

# Events and Information that Require Prompt Reporting to the IRB



**Bertha deLanda**  
**Research Compliance Office**  
**June 2011**

# Outline

## GUI-P13

- 1) UPs (discussed previously)
- 2) New information
- 3) Protocol deviations
- 4) Complaints
- 5) Incarceration
- 6) Unanticipated adverse device effect
- 7) Other events or information where “prompt reporting” to the IRB is not required

# UPs (Unanticipated Problems)

## CRITERIA

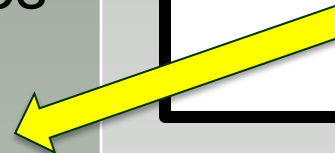
Related  
Unexpected  
Puts subject at greater risk of harm



## EXAMPLES

Internal or external  
Deaths  
Life-threatening experiences  
Injuries  
Breaches of confidentiality

**NOTE** - A "UP" warrants substantive changes in the protocol or IC document, or other actions, in order to protect the safety, welfare, or rights of subjects or others.



# 11.4 Confidentiality Breach – Unauthorized Release of Information

## The IRB:

- requires that PDs immediately report any possible or actual unauthorized release of information (breach of confidentiality)
- may receive a complaint or allegation from a participant about such a release
- will report any breach of confidentiality involving VA research information to the VA Privacy Officer

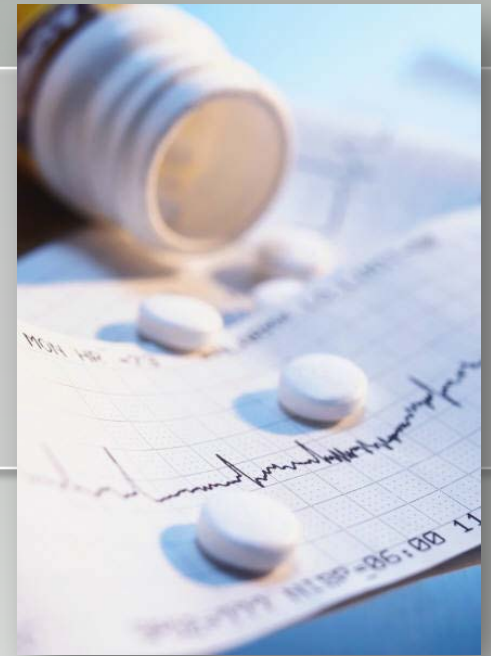


## 2) New Information

...that indicates a change to the risks or potential benefits of the research in terms of severity or frequency

***Example:***

analysis indicates lower-than-expected response rate or a more severe or frequent side effect



# 3) Protocol Violation or Deviation

## *Report only if:*

- Intended to eliminate apparent immediate hazard to a research participant
- or**
- Harmful (caused harm to participants or others, or placed them at increased risk of harm - including physical, psychological, economic, or social harm)
- or**
- Possible serious or continued non-compliance



# Non-compliance (NC)

## **Definition (non-compliance):**

*An activity...at variance with the approved IRB protocol, other requirements and determinations of the IRB, the HRPP Manual and other applicable policies of STANFORD*

***Allegation of non-compliance:*** A report of non-compliance that represents an unproven assertion

***Finding of non-compliance:*** Non-compliance that is true, or an allegation of non-compliance that is determined to be true based on a preponderance of the evidence





# Review of Allegations/Findings

## Reports are:

- Initially evaluated by staff
- Immediate action is taken, as necessary, to prevent unacceptable risk to research participants

## Report requires no further action by PD if the non-compliance is:

- ❖ A factual assertion of non-compliance;
- ❖ Neither serious nor continuing; *AND*
- ❖ Addressed by the investigator through a corrective action plan to remedy the problem

***If a report is an allegation, the RCO Director or delegate will review the report***




# Serious and Continuing NC

When determining...	Per Stanford HRPP	Per VA Handbook 1058.01
Serious	affects the rights or welfare of human subject research participants	failure to adhere to the laws, regs, or policies governing HR
<div data-bbox="156 629 301 758" style="background-color: #006400; color: white; border-radius: 50%; width: 40px; height: 40px; display: flex; align-items: center; justify-content: center; margin: 0 auto;"> <span data-bbox="179 672 285 715" style="font-weight: bold; font-size: 1.2em;">&amp;/or</span> </div> Continuing		(1) Involving substantive harm, or risk of harm, to the safety, rights, or welfare of subjects, research staff, or others; or  (2) Substantively compromising the effectiveness of a facility's HR protection/oversight programs

**Reporting to FDA, federal funding agency (sponsor) and OHRP may be necessary**

# Serious and Continuing NC

When determining...	Per Stanford HRP	Per VA Handbook 1058.01
Serious 	affects the rights or welfare of human subject research participants	failure to adhere to the laws, regs, or policies governing HR
Continuing	a pattern that indicates deficiency likely to result in further NC ...or ... (when) an investigator fails to cooperate with investigating or correcting NC	persistent failure to adhere to the laws, regulations, or policies governing human research

**Reporting to FDA, federal funding agency (sponsor) and OHRP may be necessary**

# 4) Complaint

...that is unresolved by the research team, or that indicates increased or unexpected risks

E.g., complaint by a participant about how they were treated during a study



# 5) Incarceration

...when in the opinion of the PD it is in the best interest of the participant to remain on the study



e.g., when follow up is necessary for the well-being of the subject

Subpart C –  
Additional  
Protections  
for Prisoners

- PD notifies IRB, the IRB Chair makes determination about continued participation until Subpart C is satisfied
- IRB must determine that Subpart C is satisfied

## 6) Unanticipated Adverse Device Effect (UADE)

New information about the effect on health or safety or any life-threatening problem or death

- caused by, or associated with, a device
- if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence
- or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects



# 7) Other events or info where “prompt reporting” to the IRB is not required

Such as internal events that are unexpected and related to the research, but are not UPs

Example:

Observations made by external auditors, such as sponsors

*“Report only after consulting with IRB Education”*

