

# HIPPA-NEW REQUIREMENT TO CLINICAL STUDY PROCESS

- CLINICAL TRIAL” is a systematic study of new drug in human subjects to generate data for discovering and/or verifying the clinical, pharmacological and adverse effects with the objective of determining safety and efficacy of the new drug.
- HIPPA is the Health Insurance Portability and Accountability Act of 1996.
- It is a Privacy rule provides Federal Privacy Protection for individually identifiable health information called Protected Health Information.

- Title 1 :Protects Health Insurance Coverage for workers and their families when they change or lose their job.
- Title 2: Prevents Health care Frauds and Abuse. [?]
- Title 3: Guidelines for Pre-Tax medical spending.
- Title 4: Guidelines for Group Health Insurance Plans.
- Title 5: Governs company owned Life Insurance policies.

- HIPPA – IN CLINICAL TRIALS
- **HIPPA research covered entity protected health information:** Covered Entity Physician. He should accept the Proposal developed by the Researcher for obtaining PHI. PHI is needed for writing Protocol for Clinical studies. Potential Health Subjects. An Individual's written authorization is required for Protected Health Information. Authorization Waivers can be Granted by IRB'S Accounting and Reporting of disclosures are required.

- **Multiple disclosures general disclosures:** It includes disclosure of Date , recipient , address It includes disclosure of Date , Recipient , recipient address and Purpose of Disclosure , Frequency of Disclosure.
- Accounting is not needed for Disclosures of meager information Disclosure of PHI helps to withdrawal a particular patient.
- Patient has signed a written Authorization. Institutional review board Covered Entity has de-identified the data prior to the research.
- The data are constrained between the researcher and the covered entity.
- Disclosure to the Sponsor only with the waiver of HIPPA from IRB.

- Sponsor request summary information about Physician's Patient Privacy rule.
- Privacy rule permits the physician to review for the patient medical records Protected Health Information.
- NO protected Health information should be removed from the covered entity during the review by the Sponsor.
- Power must be for a Specific Research study It should be combined with Informed consent Maintenance of a Research repository or the Database.

- Privacy rule allows the physician to recruit his own patient. If a contract Research organization wishes to recruit the patient. They should get a partial waiver of HIPPA authorization from the Institutional review board.
- Bodily injury - Within acceptable limits Exacerbation of Pre – existing bodily injury. Genetic Damage Bodily injury arises due to an addiction.
- Funding organization Agency of Healthcare Research and quality. Centers for Disease control and prevention. Centre for Medicare and Medicaid Services
- Marilyn Windschiegl HIPPA Basics For Clinical Research 2007 12-25.
- Karen Blackwell New HIPPA Privacy Regulations Governing Research

THANK YOU.