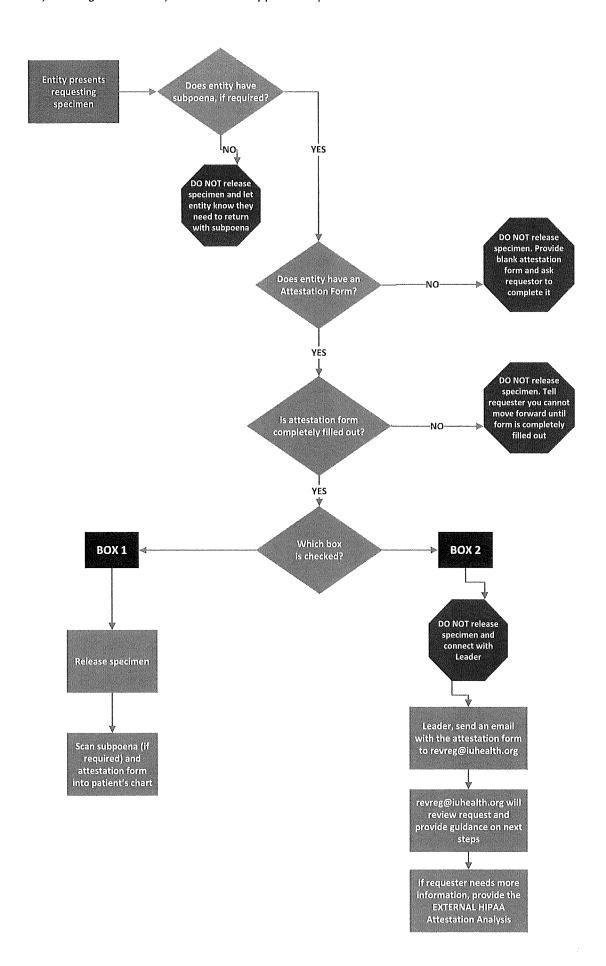
<u>DPLM PATHOLOGY LABORATORY – REQUIREMENTS FOR RELEASE OF SPECIMEN*</u>

NOTE: While release of specimen is most common for DPLM, these requirements apply to the release of all PHI, including tests ordered, test results or any protected patient information





ATTESTATION Request for Reproductive Health Care Protected Health Information

The entire form must be completed for the attestation to be valid.

	ecific Identification of the Class of Persons to or, agency, coroner, attorney and/or individual models.	-	
_	dentification of the Person or Class of Perso closure (i.e., name of IU Health Provider or Plan		
a description of the Class	HI requested, including Name(s) of Individus of Individuals, whose protected health informary for [name of individual] on [date]; list of individual [date] at [date]; list of individual].	ormation (PHI) you are	
	osure of PHI that I am requesting is not for a p 5 CFR 164.502(a)(5)(iii) because of one of t		
impose liability on any pe	or disclosure of protected health information erson for the mere act of seeking, obtaining, to identify any person for such purposes.		
liability on any person for thealth care, or to identify	or disclosure of protected health information <u>is</u> he mere act of seeking, obtaining, providing, or any person for such purposes, but the reprodusircumstances in which it was provided.	r facilitating reproductive	
knowingly and in violation	pe subject to criminal penalties pursuant to a of HIPAA obtain individually identifiable her individually identifiable health information to	ealth information relating	
Requestor/Representative Si	gnature Date		
Print Name of Requestor:			
Title or Authority of Request	or:		
Agency/Organization:	Phone Number:		
Release Of Inform	ATTESTATION Request for Reproductive Health Care PHI (07/01/2024)	RELEASE OF INFORMATION Y-99	



Release Of Inform



Indiana University Health

ATTESTATION Request for Reproductive Health Care Protected Health Information

The entire form must be completed for the attestation to be valid.

Name of Persons(s) or Specific Identification of the Class of Persons to receive the requested PHI (i.e., name of investigator, agency, coroner, attorney and/or individual making the request):

Example County Cordner Name or other Specific Identification of the Person or Class of Persons from whom You are Requesting the use or disclosure (i.e., name of IU Health Provider or Plan that maintains the PHI); Health Pathology Laboratory Description of specific PHI requested, including Name(s) of Individual(s), if practicable, or a description of the Class of Individuals, whose protected health information (PHI) you are requesting (i.e., visit summary for [name of individual and individual date of birth] on [date]; list of individuals who obtained [name of prescription medication] between [date range]): Specimen tested on 12/1/2024 for John Due, Date of birth 1/1/2021 I attest that the use or disclosure of PHI that I am requesting is not for a purpose prohibited by the HIPAA Privacy Rule at 45 CFR 164.502(a)(5)(iii) because of one of the following (check one box): The purpose of the use or disclosure of protected health information is <u>not</u> to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care or to identify any person for such purposes. The purpose of the use or disclosure of protected health information is to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, or to identify any person for such purposes, but the reproductive health care at issue was **not lawful** under the circumstances in which it was provided. I understand that I may be subject to criminal penalties pursuant to 42 U.S.C. 1320d-6 if I knowingly and in violation of HIPAA obtain individually identifiable health information relating to an individual or disclose individually identifiable health information to another person. Requestor/Representative Signature Print Name of Requestor: ___ Title or Authority of Requestor: Deputy Coroner Agency/Organization: Example County Coroner Phone Number: 317-5

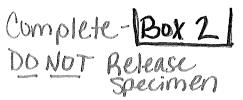
ATTESTATION

Request for Reproductive Health Care PHI

(07/01/2024)

RELEASE OF INFORMATION

Y-99





ATTESTATION Request for Reproductive Health Care Protected Health Information

The entire form must be completed for the attestation to be valid.
Name of Persons(s) or Specific Identification of the Class of Persons to receive the requested PHI (i.e., name of investigator, agency, coroner, attorney and/or individual making the request):
Example County Coroner
Name or other Specific Identification of the Person or Class of Persons from whom You are Requesting the use or disclosure (i.e., name of IU Health Provider or Plan that maintains the PHI):
IV Health Pathology Laboratory
Description of specific PHI requested, including Name(s) of Individual(s), if practicable, or a description of the Class of Individuals, whose protected health information (PHI) you are requesting (i.e., visit summary for [name of individual and individual date of birth] on [date]; list of individuals who obtained [name of prescription medication] between [date range]):
Specimen tested on 12/1/2024 for John Due, Date of birth 1/1/2021
I attest that the use or disclosure of PHI that I am requesting is not for a purpose prohibited by the HIPAA Privacy Rule at 45 CFR 164.502(a)(5)(iii) because of one of the following (check one box):
☐ The purpose of the use or disclosure of protected health information is <u>not</u> to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care or to identify any person for such purposes.
The purpose of the use or disclosure of protected health information <u>is</u> to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, or to identify any person for such purposes, but the reproductive health care at issue was <u>not lawful</u> under the circumstances in which it was provided.
I understand that I may be subject to criminal penalties pursuant to 42 U.S.C. 1320d-6 if I knowingly and in violation of HIPAA obtain individually identifiable health information relating to an individual or disclose individually identifiable health information to another person.
Requestor/Representative Signature 12/17/2024 Date
Print Name of Requestor: Jane Doe
Title or Authority of Requestor: Deputy Covered Phone Number: 317-555-555
Aganay/Organization EVO male Munty Manuel Phone Number 317-555, 555

Request for Reproductive Health Care PHI

(07/01/2024)

RELEASE OF INFORMATION

Y-99

New HIPAA Modifications – effective 06/25/2024; compliance date 12/23/2024

GENERAL INFORMATIONAL PURPOSES ONLY: The information provided in this document does not, and is not intended to, constitute legal advice; instead, all information, content, and materials available are for general informational purposes only. Additionally, the information may not be current and readers should contact their own attorney for any legal advice.

Effective June 25, 2024, HIPAA has been modified: (1) no protected health information (PHI) may be provided to Law Enforcement Officials under *administrative requests* only, as a Law Enforcement Official request for PHI must be enforceable in a court of law such as a Subpoena or Civil Investigative Demand (if no other HIPAA exception applies – for example, HIPAA exception under 45 CFR 164.152(f)(2) still applies for identification and location of suspect, fugitive, material witness or missing person + new Attestation; or required by law, such as IC 9-30-6-6 legal blood draw written exigent circumstances + Attestation); (2) no PHI may be released for a *Prohibited Purpose* under 45 C.F.R. §164.502(a)(5)(iii) – see below; (3) a *valid* **Attestation** form is to be provided if PHI requested potentially relates to reproductive health care by the following: **Law Enforcement Official** (Officer, Prosecutor, Agency), **Coroner/Medical Examiner**, **Judicial and Administrative Proceedings** (Subpoena, Court Order, Search Warrant) and **Health Oversight Activities** (the, Covered Purpose Requestors); (4) an *analysis* of the request, i.e., Subpoena, Attestation form, supplemental documentation, medical records and totality of the circumstances for a determination whether reliance on the Attestation is reasonable to permit release of PHI or not.

Patient information may NOT be released for a Prohibited Purpose.

Except as to the patient or pursuant to a signed patient authorization, covered entities and business associates may <u>not</u> disclose PHI for any of the following activities: (1) To conduct a criminal, civil, or administrative *investigation* into any person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care; (2) To impose criminal, civil, or administrative *liability* on any person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care; or (3) To *identify* any person for any purpose described in (1) or (2). Under HIPAA, reproductive health care: (i) is broadly defined to include all matters relating to the reproductive system and to its functions and processes and is not limited by gender; and (ii) is deemed lawful when lawful under law of state where provided; protected, required or authorized by federal law; or is provided by another person (provided by a person other than the regulated entity that receives the request for PHI) is presumed to be lawful. [NOTE: In order to overcome the presumption that reproductive health care performed by "another person" is lawful (and to reach a decision that it was *not lawful*), the covered entity or business associate must have any of the following: (A) Actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided; or (B) Factual information provided by the requestor of the PHI that demonstrates a *substantial factual basis* that the reproductive health care was not lawful under the specific circumstances in which it was provided. A *blanket statement* without supporting documentation from the requestor that it was unlawful is *insufficient*.]

Analysis

Once the *new* Attestation form is submitted along with the request (*i.e.*, Subpoena, Search Warrant, Court Order, form), a *new* analysis is conducted to determine whether the PHI can be produced or not. As stated above, PHI may <u>not</u> be disclosed for a **Prohibited Purpose**, and the **Attestation** form requires the Covered Purpose Requestor to state the purpose of the request (*i.e.*, box checked on form). A covered entity or business associate may rely upon the representations in an **Attestation** only if such reliance is *reasonable* under the *circumstances* taking into consideration the *stated purpose* of the requested use or disclosure of the PHI (*i.e.*, consider *totality of the circumstances*, is the request overly broad compared to the *stated purpose*, does box checked on Attestation conflict with underlying request, any public comments to the contrary; if a *reasonable* covered entity or business associate in the *same position* would not believe the **Attestation** as true, then it may not rely on it as not a *valid* Attestation). PHI may not be released in response to a *deficient* or *invalid* **Attestation** form submitted. Due to steps involved in the new analysis, an immediate determination may not be available.

45 C.F.R. §164.509; 45 C.F.R. §164.502(a)(5)(iii); 45 C.F.R. § 164.103; 45 C.F.R. § 160.203; 45 C.F.R. §164.512; 89 Fed. Reg. 32976 (April 26, 2024); https://www.hhs.gov/hipaa/for-professionals/special-topics/reproductive-health/final-rule-fact-sheet/index.html



Original Creation Date: 11/25/2024	Publication Date: 12/18/2024	
Owner: Julia Ohl (Associate General Counsel)	Next Review: 12/18/2026	
Category: HIPAA		

Approval Signatures: Michelle Altobella (Vice President-Chief Privacy Officer) (12/18/2024)

HIPAA Reproductive Health Care Attestation and Analysis

Education: Level 3

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

I. PURPOSE

On April 26, 2024, the Office for Civil Rights published a Final Rule entitled *HIPAA Privacy Rule to Support Reproductive Health Care Privacy* (the **Final Rule**), with an effective date of June 25, 2024, and compliance date of December 23, 2024. The Final Rule includes provisions to strengthen the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule by prohibiting the disclosure of protected health information related to lawful reproductive health care in certain circumstances and when to require an Attestation form.

II. SCOPE

This policy shall apply to all Covered Entity participants of the Indiana University Health Affiliated Covered Entity (IU Health ACE), all Workforce Members of IU Health ACE, IU Health Providers and when rendering services as Business Associates. Each reference to IU Health in this policy includes the IU Health ACE participating Covered Entities designated as a single Affiliated Covered Entity under 45 CFR 164.105(b).

Both Covered Entities and Business Associates are required to comply with the Final Rule requirements.

III. EXCEPTIONS

Any exception to this policy requires the approval of IU Health's Chief Privacy Officer, IU Health Legal Services or the IU Health Reproductive Health Care Review Committee.

IV. DEFINITIONS

Attestation means an Attestation form, in accordance with the specifications and content required by 45 C.F.R. §164.509, to be submitted to IU Health by a Covered Requestor who seeks Protected Health Information potentially related to Reproductive Health Care.

Breach means the unauthorized acquisition, access, use or disclosure of protected health information which compromises the security or privacy of such information. An impermissible use or disclosure of protected health information is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the protected health information has been compromised based on a risk assessment.

Business Associate means an individual or entity who acts on behalf of IU Health and assists in the performance of a function or activity involving the use or disclosure of Protected Health Information, such as claims processing or administration; data analysis, processing or administration; utilization review; quality assurance; billing; benefit management; practice management; or repricing.

Covered Purpose Requests means a *request* for any of the following *purposes* specified in 45 C.F.R. §164.509 for the use or disclosure of Protected Health Information potentially related to Reproductive Health Care: Health Oversight Activities [45 CFR §164.512(d)], Judicial and Administrative Proceedings [45 CFR §164.512(e)], Law Enforcement Official Activities [45 CFR §164.512(f)], and Coroners/Medical Examiner Activities [45 CFR §164.512(g)(1)].

Covered Requestor means a *requestor* of Protected Health Information potentially related to Reproductive Health Care for any of the following *purposes* specified in 45 C.F.R. §164.509: Health Oversight Activities, Judicial and Administrative Proceedings, Law Enforcement Official Activities, and Coroners/Medical Examiner Activities.

Health Oversight Activities means for health oversight agency activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of: (i) The health care system; (ii) Government benefit programs for which health information is relevant to beneficiary eligibility; (iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or (iv) Entities subject to civil rights laws for which health information is necessary for determining compliance. [45 CFR §164.512(d)]

Health Oversight Agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant. [45 CFR §164.501]

HIPAA means the Health Insurance Portability and Accountability Act of 1996, including the Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164), Security Rule (45 CFR Part 160 and Subparts A and C of Part 164) and Breach Notification Rule (45 CFR §§ 164.400-414), all as amended from time to time.), Security Rule (45 CFR Part 160 and Subparts A and C of Part 164) and Breach Notification Rule (45 CFR §§ 164.400-414), all as amended from time to time.

Individually Identifiable Health Information means individually identifiable health information, including demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse (or their business associates); and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual (including genetic information); or the past, present, or future payment for the provision of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Law Enforcement Official means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to: (1) Investigate or conduct an official inquiry into a potential violation of law; or (2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law. [45 CFR §164.103]

Minimum Necessary is a HIPAA standard that requires uses, disclosures and requests for PHI to be limited to the amount necessary to accomplish the intended purpose.

Prohibited Purpose means the *purpose* of the requested use or disclosure of Protected Health Information is (1) to conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating lawful Reproductive Health Care; (2) to impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating Reproductive Health Care; or (3) to identify any person for any purpose described in (1) or (2). [45 CFR §164.502(a)(5)(iii)]

Protected Health Information (PHI) means "individually identifiable health information" that is: (i) Transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium (e.g. electronic, oral or paper). PHI shall not include "individually identifiable health information" in education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g; records described at 20 U.S.C. 1232g(a)(4)(B)(iv); employment records held by a covered entity in its role as employer; and regarding a person who has been deceased for more than fifty (50) years.

Public Health, as used in the terms of "public health surveillance", "public health investigation", and "public health intervention" means population-level activities to prevent disease in and promote the health of populations. Such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of Protected Health Information. But such activities do not include those for a **Prohibited Purpose** (see definition above). [45 C.F.R. § 160.103]

Public Health Authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. [45 C.F.R. § 164.501]

Reproductive Health Care (RHC) means health care that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes. This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care. The definition includes the following non-exclusive list of examples: "contraception, including emergency contraception; preconception screening and counseling; management of pregnancy and pregnancy-related conditions, including pregnancy screening, prenatal care, miscarriage management, treatment for preeclampsia, hypertension during pregnancy, gestational diabetes, molar or ectopic pregnancy, and pregnancy termination; fertility and infertility diagnosis and treatment, including assisted reproductive technology and its components (e.g., in vitro fertilization (IVF)); diagnosis and treatment of conditions that affect the reproductive system (e.g., perimenopause, menopause, endometrios is, adenomyosis); and other types of care, services, and supplies used for the diagnosis and treatment of conditions related to the reproductive system (e.g., mammography, pregnancy-related nutrition services, postpartum care products)." Reproductive Health Care is not limited by gender. [45 CFR § 164.103; 89 Fed. Reg. 33006 (April 26, 2024)].

Reproductive Health Care Review Committee means a multi-disciplinary team under the direction and advice of inhouse corporate legal counsel that review escalated requests for Protected Health Information covered by this policy, receives legal advice and recommends action. The Committee is for internal IU Health requests for assistance only that may be sent to RevReq@IUHealth.org.

Required by Law means a mandate contained in law that compels an entity to make a use or disclosure of Protected Health Information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits. [45 CFR §164.103]

Treatment means the provision, coordination, or management of health care and related services among health care providers or by a health care provider with a third party, consultation between health care providers regarding an individual, or the referral of an individual from one provider to another.

V. POLICY STATEMENTS

- 1. Except as to the patient or pursuant to a signed authorization (*i.e.*, a signed Authorization for Release of Protected Health Information or ROI), IU Health may <u>not</u> disclose Protected Health Information if the *purpose* of the request is for any of the following **Prohibited Purposes**:
 - a. To conduct a criminal, civil, or administrative investigation into any person for the *mere act* of seeking, obtaining, providing, or facilitating **lawful** Reproductive Health Care;
 - b. To impose a criminal, civil, or administrative liability on any person for the *mere act* of seeking, obtaining, providing, or facilitating **lawful** Reproductive Health Care; or
 - c. To identify any person for the purposes described in a. and b. above.

"Seeking, obtaining, providing, or facilitating reproductive health care" is intended to be broad and includes but is not limited to any of the following: expressing interest in, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, administering, authorizing, providing coverage for, approving, counseling about, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same.

- 2. Reproductive Health Care is deemed "lawful" when:
 - The Reproductive Health Care is lawful under the law of the state where it is provided;
 - The Reproductive Health Care is protected, required, or authorized by Federal law; or
 - The Reproductive Health Care is provided by "another person" (i.e., provided outside IU Health) and is

presumed to be lawful.

- 3. In order to overcome the presumption that Reproductive Health Care performed by "another person" is lawful (and to reach the conclusion that it was *not lawful*), IU Health must have any of the following:
 - Actual knowledge that the Reproductive Health Care was <u>not</u> "lawful" under the circumstances in which it was provided; or
 - Factual information provided by the Covered Requestor requesting the PHI that "demonstrates a substantial factual basis" that the Reproductive Health Care was <u>not</u> "lawful" under the specific circumstances in which it was provided.
- 4. Analysis: Once the Attestation form is submitted by the Covered Requestor along with the request (i.e., Subpoena, Search Warrant, Court Order), a new analysis is conducted to determine whether the PHI requested can be disclosed or not. As stated above, PHI may <u>not</u> be disclosed for a **Prohibited Purpose**, and the Attestation form requires the Covered Requestor to state the *purpose* for which they are requesting PHI, under either:
 - a. Box 1 (i.e., PHI is <u>not</u> requested to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating lawful Reproductive Health Care or to identify any person for such purposes); or
 - b. Box 2 (i.e., PHI <u>is</u> requested to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating Reproductive Health Care or to identify any person for such purposes, but the Reproductive Health Care at issue was <u>not lawful</u> under the circumstances in which it was provided).

IU Health may rely upon the representations in an **Attestation** only if such reliance is *reasonable* under the *circumstances* taking into consideration the *stated purpose* of the requested use or disclosure (*i.e.*, consider *totality of the circumstances*, is the request overly broad compared to the *stated purpose*, does box checked on **Attestation** conflict with underlying request, any public comments to the contrary; if a *reasonable* Covered Entity or Business Associate in *same position* would not believe the **Attestation** as true, then may not rely on it as is not a *valid* **Attestation**). PHI may not be disclosed in response to a *deficient* or *invalid* **Attestation** form submitted.

IU Health must make a *reasonableness determination* about the lawfulness of the Reproductive Health Care under the circumstances in which such health care was provided. If IU Health provided the Reproductive Health Care and reasonably determines following a records review that the Reproductive Health Care was **lawful** under the circumstance in which it was provided, IU Health may <u>not</u> disclose the PHI requested under a Subpoena and **Attestation** where *Box 2* is selected. Likewise, where *Box 2* is selected on the **Attestation** and "another person" (outside of IU Health) provided the Reproductive Health Care, then IU Health must presume it was **lawful** and <u>not</u> disclose the PHI requested *unless* the Covered Requestor provides additional documentation to "demonstrate a substantial factual basis" that the Reproductive Health Care was <u>not</u> lawful or IU Health has "actual knowledge" that the Reproductive Health Care was <u>not</u> lawful. Due to the steps involved with the new analysis, an immediate determination may not be available.

- 5. Public Health: The Final Rule does not prevent disclosure of PHI to Public Health Authorities for Public Health purposes (*i.e.*, public health surveillance, investigation, or intervention), which may continue without an **Attestation**; provided, however, the Final Rule further states that permitted disclosures of PHI for Public Health purposes does <u>not</u> include permission to use or disclose PHI for a **Prohibited Purpose** (*i.e.*, PHI may <u>not</u> be disclosed to a Public Health Authority for the purposes of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing or facilitating lawful Reproductive Health Care, or to identify any such person). [89 Fed. Reg. 32999-33004, 33035 (April 26, 2024)]
- 6. Mandatory Reporting Laws: The Final Rule commentary provides that the **Attestation** is not required for (i) mandatory reporting for Public Health Activities under 45 C.F.R. § 164.512(b) such as report of child abuse and neglect or reporting of disease, injuries, birth or death; and (ii) mandatory reporting Required by Law under 45 C.F.R. § 164.512(a) such as report of death to a Coroner; provided, however, PHI may <u>not</u> be used or disclosed for a **Prohibited Purpose**. The **Attestation** applies when IU Health is disclosing PHI to a Coroner under 45 C.F.R. § 164.512(g)(1) such as for the purpose of identifying a deceased person or determining a cause of death. Further, the Final Rule commentary provides that the reporting of abortions is not included in the category

of reporting of deaths for the Public Health purposes under HIPAA and does not fall within the scope of state death reporting activities. [89 Fed. Reg. 32998, 33000, 33036 (April 26, 2024)]

VI. PROCEDURES

- A. IU Health must obtain a *valid* **Attestation** form if the *request* for PHI by a Covered Requestor is potentially related to Reproductive Health Care for *purposes* specified in 45 C.F.R. §164.509, the **Covered Purpose Request**:
 - Health Oversight Activities (*i.e.*, Indiana Department of Health; FDA; CMS; OSHA; EPA; OCR; Indiana Department of Insurance)
 - Judicial and Administrative Proceedings (i.e., Subpoena, Discovery Request, Court Order)
 - Law Enforcement Official Activities (*i.e.*, Search Warrant; Grand Jury Subpoena; Subpoena; Prosecutor Subpoena; Court Order; Attorney General Subpoena; any Agency when exercising Law Enforcement Official activities)
 - Coroners and Medical Examiners (i.e., Coroner Subpoena)
- B. The Covered Requestor submitting the **Attestation**:
 - a. Must sign the Attestation verifying that they are not requesting PHI for a **Prohibited Purpose** and acknowledging that criminal penalties may apply if untrue.
 - b. Must fully complete all blanks, not delete any content and not add any other content to the Attestation which is not required under 45 C.F.R. § 164.509.
 - c. May not combine the Attestation with any other document (*i.e.*, the Attestation may not be embedded within a subpoena but may accompany a subpoena as a separate document).
 - d. May submit additional documentation if requesting PHI provided by someone other than IU Health ("another person") to "demonstrate a substantial factual basis" the Reproductive Health Care in question was not lawful under the specific circumstances in which it was provided.
- C. IU Health may <u>not</u> rely on an **Attestation** to disclose PHI requested if any of the following is true (and, therefore, the Attestation is not *valid*):
 - It is missing any of the required elements or statements or contains other elements or statements that
 are not required.
 - It is combined with other documents, except for documents provided to support the Attestation.
 - IU Health knows that material information in the Attestation is false.
 - A reasonable Covered Entity or Business Associate in the same position would not believe the Covered Requestor's statement on the Attestation (i.e., box checked on Attestation form) that the use or disclosure is not for a **Prohibited Purpose**.
- D. If IU Health later discovers information that reasonably shows any representation made in the **Attestation** is materially false, leading to a use or disclosure for a **Prohibited Purpose**, IU Health must stop making the requested use or disclosure.
- E. IU Health must obtain a new Attestation for each specific use or disclosure request.
- F. The **Attestation** form is available *internally* on the IU Health Team Member Portal, *internally* from the IU Health, Health Information Management Department or *externally* on the IU Health website.
- G. IU Health must maintain a written copy of the **Attestation** and any relevant supporting documentation. Send all Covered Purpose Requests, **Attestation** form and any relevant supporting documentation directly to the IU Health, Health Information Management (HIM) Department (or your local medical records release clerk vendor under contract with HIM) for review, processing and to be scanned into the patient's electronic medical record. HIM (or medical records release clerk vendor) may escalate to the Reproductive Health Care Review Committee for assistance. Likewise, any IU Health Workforce Member may seek assistance under this policy by sending the Covered Purpose Request, **Attestation** form and any relevant supporting documentation directly to the Reproductive Health Care Review Committee at RegReg@iuhealth.org for review at its next meeting.
- H. When disclosing PHI pursuant to an Attestation, only the Minimum Necessary information required to meet

the request may be disclosed.

- I. Pursuant to an underlying service arrangement and HIPAA Business Associate Agreement, IU Health may continue to disclose PHI without an **Attestation** to IU Health Business Associates to perform services on behalf of IU Health. Once a Business Associate is in possession of the PHI, a Business Associate must comply with the new Final Rule, **Attestation** requirement, and analysis whether PHI may be disclosed or not in the same manner as IU Health.
- J. IU Health may disclose PHI to comply with certain mandatory reporting requirements Required by Law if the purpose is not a **Prohibited Purpose** and as specified in the Final Rule.

VII. CROSS REFERENCES

Business Associates
Disclosures for Law Enforcement Purposes
Privacy Breach Investigation and Breach Notification
Use and Disclosure of Protected Health Information

VIII. REFERENCES/CITATIONS

45 CFR 164.512(d)

45 CFR 164.512(e)

45 CFR 164.512(f)

45 CFR 164.512(g)(1)

45 CFR 164.509

45 CFR 164.502(a)(5)(iii)

45 CFR 164.501

45 CFR 164.103

Final Rule and Commentary at 89 Fed. Reg. 32976-33066 (April 26, 2024)

IX. FORMS/APPENDICES

Attestation Request for Reproductive Health Care Protected Health Information Form

Reproductive Health Care Attestation (*external* on IU Health website): https://iuhealth.org/patient-family-support/medical-records

X. APPROVAL BODY, IF APPLICABLE

None