**Uses and Disclosures of Protected Health Information**

**Purpose:**

To provide guidance on the appropriate uses and disclosures of Protected Health Information (PHI) for all employees.

**Policy:**

Trialomics, Inc will use and disclose Protected Health Information contained in a designated record set as required by and in compliance with the privacy regulations and state law.

**Procedure:**

1. Disclosing PHI for an approved request
   1. All PHI will be stored in an encrypted and password protected archive file and shared via an SFTP server with the individual.
2. De-identified health information and limited data set information
   1. Health information that has been de-identified is no longer considered protected health information and cannot be re-identified.
   2. De-identification consists of removal of the following identifiers of the individual or of relatives, employers, or household members of the individual:
      1. Names
      2. Geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code
      3. All elements of dates, except year, for dates directly related to an individual, including birth date, admission date, discharge date, date of death
      4. Telephone numbers
      5. Fax numbers
      6. Electronic mail addresses
      7. Social security numbers
      8. Medical record numbers
      9. Health plan beneficiary numbers
      10. Account numbers
      11. Certificate/license numbers
      12. Vehicle identifiers and serial numbers, including license plate numbers
      13. Device identifiers and serial numbers
      14. Web universal resource locators (urls)
      15. Internet protocol (IP) address numbers
      16. xvi.Biometric identifiers, including finger and voice prints
      17. xvii.Full-face photographic images and any comparable images
      18. xviii.Any other unique identifying number, characteristic, or code.
   3. Information that is contained in a limited data set may be used or disclosed in conjunction with a limited data set agreement when the above direct identifiers of the individual or of relatives, employers, or household members of the individual have been eliminated.
3. Minimum necessary
   1. Trialomics, Inc will only disclose the minimum amount of PHI necessary to accomplish the intended purpose of the use or disclosure.
   2. Trialomics, Inc will independently determine the necessary minimum disclosure and will verify that only the minimum necessary information is used or disclosed.
   3. This minimum necessary requirement does not apply to uses and disclosures of PHI to the patient, for treatment, pursuant to an authorization, a disclosure required by law, a disclosure to a health oversight agency, a disclosure necessary to comply with the privacy rule, or a disclosure to the Secretary of Health and Human Services.
   4. Trialomics, Inc will identify persons in the workforce and other persons (medical staff, business associates) who require access to PHI to carry out their specific duties and will take reasonable steps to limit access to PHI for those individuals or categories of individuals in carrying out their duties.
4. Verification
   1. When a disclosure of PHI is conditioned upon particular documentation, statements, or representations, prior to the disclosure of the PHI, the identity of the person making the request and the authority of the person to make the request shall be verified. The verification method and request will be documented in the PHI Requests tab of the Periodic Ledger.
   2. Verification may consist of written representations, verbal representations and personal knowledge.
   3. Trialomics, Inc may rely upon the representations and documentation provided to it, if the reliance is reasonable under the circumstances (for example, a law enforcement officer’s badge or a letter written on agency letterhead).
5. Incidental disclosures
   1. An incidental disclosure is a disclosure that is a by-product of an authorized use or disclosure of PHI.
   2. It is a disclosure that is limited in nature and cannot be reasonably prevented.
      1. Example: posting the name of a patient on a white board or maintaining a sign in sheet.
   3. Prior to making an incidental disclosure, the employee or business associate will verify that the disclosure cannot reasonably be prevented or minimized.
6. Authorization
   1. When a use or disclosure is not otherwise permitted under these policies, Trialomics, Inc will secure a valid authorization prior to making any use or disclosure of PHI.
   2. If Trialomics, Inc sells PHI, or otherwise uses or disclosures PHI for marketing purposes, an authorization will be secured prior to such sale or use/disclosure for marketing purposes. *[see Authorization to Use and Disclose Protected Health Information.]*
7. Uses and disclosures for treatment, payment, and health care operations
   1. No authorization is necessary for uses and disclosures of PHI for the patient’s treatment, for payment of the patient’s treatment, or for Trialomics, Inc’s health care operations.
      1. Health care operations include quality assessment and improvement activities such as:
         1. Evaluations and development of clinical guidelines (provided that the obtaining of generalized knowledge is not the primary purpose for these studies)
         2. Population-based activities relating to improving health care or reducing health care costs, protocol development, case management and care coordination
         3. Contacting providers and patients about treatment alternatives
         4. Activities of patient safety organizations
         5. Reviewing the competence and qualifications of health care professionals
         6. Evaluating health plan, practitioner, and provider performance
         7. Conducting training programs in which students and trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers
         8. Training of non-health care professionals
         9. Accreditation, certification, licensing, and credentialing
         10. Underwriting, premium rating, or activities relating to the creation, renewal or replacement of a health insurance or benefits contract
         11. Medical reviews
         12. Legal services
         13. Auditing functions (including fraud and abuse, compliance programs)
         14. Business planning, business development, cost planning and management-related analysis of the entity’s operations
         15. Formulary development and administration
         16. Development or improvement of methods of payment or coverage policies
         17. Business management
         18. General administrative activities
         19. Customer service
         20. Resolution of internal grievances
         21. Activities related to the sale, transfer or merger of the covered entity
8. Uses and disclosures to individuals involved in the patient’s care (including descendants) or for disaster relief
   1. No authorization is necessary and PHI may be used or disclosed, to:
      1. Any person identified by the patient (or the personal representative) as being involved in his/her care, including a “support person”
      2. Notify a family member, personal representative, or other person responsible for the care of the patient of his/her location, general condition, or death
      3. A disaster relief organization. To make such disclosure:
         1. The person must be present during the health care communication and the patient must not object to his/her presence.
         2. The patient must agree to the disclosure or it is reasonable to infer (based upon the provider’s professional judgment) from the circumstances that the patient would not object to the disclosure.
         3. If the patient is not present or is not able to object, a disclosure may be made when, in the professional judgment of the provider, the disclosure is in the patient’s best interests.
         4. Disclosures must be limited to information directly related to the individual’s involvement in the patient’s care.
      4. PHI about a descendent may also be released to family members or individuals involved in the patient’s care or payment for care prior to death, unless doing so is inconsistent with any known prior expressed preference of the descendent.
         1. The disclosure is limited to the family member’s or other individual’s actual involvement in the patient’s care or payment for care.
            1. Example: Trialomics, Inc could describe the circumstances that led to the descendent’s death with the descendent’s sister who asks about her sibling’s death.
            2. It is also appropriate to disclose billing information to a family member that is assisting with the descendent’s estate. The disclosure will not include information about past, unrelated medical problems.
      5. Prior to making a disclosure about a descendent, Trialomics, Inc will obtain reasonable assurances that the family member or individual requesting the PHI was involved in the patient’s care or payment for care prior to the descendent’s death.
         1. Example: the family member or individual may be asked to provide information concerning how he/she is related to the descendent or details about the descendent’s condition prior to his/her death.
9. Uses and disclosures required by law
   1. Trialomics, Inc may use and disclose PHI without authorization when the disclosure is required by federal or state statute or regulation and the disclosure complies with and is limited to the requirements of the law.
   2. The particular privacy requirements pertinent to those subjects (and as described in this policy) must be met if the disclosure:
      1. Involves adult abuse, neglect or domestic violence
      2. Involves judicial or administrative proceedings
      3. Is for law enforcement purposes
10. Uses and disclosures for public health activities
    1. A public health authority is an authority mandated by law or regulation to collect or receive information to prevent or control disease, injury, disability, or to conduct public health surveillance, investigations, or interventions.
    2. Trialomics, Inc may use and disclose PHI without authorization to a public health authority for public health activities.
    3. Public health activities include but are not limited to:
       1. Reporting specific diseases and conditions
       2. Reporting births and deaths for vital statistics
       3. Reporting child/adult abuse and neglect
       4. Reporting FDA-regulated products or activities
       5. Reporting persons exposed to or at risk for contracting or spreading communicable diseases.
       6. When the patient is provided with a written communication prior to treatment, PHI may be disclosed without authorization to an employer when the treatment is provided to the patient at the employer’s request for a work-related illness or injury, for workplace related health surveillance, or for OSHA compliance
11. Uses and disclosures of immunizations
    1. Trialomics, Inc may disclose immunization information to a school upon the written or verbal consent of a parent, guardian, or person acting in place of the parent (pursuant to the parent’s direction).
    2. This consent must be documented in the child’s health record.
       1. Example: if the parent submits a letter or email request to Trialomics, Inc for the disclosure of the child’s immunization records to the child’s school, a copy of the letter or email will be maintained in the child’s health record.
       2. If the parent calls the office and requests over the telephone that his/her child’s immunization records be disclosed to the minor’s school, Trialomics, Inc will make a notation in the minor’s health record of the telephone call.
          1. The notation must include the time the telephone call was received
          2. The workforce member who took the telephone call
          3. The workforce member who logged the telephone call into the child’s health records
          4. A general description of the request
12. Uses and disclosures about victims of abuse, neglect, or domestic violence
    1. Trialomics, Inc will report child and adult abuse as required by law. No authorization is necessary to use and disclose PHI for reporting abuse or neglect.
    2. Child abuse reports
       1. When Trialomics, Inc has reason to suspect that a child has been injured as a result of physical, mental, or emotional abuse, neglect, or sexual abuse, Trialomics, Inc will report the suspected abuse or neglect to law enforcement or other proper authorities.
       2. The report must include:
          1. Name of child
          2. Address
          3. Location
          4. Names of persons responsible for child and their addresses
          5. Gender
          6. Race
          7. Age
          8. Reasons why the reporter suspects the child may be in need of care
          9. Nature and extent of harm to child, including evidence of previous harm
          10. Any other information the reporter believes is helpful to establish the cause of harm
    3. Adult abuse reports
       1. When Trialomics, Inc has reason to suspect that an individual over the age of 18 who is cared for in a facility or the home of a family member, friend, or caretaker, Trialomics, Inc will report the suspected abuse or neglect to law enforcement or other proper authorities.
       2. Receives community services funded by the state
       3. An individual who is over the age of 18 who is unable to otherwise protect his/her own interests, has been abused, neglected, exploited, is in a condition that is the result of abuse, neglect, or exploitation
       4. Is in need of protective services, Trialomics, Inc will report the suspected abuse or neglect to law enforcement or other proper authorities.
       5. The report must include:
          1. The name and address of the reporter
          2. Name and address of the caretaker of the individual
          3. Information regarding the nature and extent of abuse, neglect or exploitation
          4. Name of next of kin
          5. Any other information the reporter believes might be helpful in an investigation of the case and the protection of the individual.
    4. In addition to mandated child and adult abuse or neglect reports, Trialomics, Inc may disclose PHI to report child or adult abuse or neglect without authorization:
       1. When the patient/personal representative agrees to the disclosure and the agreement is documented in the health record.
       2. When the disclosure is authorized by statute and Trialomics, Inc believes the disclosure is necessary to prevent serious harm to the patient or another potential victim.
       3. When the disclosure is authorized by statute and the patient is unable to agree because of incapacity.
       4. When the agency or law enforcement official receiving the report agrees not to use the information against the patient and the reporter believes that immediate law enforcement activity is necessary and cannot wait for patient/personal representative agreement.
       5. And, unless the patient would be placed at risk of harm or the personal representative is believed to be the perpetrator of the abuse or neglect, Trialomics, Inc must inform the patient/personal representative of the disclosure.
13. Uses and disclosures for health oversight activities
    1. A health oversight agency is an agency of the United States, a state, a political subdivision of a state, a Native American Tribe, or any person, contractor, or entity acting on its behalf.
    2. Trialomics, Inc may use and disclose PHI without authorization to a health oversight agency for its oversight activities including:
       1. Audits
       2. Civil
       3. Criminal
       4. Administrative investigations
       5. Inspections
       6. Licensure
       7. Disciplinary actions
       8. Determinations of regulatory compliance
    3. Authorization is necessary when:
       1. The patient is the subject of an investigation and the investigation does not arise out of or is not directly related to the delivery of health care services to the patient
       2. A health care related claim for public benefits is made and the patient’s health is integral to the claim
       3. The patient qualifies for or receives public benefits.
14. Uses and disclosures for judicial and administrative proceedings
    1. Trialomics, Inc may use and disclose PHI (except substance abuse treatment records and psychotherapy notes) when the information is requested for judicial or administrative proceedings.
    2. To disclose PHI without authorization the patient’s condition is an issue in the proceeding and:
       1. There is a court order (approved and signed by a judge) authorizing the disclosure of PHI
       2. A judge has signed a subpoena requiring the production of PHI
       3. A district attorney or attorney general has issued a subpoena for a properly formed inquisition or investigation
       4. A subpoena or other discovery request has been issued, and there are satisfactory assurances accompanying the subpoena or discovery request in the form of a written statement and supporting documentation that show:
          1. The requesting party has notified the patient of the request for his/her PHI
          2. The requesting party has provided sufficient information so the patient could object to the request
          3. The time to object has passed without the patient making an objection or the court has ruled on an objection in favor of the requestor
       5. The parties in the legal proceeding have agreed to a protective order and have presented a protective order to the court and the subpoena or other discovery request contains a copy of the proposed order and the proposed order prohibits the parties from disclosing the PHI for any purpose other than the judicial proceeding and requires the parties destroy or return the PHI at the end of the case
    3. Substance abuse treatment records of providers may only be disclosed without an authorization when there is a court order and a subpoena.
    4. In civil cases:
       1. The order must limit disclosure to parts of the patient record necessary to fulfill the objective of the order and limit disclosure to persons whose need for the information is the basis for the order.
       2. The order must contain findings that the disclosure is necessary.
       3. Other ways of obtaining the information are not effective or would not be available.
       4. The public interest or need for the disclosure outweighs the potential injury to the patient or the physician-patient relationship.
    5. In criminal cases:
       1. The order must limit disclosure to parts of the patient record necessary to fulfill the objective of the order
       2. The order must limit disclosure to those law enforcement and prosecution officials who are responsible for conducting the investigation or prosecution
       3. The order must limit use of the records to investigation and prosecution of an extremely serious crime or suspected crime
       4. The order must contain findings that the crime is serious
       5. There is a reasonable likelihood that the records will disclose information of substantial value to the investigation or prosecution
       6. Other ways of obtaining the information are not effective or would not be available
       7. The potential injury to the patient or the physician-patient relationship is outweighed by the public interest and need for disclosure
       8. If the applicant for the order is a law enforcement official that the entity holding the records has been afforded the opportunity to be represented by counsel
15. Uses and disclosures for law enforcement purposes
    1. Trialomics, Inc may use and disclose PHI without authorization to a law enforcement official, state attorney general, district attorney or police officer:
       1. To report suspected child or adult abuse
       2. To report bullet wounds, gunshot wounds, powder burns, injuries caused by discharge of a firearm, knife wounds, or wounds from other sharp objects which are likely to result in death
       3. To report a death that is the result of criminal activity
       4. To report criminal conduct on Trialomics, Inc’s property
       5. To alert law enforcement officials about a crime which was not committed on Trialomics, Inc‘s property, when the information comes from the provision of emergency treatment
          1. The information reported may include:
             1. The location of the crime
             2. Victims of the crime
             3. The identity of the alleged perpetrator
             4. A description of the alleged perpetrator
             5. The location of the alleged perpetrator
       6. When a law enforcement officer requests information to identify or locate a suspect, fugitive, missing person, or material witness
          1. The information disclosed must be limited to:
             1. Name
             2. Address
             3. Date of birth
             4. Blood type
             5. Type of injury
             6. Distinguishing characteristics
             7. Date of treatment
             8. Time of treatment
             9. Date of death
             10. Time of death
       7. When a patient is the victim of a crime and a law enforcement official requests information
          1. The patient agrees to the disclosure of information
          2. If the patient is not able to agree:
             1. The law enforcement officer denotes that the information is necessary to determine if a crime has been committed by someone other than the patient
             2. That delay in obtaining the information would adversely impact law enforcement activity
             3. Trialomics, Inc determines in its professional judgment that disclosure is in the best interests of the patient
    2. The patient’s health information should contain documentation of law enforcement disclosures.
16. Uses and disclosures about descendents
    1. Trialomics, Inc may, without authorization, use and disclose PHI to a coroner or medical examiner to determine the identity of the descendent and/or determine the cause of death.
    2. Trialomics, Inc may, without authorization, disclose PHI to a funeral director to carry out his/her duties.
    3. Trialomics, Inc may, without authorization, disclose information to family members and individuals involved in the descendent’s care provided the disclosure is limited to the family member or other individuals involved in the care
    4. A descendent’s protected health information is no longer protected by the privacy regulations after fifty (50) years from the date of death
17. Uses and disclosures for organ donations
    1. Trialomics, Inc may, without authorization, use and disclose PHI to an organ procurement organization or entity engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating donation and transplantation.
18. Uses and disclosures to avert serious threats to health and safety
    1. Trialomics, Inc may, without authorization, use and disclose PHI whenTrialomics, Inc in good faith believes the use or disclosure is necessary to lessen or prevent a serious and imminent threat to the health or safety of a person and
       1. The use or disclosure is made to a person or entity that is able to prevent or lessen the threat, including the target of the threat
       2. The use or disclosure is necessary for law enforcement to identify or apprehend an individual based upon that individual making a statement which admits participation in a violent crime which may have caused serious physical harm to the victim
       3. When it appears from all the circumstances that the individual has escaped from a correctional institution or law enforcement custody
       4. Unless Trialomics, Inc learns about this information during a course of treatment to affect the propensity to commit the criminal conduct that is the basis for the statement
       5. Or person making the statement is seeking to initiate treatment or be referred for treatment for the type of conduct that is the basis for the statement
    2. Trialomics, Inc may only disclose
       1. Name and address
       2. Date and place of birth
       3. Social security number
       4. Blood type
       5. Type of injury
       6. Date and time of treatment
       7. Date and time of death
       8. Description of distinguishing characteristics.
19. Uses and disclosures for special government functions
    1. Trialomics, Inc may use and disclose without authorization:
       1. PHI of armed forces personnel to military command authorities for activities necessary for proper execution of the military mission
          1. If a patient is a component of the department of defense, Trialomics, Inc may use and disclose the PHI of a veteran or of a member of the armed forces upon separation or discharge to the department of veteran’s affairs for a determination of eligibility or entitlement for veteran’s benefits
       2. PHI of a member of a foreign military force to a foreign military authority for proper execution of the military mission
       3. To authorized federal officials to conduct lawful intelligence and counterintelligence activities authorized by the national security act
       4. To authorized federal authorities for the security and protection of the president, other individuals who are provided federal protective services, or foreign heads of state provided protective services
       5. To determine medical suitability for a state department security clearance
       6. To determine medical suitability for foreign service
       7. To determine medical suitability for a family member to accompany a member of the foreign service abroad.
20. Uses and disclosures to correctional institutions or about persons in law enforcement custody
    1. Trialomics, Inc may use and disclose without authorization the protected health information of a person who is in custody or who is presently incarcerated to a correctional facility or law enforcement official when
       1. The disclosure is necessary to treat the person
       2. The information is necessary to protect the health and safety of other inmates, persons, or employees at the correctional facility or who transport the person*.*
21. Uses and disclosures for workers compensation
    1. Trialomics, Inc may use or disclose without authorization PHI for treatment related to a worker’s compensation claim when the disclosure is made to the
       1. Patient
       2. Employer
       3. State division of worker’s compensation
       4. Parties to the worker’s compensation proceeding
       5. Third party worker’s compensation payer
       6. Individuals providing treatment.
22. Trialomics will not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any individual for the exercise by the individual of any right established, or for participation in any process against any individual who files a complaint.