DREXEL UNIVERSITY
Office of
Research &
Innovation

POLICY: Prompt Reporting Requirements			
Document No.:	**Edition No.:**	**Effective Date:**	**Page:**
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1. PURPOSE

1.1. This policy describes the information investigators must promptly report to the Drexel University's local IRB when the research is subject to oversight by Drexel University's local IRB.

1.2. For research overseen by an IRB other than Drexel University's local IRB, investigators should follow the requirements of that IRB.

2. POLICY

2.1. Report the following information items to the IRB within 5 days:

2.1.1. New or increased risk[1]

2.1.2. Protocol deviation that harmed a subject or placed subject at risk of harm

2.1.3. Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject

2.1.4. Protocol deviation due to the action or inaction of the investigator or research staff

2.1.5. Audit, inspection, or inquiry by a federal agency

2.1.6. Written report or action of a government agency, regarding the research, the PI, or the research staff, or if research staff are added, a past history of such report or action, including:

2.1.6.1. Conviction of a crime

2.1.6.2. FDA Warning Letter

2.1.6.3. NIDPOE (Noticed of Initiation of Disqualification Proceedings and Opportunity to Explain)

2.1.6.4. Suspension or termination by an IRB

2.1.6.5. Suspension by a federal or governmental agency (such as FDA, HHS, or Health Canada)

2.1.6.6. OHRP Determination Letter, Health Canada Inspection Letter with observations, or similar

2.1.6.7. Form FDA 483 in the past 5 years

2.1.7. **Allegation of Noncompliance** or **Finding of Noncompliance**

2.1.8. Unauthorized disclosure of confidential information

2.1.9. Unresolved subject complaint

2.1.10. Suspension or premature termination by the sponsor, investigator, or institution

2.1.11. Incarceration of a subject in a research study not approved to involve prisoners

2.1.12. Adverse event or IND safety report that requires a protocol or consent change

[1] For example, publications indicating a new risk, new risk in an investigator brochure, FDA black box warning, new risk identified in a data safety monitoring report, information or change that adversely affects subject safety, or information or change that adversely affects the conduct of the research.

2.1.13. State medical board or hospital medical staff actions, (denial, revocation, suspension, reduction, limitation, probation, non-renewal, relinquishment, sanction, fine, or discipline) regarding any of the following for the PI or research staff, or if research staff are added, a past history of such action:

2.1.13.1. Clinical privileges at any site
2.1.13.2. DEA licensure
2.1.13.3. Fellowship/board certification
2.1.13.4. Medical licensure in any state, nation, or province
2.1.13.5. Membership on any hospital staff
2.1.13.6. Prescribing privileges
2.1.13.7. Professional sanctions including fines and public reprimands
2.1.13.8. Professional society membership
2.1.13.9. Research privileges at any site

2.1.14. Unanticipated adverse device effect[2]
2.1.15. Written report of a study monitor
2.1.16. Change in financial interest disclosure (submit as a modification)
2.1.17. Change in any other information previously submitted to the IRB (submit as a modification)

2.2. Information not listed above does not require prompt reporting to Drexel University's IRB.

3. REFERENCES

3.1. 21 CFR §56.108(b)
3.2. 45 CFR §46.107(a)(4)

[2] Unanticipated adverse device effect means any serious adverse 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 in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.