitis -7 days;
- (3) anaplasmosis 7 days;
- (4) anthrax immediately;
- (5) arboviral infection, neuroinvasive 7 days;
- (6) babesiosis 7 days;
- (7) botulism immediately;
- (8) brucellosis 7 days;
- (9) campylobacter infection 24 hours;
- (10) Candida auris 24 hours;
- (11) Carbapenem-Resistant Enterobacteriaceae (CRE) 24 hours;
- (12) chancroid 24 hours;
- (13) chikungunya virus infection 24 hours;
- (14) chlamydial infection (laboratory confirmed) 7 days;
- (15) cholera 24 hours;
- (16) Creutzfeldt-Jakob disease 7 days;
- (17) cryptosporidiosis 24 hours;
- (18) cyclosporiasis 24 hours;
- (19) dengue 7 days;
- (20) diphtheria 24 hours;
- (21) Escherichia coli, shiga toxin-producing infection 24 hours;
- (22) ehrlichiosis 7 days;
- (23) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other and unknown causes - 24 hours;
- (24) gonorrhea 24 hours;
- (25) granuloma inguinale 24 hours;
- (26) Haemophilus influenzae, invasive disease 24 hours;
- (27) Hantavirus infection 7 days;
- (28) Hemolytic-uremic syndrome 24 hours;
- (29) Hemorrhagic fever virus infection immediately;
- (30) hepatitis A 24 hours;
- (31) hepatitis B 24 hours;
- (32) hepatitis B carriage 7 days;
- (33) hepatitis C, acute -7 days;
- (34) human immunodeficiency virus (HIV) infection confirmed 24 hours;
- (35) influenza virus infection causing death -24 hours;
- (36) legionellosis 7 days;
- (37) leprosy 7 days;
 - (38) leptospirosis 7 days;

Permitted Disclosures

- 1. Release only of deidentified medical/epidemiological information for statistical purposes
- 2. Written consent by the person who the information is about (or their personal representative)
- 3. Treatment, payment, and health care operations (TPO) or research, as defined under HIPAA
- 4. As necessary to protect the public health and in accordance with control measure rules
 - 5. In accordance with other laws in G.S. 130A, Article 6
 - 6. Release pursuant to a court order or subpoena by a judicial official
 - 7. Release is by NCDHHS or a LHD for enforcement under G.S. 130A, Article 6 or Article 22
- 8. Release is by NCDHHS or LHD to law enforcement (specific purposes only)
 - 9. Release is by NCDHHS or LHD to another federal, State, tribal, or local public health agency for purpose of preventing or controlling the spread of a communicable disease/condition
 - 10. Release is by NCDHHS for "bona fide research purposes" and in accordance with administrative rules
- 11. Release is made in accordance with G.S. 130A-144(b) to State Health Director or local health director
 - .2. Release is made pursuant to other laws specifically allowing/requiring release of AIDS information

Reminder: This is only a summary- please see the law for information about specific requirements for each disclosure.

G.S. 130A-143 Permitted Disclosures: Select Examples for Emergencies

As necessary to protect the public health and in accordance with control measure rules	 Both criteria must be satisfied: Necessary to protect the public health and Disclosure is made in accordance with control measure rules NC control measure rules are found at 10A NCAC 41A.0200 Specific rules for certain diseases (e.g., HIV, Hep C, syphilis) Otherwise, our rules refer to CDC control measures
Disclosure by NCDHHS or LHD to law enforcement	 Only permitted for the following purposes: To prevent or lessen a serious imminent threat to the health/safety of an individual or the public (as permitted under HIPAA) To enforce G.S. 130A, Article 6 (communicable disease) or Article 22 (terrorism incidents) For law enforcement investigation of a terrorist incident involving nuclear, biological, or chemical agents When NCDHHS or LHD seeks law enforcement help to prevent/control spread of disease

G.S. 130A-143 Permitted Disclosures: Select Examples for Emergencies (cont.)

Disclosure by NCDHHS or LHD to another gov. public health agency	Disclosure is made by NCDHHS or LHD to another federal, State, tribal, or local public health agency for the purpose of preventing or controlling the spread of a communicable disease
Disclosure is to State Health Director or local health director	 G.S. 130A-144(b) requires physicians, labs, and "all other persons" to- upon request and proper identification- allow the state or a local health director to examine, review, or get copies of health records that, in the state or local health director's opinion, pertain to the: Diagnosis, treatment, or prevention of a communicable disease for a person infected, exposed, or reasonably suspected of being infected or exposed to such a disease or condition, or The investigation of a known or reasonably suspected outbreak of a communicable disease or communicable condition.

References

Confidentiality Laws Covered in this Presentation

Name/description of law	What does it protect?	Legal citation
НІРАА	Protected health information (PHI)	45 CFR 160, 162, 164
G.S. 130A-143	Information about a person who has or may have a reportable communicable disease or condition	G.S. 130A-143 (for list of reportable diseases and conditions, see 10A NCAC 41A .0101)

Other Confidentiality Laws

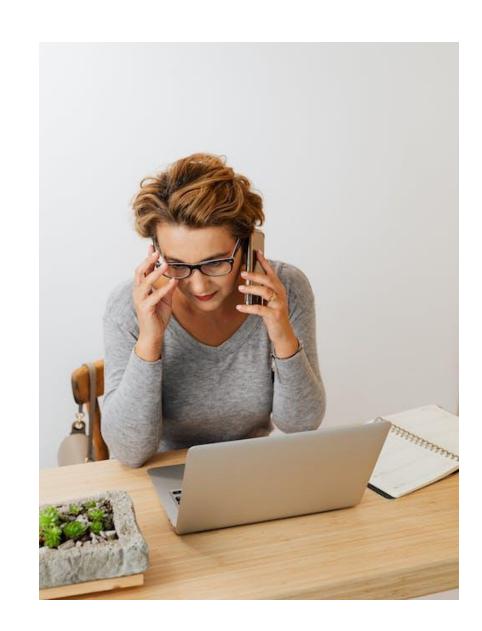
(this is not an exhaustive list)

Name/description of law	What does it protect?	Legal citation
State health director/local	Information provided to the state health	G.S. 130A-15(b)
health director right of access	director or local health director as	
law	required by G.S. 130A-15(a)	
Birth certificate confidentiality	Birth certificate information and records	G.S. 130A, Article 4
FERPA	Education records (including most school	20 U.S.C. 1232g; 34 CFR 99
	health records)	
Personnel information laws	Personnel information about LHD	G.S. 153A-98 (county and
	employees	district LHDs, some CHSAs)
NC's social security number	Social security numbers collected by	G.S. 132-1.10
law	government entities	
Mental and behavioral health	Information about individuals receiving	G.S. 122C
and IDD law	services for IDD, mental or behavioral	
	health	
42 CFR Part 2	Substance use disorder (SUD) treatment	42 CFR Part 2
	information	
Minor's consent confidentiality	Information about services provided to a	G.S. 90-21.4(b)
law	minor patient under G.S. 90-21.5(a)	

Image References

All images included in this presentation are from Pexels (<u>www.pexels.com</u>) unless otherwise noted and were last accessed on April 5, 2024.

Additional information about the license and use of images available from Pexels can be found here: <u>https://www.pexels.com/license/</u>.



Questions?

Thank you for your time.

If you have additional questions at a later date, please send me an email or give me a call.

Email: Kirsten@sog.unc.edu (preferred)

Office: 919-966-4210