REPORTING AND MANAGEMENT OF CONCERNS

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- Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the HRPP may be reported orally or in writing
- The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions
- The IO/OO has the responsibility to investigate all other reports and take corrective actions
- Report within **5 days**

REPORTING AND MANAGEMENT OF CONCERNS

- **Contact the IRB** office with questions (cuhs@harvard.edu)
- Submit Report of New Information (**RNI**) in ESTR
- Contact the IO/OO
  - Ara Tahmassian, Ph.D. (ara_tahmassian@harvard.edu)

IRB DETERMINES

- Not noncompliance or an unanticipated problem
- Minor noncompliance: Noncompliance that is neither serious nor continuing
- An unanticipated problem involving risks to subjects or others
- Serious or continuing non-compliance with the regulations or the requirements or determinations of the IRB
- Necessitates suspension or termination of IRB approval

UPIRTSO DEFINITION

Any information that is

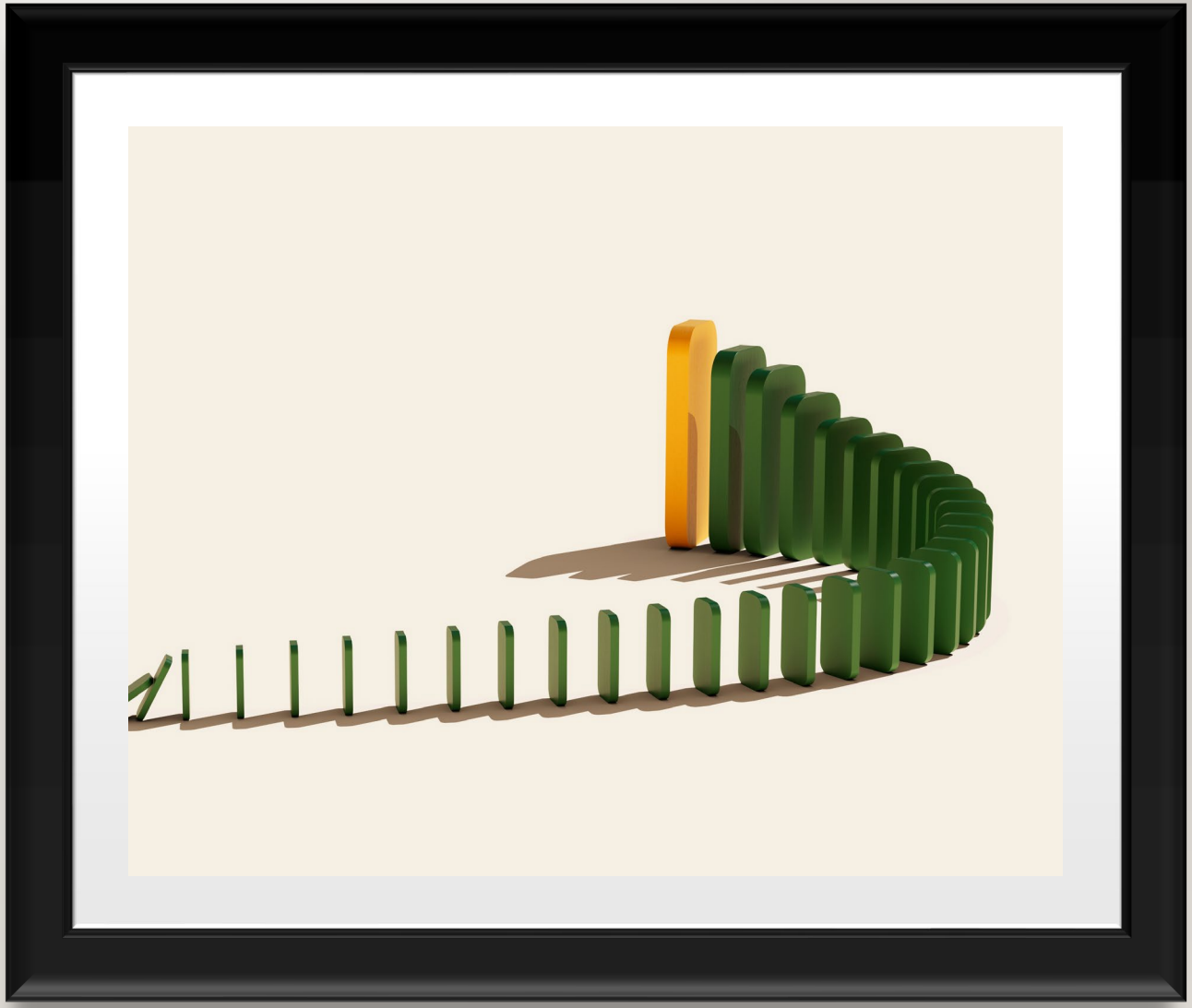
- Unanticipated
- Related to the research, and
- Indicates that subjects or others are at increased risk of harm

UPIRTSO CRITERIA

Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied

UPIRTSO CRITERIA

Related or possibly related to participation in the research (where possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research)



UPIRTSO CRITERIA

Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized

IRB DETERMINES: ACTION PLAN

- Modify protocol or consent process
- Give additional info to participants
- Observation by IRB and/or monitor
- Request PI receive training
- Notify other relevant parties
- Transfer, suspend, or terminate study

UPIRTSO ACTION PLAN

- Changes to the research protocol initiated by the investigator prior to obtaining IRB approval to eliminate apparent immediate hazards to subjects;
- Modification of inclusion or exclusion criteria to mitigate the newly identified risks;
- Implementation of additional procedures for monitoring subjects;
- Suspension of enrollment of new subjects;
- Suspension of research procedures in currently enrolled subjects;
- Modification of informed consent documents to include a description of newly recognized risks; and
- Provision of additional information about newly recognized risks to previously enrolled subjects.

UPIRTSO ACTION PLAN

- Consider whether the affected research protocol still satisfies the requirements for IRB approval under HHS regulations at 45 CFR 46.111
- Consider whether risks to subjects are still minimized and reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result

REPORTING AND MANAGEMENT OF CONCERNS

For more on reporting see:

- **HRP-101** HUA Human Research Protection Program Plan
- **HRP-103** HUA Investigator Manual
- **HRP-321** WORKSHEET Review of Information Items
- "Researcher Responsibilities After Review" in the **IRB Lifecycle** at cuhs.harvard.edu