



Reportable New Information – Standard Operating Procedures

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1. Overview

Purpose

Regulations require an organization to establish and follow written procedures for ensuring prompt reporting and review of unanticipated problems involving risk to subjects or others (UPIRSO), serious or continuing non-compliance, suspensions and terminations of IRB approval, changes made to research without IRB approval, and other significant information to the IRB, organizational officials, and applicable federal agencies.

These procedures detail the information investigators must promptly report to the Drexel University's HRP-IRB. Investigators conducting research under the oversight of Drexel's IRB, must comply with the reporting requirements of Drexel's IRB as outlined in Section 3 and their institution's internal reporting requirements, if applicable. Investigators conducting research under the oversight of an external IRB must comply with the reporting requirements of the external IRB and the internal reporting requirements as applicable.

In conducting a review of noncompliance, UPIRSO, and other reportable events, the IRB will also consider whether the event or issue was caused by, contributed to, or otherwise related to other determinations (e.g., when a report is submitted as a potential UPIRSO the IRB will also consider whether noncompliance occurred).

2. Definitions

Complaint – a concern expressed by subjects or others about the conduct of the study or a subject's participation.

Noncompliance – any failure to follow:

- Applicable federal regulations, state or local laws, or institutional policies governing human subject protections, or
- The requirements or determinations of the IRB, including the requirements of the approved investigational plan (i.e., protocol deviations).

Noncompliance can result from performing an act that violates these requirements or failing to act when required. Noncompliance may be minor or sporadic or it may be serious or continuing.

Serious Noncompliance – noncompliance that increases risk of harm to subjects; adversely affects the rights, safety, or welfare of subjects; or adversely affects the integrity of the data or the research.

Continuing Noncompliance – a pattern of repeated noncompliance which continues after it has been determined that noncompliance occurred, including inadequate effort to take corrective actions or comply with IRB requirements within a reasonable timeframe.

Apparent Noncompliance – an event that appears to constitute noncompliance, but the IRB has not yet made a formal assessment of the event.



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Unanticipated problems involving risk to subjects or others (UPIRSO) – Unanticipated problems involving risks to subjects or others refer to any incident, experience, outcome, or new information that:

1. Is unexpected; **and**
2. Is at least possibly related to participation in the research; **and**
3. Indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, legal or social harm) than was previously known or recognized

UPIRSOs also encompass Unanticipated Adverse Device Effects, as defined below, and information that sponsors are required to report to the FDA in IND Safety Reports under [21 CFR 312.32](#).

UPIRSOs may also be referred to as UPs, UAPs, and UPIRTSOs.

Unexpected – The incident, experience or outcome is not expected (in terms of nature, severity, or frequency) given the research procedures that are described in the study-related documents, such as the IRB-approved research protocol/research plan and informed consent documents; and the characteristics of the subject population being studied.

Related – There is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.

Adverse Event – For the purposes of these policies and procedures, an adverse event (AE) is any untoward medical occurrence in a study participant undergoing intervention which does not necessarily have a causal relationship with the intervention. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the study intervention, whether or not related to the study intervention. Adverse events encompass both physical and psychological harms.

Serious Unexpected Suspected Adverse Reaction – For clinical trials subject to FDA’s IND regulations, a Serious Unexpected Suspected Adverse Reaction refers to any suspected adverse reaction to study treatment, including active comparators, that is both serious and unexpected. Sponsors are responsible for determining whether an event meets all three components of this definition and thus must be reported to the FDA in an IND Safety Report.

Unanticipated Adverse Device Effect – An Unanticipated Adverse Device Effect (UADE) 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 related to the rights, safety, or welfare of subjects [[21 CFR 812.3\(s\)](#)].

3. Reporting

Investigators must report events or issues that meet the criteria for serious or continuing noncompliance, UPIRSO, or otherwise reportable information within **7 working days** after the



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investigator first learns of the event by submitting a Reportable New Information form with PI certification.

Adverse events in FDA-regulated clinical trials must be reported to the sponsor in compliance with FDA regulations and sponsor requirements. Unless specifically required by the IRB for a given protocol, the Drexel IRB does not accept reports of adverse events that are not also an unanticipated problem involving risks to subjects or others (UAP).

Additionally, anyone may report concerns of possible noncompliance to the HRPP or IRB verbally, by email, or other means. In such cases, the reporting party is responsible for making these reports in good faith, maintaining confidentiality and, unless reporting anonymously, cooperating with any subsequent fact-finding in relation to the report.

3.1 UPIRSO

If investigators are uncertain but believe that the event might represent a UPIRSO a report should be submitted.

Examples of UPIRSOs include:

1. A single occurrence of a serious, unexpected event that is uncommon and strongly associated with drug exposure (such as angioedema, agranulocytosis, hepatic injury, or Stevens-Johnson syndrome);
2. A single occurrence, or more often a small number of occurrences, of a serious, unexpected event that is not commonly associated with drug exposure, but uncommon in the study population (e.g., tendon rupture, progressive multifocal leukoencephalopathy);
3. Multiple occurrences of an AE that, based on an aggregate analysis, is determined to be an unanticipated problem. There should be a determination that the series of AEs represents a signal that the AEs were not just isolated occurrences and involve risk to human subjects (e.g., a comparison of rates across treatment groups reveals higher rate in the drug treatment arm versus a control). A summary and analyses supporting the determination should accompany the report;
4. An AE that is described or addressed in the investigator's brochure, protocol, or informed consent documents, but occurs at a specificity or severity that is inconsistent with prior observations. For example, if transaminase elevation is listed in the investigator's brochure and hepatic necrosis is observed in study subjects, hepatic necrosis would be considered an unanticipated problem involving risk to human subjects. A discussion of the divergence from the expected specificity or severity should accompany the report;
5. A serious AE that is described or addressed in the investigator's brochure, protocol, or informed consent documents, but for which the rate of occurrence in the study represents a clinically significant increase in the expected rate of occurrence (ordinarily, reporting would only be triggered if there were a credible baseline rate for comparison). A discussion of the divergence from the expected rate should accompany the report;
6. AEs involving direct harm to subjects enrolled by the local investigator which in the opinion of the investigator or sponsor, may represent an UAP;



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7. IND Safety Reports from sponsors that meet the criteria for reporting to the FDA under [21 CFR 312.32](#). Such reports must be accompanied by confirmation that the sponsor has submitted the report to the FDA. For more information on IND safety reporting, see FDA's guidance "[Safety Reporting Requirements for INDs and BA/BE Studies](#)";
8. Unanticipated Adverse Device Effects (UADEs);
9. Any other AE or safety finding (e.g., based on animal or epidemiologic data) that indicates subjects or others might be at risk of serious, unanticipated harms that are reasonably related to the research. These would cause the sponsor to modify the investigator's brochure, study protocol, or informed consent documents, or would prompt other action by the IRB to ensure the protection of human subjects. An explanation of the conclusion should accompany the report.
10. Reports (including reports from DSMBs/DMCs) that indicate that risks are greater than previously known or that indicate that the research should be modified, suspended, or halted.
11. Sponsor or lead investigator/coordinating center-imposed suspension or termination of some or all research activities;
12. An unanticipated event related to the research that exposes subjects or others to potential risk but that does not involve direct harm;
13. A breach of confidentiality or loss of research data (e.g., a laptop or thumb drive is lost or stolen);
14. An unanticipated event related to the research that results in actual harm or exposes individuals other than the research subjects (e.g., investigators, research assistants, students, the public, etc.) to potential risk;
15. New information that indicates increased risk, new risk(s), or decrease to potential benefit from what was previously understood. Examples include:
 - a. An interim analysis or safety monitoring report indicates that the frequency or magnitude of harms or benefits may be different than initially presented to the IRB;
 - b. A report or publication that indicates the risks, benefits, or merit of the research are different from what was previously understood.

3.2 Noncompliance

If an individual, whether investigator, study staff or other, is uncertain whether there is cause to report noncompliance, he or she may contact the HRP Executive Director, Institutional Official, or IRB Chair directly to discuss the situation informally.

Examples of Noncompliance include:

1. Protocol deviation due to the action or inaction of the investigator or research staff.
 - a. Conducting human subjects research without an IRB-approved protocol or exemption.
 - b. Starting research prior to meeting the conditions required by the IRB and receiving an IRB notification of approval or conducting research during a lapse in approval.
 - c. Failure to obtain informed consent or re-consent as required by the IRB.



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- d. Failure to complete the IRB application or other forms related to human subjects research in a true and accurate manner.
 - e. Enrollment of participants beyond what has been approved by the IRB in a study that is greater than minimal risk.
2. Written report or action of a government agency, regarding the research, the PI, or the research staff, including:
 - a. Conviction of a crime
 - b. FDA Warning Letter
 - c. NIDPOE (Noticed of Initiation of Disqualification Proceedings and Opportunity to Explain)
 - d. Suspension, termination, or restriction of an IRB's authority to oversee research
 - e. Suspension, termination, restriction, or expiration of an institution's FWA.
 - f. Suspension by a federal or governmental agency (e.g., FDA, HHS, or Health Canada).
 - g. OHRP Determination Letter, Health Canada Inspection Letter with observations, or similar.
 - h. Allegation of Noncompliance or Finding of Noncompliance
 - i. Unauthorized disclosure of confidential information.

3.3 Other Reportable Information

When research is under the oversight of the Drexel IRB, in addition to UAPs, noncompliance, and complaints, any change to the research implemented without IRB approval and any information that may impact the rights, safety, or welfare of subjects or inform the IRB's oversight of the research must be reported to the IRB within **7 working days** of discovery by submitting a Reportable New Information report with PI certification. Investigators conducting research under the oversight of an external IRB must comply with the reporting requirements of the external IRB and the internal reporting requirements outlined in Section 5.

Other reportable information includes, but is not limited to, the following:

1. Changes made to the research without prior IRB approval to eliminate apparent immediate hazards to the subject(s);
 - a. For device studies subject to FDA's IDE regulations, any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency must be reported to the sponsor and the IRB of record **no later than 5 working days** after the emergency occurred.
2. Protocol deviations that are made to eliminate an immediate hazard to a subject without IRB approval;
3. Monitoring, audit, and inspection reports;
4. Notice of:
 - a. Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated (classification as "OAI" is typically made after FDA has



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had the opportunity to review the responses to a 483), FDA Restrictions Placed on IRBs or Investigators, and any corresponding compliance actions taken under non-US authorities related to human research protections.

- b. Any litigation, arbitration, or settlements initiated related to human research protections.
- c. Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding human subjects research conducted at or by Drexel University or Drexel's program for the protection of human research participants.

NOTE: The above events (4.a, b, and/or c) must be reported to the HRPP/IRB office by email **as soon as anyone becomes aware**, with the formal submission within the 7-day timeline as noted above. See Section 9 for more information.

- 5. Sponsor or coordinating center reports;
- 6. Data Safety Monitoring reports, including reports from DSMBs, DMCs, and others that indicate that risks are greater than previously known or that indicate that the research should be modified, suspended, or halted;
- 7. Enrollment or inclusion of vulnerable populations not previously approved by the IRB for the study (e.g., prisoner, pregnant woman, neonate, child, adult with impaired decision-making capacity);
- 8. When an existing subject becomes a member of a vulnerable population not previously approved by the IRB for inclusion in the study (e.g., incarceration, pregnancy, or change in decision-making capacity of an already enrolled subject);
- 9. Holds, suspensions, or terminations of a study, in part or in full, by an investigator, sponsor, or others;
- 10. Changes that impact the ability of the PI to conduct or supervise the study, temporarily or permanently;
- 11. Changes that impact the qualifications of investigators or research staff members such as actions taken by regulatory authorities, licensing boards, or credentialing committees, including but not limited to:
 - a. 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:
 - i. Clinical privileges at any site
 - ii. DEA licensure
 - iii. Fellowship/board certification
 - iv. Medical licensure in any state, nation, or province
 - v. Membership on any hospital staff
 - vi. Prescribing privileges
 - vii. Professional sanctions including fines and public reprimands
 - viii. Professional society membership



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- ix. Research privileges at any site
- x. Written report by study monitor
- 12. New information that may impact the rights, welfare, or willingness of subjects to continue in the research.
- 13. Unresolved subject complaint (as outlined in Section 4)
- 14. Incarceration of a subject in a research study not approved to enroll or otherwise involve prisoners.

4. Complaints

The HRPP & IRB will be responsive and sensitive to the complaints or concerns expressed by subjects or others and will respond to all complaints or concerns in a confidential and timely manner. The PI and all other research team members are responsible for the safety and welfare of all subjects enrolled in their studies. When investigators or team members hear complaints or concerns from subjects, he or she will try to resolve them.

Investigators conducting research under the oversight of the Drexel IRB must report complaints unable to be resolved by the investigator by submitting a Reportable New Information form with PI certification. All complaints, including those resolved by the investigator, should be summarized at the time of continuing review, when continuing review is applicable.

Investigators conducting research under the oversight of an external IRB must comply with the reporting requirements of the external IRB and the internal reporting requirements outlined in Section 5.

Investigators are encouraged to contact the HRP Executive Director or IRB Chair when they are having difficulty resolving a complaint or concern, and whenever circumstances warrant (e.g., immediate attention is needed).

When the HRPP or IRB office is the direct recipient of complaints or concerns, the staff will do the following:

1. Document the complaint or allegation. When appropriate, the staff may request that the subject submit the complaint in writing.
2. Reassure the subject that the HRPP/IRB will take all necessary measures to inquire into the circumstances and to address the issue.
3. Provide written confirmation of receipt of the complaint to the subject if the subject is willing to provide contact information.
4. Convey the information to the IRB of record in a timely manner.
5. When appropriate, contact the investigator for additional information or to assist with resolution.
6. When appropriate, contact other resources (e.g., Research Compliance, Risk Management, Patient Relations, Privacy) to assist with information-gathering or resolution.



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For research under the oversight of the Drexel IRB, the IRB Chair or designee will consider the complaint or concern and take any reasonable steps necessary to investigate and/or resolve the issue, if appropriate, prior to review and consideration by the IRB. A report will be provided to the IRB at the next available meeting if the research is subject to convened IRB review or provided to the designated expedited reviewer if the research is eligible for expedited review. When reviewing complaints, the IRB will consider whether the complaint was the result of, or related to, an UPIRSO or noncompliance, and, if so, will follow the relevant procedures. The IRB Chair or designated expedited reviewer may refer any complaint for review by the convened IRB. The IRB minutes, or reviewer comments for expedited reviews, will reflect the action(s) taken and, if necessary, notice to the appropriate officials and/or agencies.

The HRPP will maintain written copies of complaints and concerns and will document the investigation and resolution. The complainant will be notified promptly following resolution of the complaint or concern, when appropriate, if contact information has been provided. If the HRPP or IRB receives a complaint, or identifies information while investigating a complaint, that is indicative of possible misconduct in research, Drexel's Research Integrity Officer will be notified immediately.

5. External IRB Review Reporting Requirements

Investigators approved through external IRB review must still report local unanticipated problems, complaints, and noncompliance to the Drexel HRP/IRB office by submitting a Reportable New Information form with PI certification, in addition to reporting to the external IRB per the reviewing IRB requirements.

Copies of the report submitted to the external IRB are generally acceptable, but additional information may be requested on an as-needed basis.

Notices about and reports from external monitors, auditors, or inspectors must be provided to the HRP/IRB Office as described in Section 3.3 of this policy.

Any of the following issues must be reported immediately (**as soon as anyone becomes aware**) to the Drexel HRP/IRB office by phone or email:

- Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated (classification as "OAI" is typically made after the FDA has the opportunity to review any responses to a 483), FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections;
- Any litigation, arbitration, or settlements initiated related to human research protections; and/or
- Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding human research at Drexel or Drexel's HRPP.

Investigators are reminded that other Drexel University Reporting requirements, such as to Compliance, Privacy, and Risk Management, remain applicable in addition to HRPP reporting requirements.

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Upon receipt of the Reportable New Information form, the HRP Executive Director or designated IRB staff reviews the information and, if needed, contacts the investigator for corrections or additional information. The HRP Executive Director or designee as applicable will notify the IO, IRB Board, and others as applicable to ensure any necessary steps are taken to confirm the safety of subjects across the institution.

6. Review Procedures

1. Upon receipt of the Reportable New Information form, the IRB staff pre-reviews the submission and, if needed, contacts the investigator for additional information. If the report was received verbally, by email, or by other means by someone other than the investigator, the HRP Executive Director or assigned staff will develop a written report summarizing the available information and will upload the report into the IRB electronic system. If the information provided suggests that subjects may be at risk of harm without immediate intervention or that research misconduct may have occurred, the HRP Executive Director, IRB Chair, and, when appropriate, the IO and/or Research Integrity Officer, will be notified to take any necessary steps to ensure the safety of subjects, including full or partial study suspension.
2. **For IND Safety Reports and UADEs**, the IRB Chair or designated reviewer receives and reviews the report and determines whether (1) the report can be accepted as submitted without any further action needed to ensure the protection of subjects who are enrolled at sites for which the Drexel IRB is the IRB of record; or (2) if review by the convened IRB is warranted to determine whether additional actions are necessary. If needed, the Chair or designee may request additional information from the investigator, sponsor, or others. When circumstances warrant, the HRP Executive Director or designee may bypass this step and assign the report for convened board review. It is FDA's position that, in general, information that must be reported to the FDA in an IND Safety Report or as an UADE are UPIRSOs, therefore the IRB does not need to determine whether the reported problem is a UPIRSO.
3. **For reports other than IND Safety Reports and UADEs**, the IRB Chair or designated reviewer receives and reviews the report and makes an initial determination as to whether the event may represent an UPIRSO or Serious or Continuing Noncompliance. When circumstances warrant, the HRP Executive Director or IRB Manager may bypass this step and assign the report for convened board review. If needed, the Chair or designee may request additional information from the investigator, sponsor, or others (including study committees, such as data monitoring committees, data safety monitoring boards, or steering committees).
 - a. If the reviewer determines that the event does not meet the definition of an UPIRSO or Serious or Continuing Noncompliance, they will review the proposed corrective and preventive action plan and determine if it is acceptable or whether any additional actions or modifications are necessary to ensure the protection of human subjects. As warranted, the reviewer may refer the matter to the convened IRB for review. The results of the review will be recorded in the electronic system and communicated to the investigator.
 - b. If the reviewer determines that the event may be an UPIRSO or Serious or Continuing Noncompliance, the report will be referred for review by the convened IRB. The convened IRB will determine whether the event is a UPIRSO or Serious or Continuing Noncompliance. The IRB will review any proposed corrective and preventive action plans and determine if the plan is acceptable as proposed or if modifications to the plan or



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additional actions, such as those outlined below, are necessary to ensure the protection of human subjects. If needed, the IRB may request additional information from the investigator or others. The results of the review will be recorded in the IRB minutes and communicated to the investigator.

4. Based upon the circumstances, the IRB may take any of the following actions, or others, to ensure the protection of human subjects:
 - a. Requiring modifications to the protocol or procedures (Research Plan) as described in the application and other materials submitted to the IRB;
 - b. Revising the continuing review timetable;
 - c. Modifying the consent process;
 - d. Modifying the consent document;
 - e. Providing additional information to current participants (e.g., whenever the information may relate to the subject's rights, welfare, or willingness to continue participation);
 - f. Providing additional information to past participants;
 - g. Requiring additional training of the investigator and/or study staff;
 - h. Requiring that current subjects re-consent to participation;
 - i. Monitoring the research, or similar research in nature, study personnel, or as otherwise recommended by the IRB, HRPP, or other compliance offices;
 - j. Monitoring the informed consent process;
 - k. Reporting or referral to appropriate parties (e.g., the IO, Research Integrity Officer, General Counsel, Conflict of Interest, Privacy);
 - l. Suspending IRB approval;
 - m. Terminating IRB approval;
 - n. Other actions as appropriate given the specific circumstances.
5. When the IRB determines that an event is an UPIRSO or Serious or Continuing Noncompliance the IRB staff will follow the procedures for reporting to regulatory agencies, sponsors, and organizational officials in Section 8.1. When appropriate, a preliminary report may be submitted while more information is obtained to inform the determination or actions. IND Safety Reports, UADE Reports, and any other reports that have already been reported to the federal oversight agency (e.g., by a Sponsor, Coordinating Center, or sIRB) do not also need to be reported by Drexel HRP/IRB.
6. An investigator may request the IRB reconsider its determination and/or corrective and preventive action plan based on new information that was not available or previously submitted to the IRB at the time the determination was made. The request to re-review based on new information must be made within 10 calendar days of notification of the IRBs findings.



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7. Apparent IRB Noncompliance

When there has been apparent serious or continuing noncompliance on the part of the IRB (e.g., repeated failure to make a required determination), the HRP Executive Director will gather the relevant facts and report the matter, with any recommendations, to the IO. The IO may take actions as needed to further investigate the matter (e.g., a directed audit) prior to determining whether the apparent noncompliance is serious or continuing. The IO may also require corrective and preventive actions as warranted to remedy the matter and prevent recurrence. Serious or continuing noncompliance on the part of the IRB will be reported as necessary following the procedures outlined in Section 8.

8. Reporting to Federal Agencies, Departments, and Organizational Officials

Federal regulations require prompt reporting to appropriate institutional officials and, as applicable, the federal department or agency (e.g., OHRP, FDA), of (i) any unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with the applicable federal regulations or the requirements or determinations of the IRB; and (iii) any suspension or termination of IRB approval. Drexel IRB complies with this requirement as follows.

When research is under the oversight of an external IRB, the terms of the agreement with that IRB will guide reporting.

IND Safety Reports, UADE Reports, and any other reports that have already been reported to the applicable federal oversight agency (e.g., by a Sponsor, Coordinating Center, or sIRB) do not also need to be reported by Drexel IRB. The Drexel IO and any other appropriate parties will be informed of such reports by the Drexel HRP/IRB Office when the matter involves local subjects or significantly impacts the conduct of the research at Drexel University.

8.1 Procedures

IRB staff will initiate these procedures as soon as the IRB takes any of the following actions:

1. Determines that an event is considered an unanticipated problem involving risks to participants or others
2. Determines that noncompliance was serious or continuing
3. Suspends or terminates approval of research

The HRP Executive Director or designee is responsible for preparing reports in accordance with the instructions of the Federal department or agency (e.g., [OHRP](#), [FDA](#)).

The HRP Executive Director or designee sends a copy of the report to:

1. The IRB Chair
2. The IO
3. Federal departments or agencies, as follows:



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- a. OHRP, if the research is conducted or supported by [DHHS](#), or if an engaged institution's FWA has been voluntarily extended to all non-exempt human subjects research.
- b. If the research is conducted or supported by a Common Rule Dept. or Agency other than DHHS, the report is sent to the party identified by the Dept. or Agency. A list of contacts is available on OHRP's [Reporting Incidents](#) webpage.
- c. If the study is conducted or supported by a federal dept. or agency that has not adopted the Common Rule, and reporting is required, the report is sent to the party identified by the dept. or agency.
- d. FDA, if the study is subject to FDA regulations, including IND exempt or Non-significant risk device studies.

Reports are not submitted to federal departments or agencies such as OHRP or FDA unless the research is subject to federal regulations or another mandate that necessitates such reporting.

4. Sponsor, if applicable
5. Principal Investigator, when applicable
6. Department Chair
7. Other research related departments, as applicable (e.g., Research Integrity Officer, Office of Sponsored Research, SCHC Leadership)

The HRP Executive Director ensures that all steps of this policy are completed within 30 working days of the determination. For more serious actions, the Executive Director expedites reporting. If additional time is needed to gather facts, or determine corrective actions, a preliminary report will be submitted within 30 days, to be followed by a final report as described above.

9. Reporting to AAHRPP

Drexel's HRPP is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). In addition to the information that Drexel's HRPP routinely provides to AAHRPP in annual reports and the re-accreditation application, AAHRPP requires that any of the following are reported to AAHRPP as soon as possible but within 48 hours after the organization or any researcher (if the researcher is notified rather than the organization) becomes aware:

- Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections;
- Any litigation, arbitration, or settlements initiated related to human research protections; and/or
- Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding human research at Drexel or Drexel's HRPP.

The HRP Executive Director (or designee) is responsible for ensuring that such reports are made to AAHRPP and for informing appropriate organizational officials. Investigators, research staff, HRPP/IRB staff, IRB members, and other organizational officials or offices (e.g., the IO, Vice Provost for Research, Legal, etc.) are responsible for informing the HRPP/IRB office as soon as they become aware of any of the above so that these reporting obligations may be fulfilled.



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10. Responsibilities

10.1 Office for Research & Innovation and Human Research Protections

Responsibilities

The Office of Research & Innovation and Human Research Protections Office are responsible for maintaining these procedures, applicable tools, monitoring and reporting requirements. For inquiries regarding these procedures, please contact the Executive Director for Human Research Protections, as part of the Office for Research & Innovation (ORI).

10.2 IRB Responsibilities

The IRB is responsible for reviewing reportable information and making applicable determinations. Designated reviewers may conduct a pre-review of the reportable information and refer potential UPIRSOs, serious or continuing noncompliance events for committee review or may resolve events which do not meet these criteria per these procedures.

10.3 Principal Investigator and Faculty Mentor Responsibilities

The Principal Investigator (and Faculty Mentor as applicable) is ultimately responsible for the conduct and oversight of the project. Please refer to ORI-002, Principal Investigator Eligibility and Responsibilities, for a listing of the PI and Department Responsibilities. The PI is responsible for following these procedures, ensuring prompt reporting of new information, and addressing events with appropriate corrective and preventive actions.

11. Resources

- [FDA's Safety Reporting Requirements for INDs and BA/BE Studies](#)
- [OHRP's Incident Reporting Requirements](#)
- [FDA's Mandatory IRB Reporting Requirements](#)

12. Revision

*Please note that this document corresponds with former procedures HRP-071, Prompt Reporting Requirements. Changes and revision dates for these procedures were not previously formally documented.

Version 002/Effective Date 06/27/22 – Prompt Reporting Requirements

Version 003/Effective Date 09/28/26 – Reportable New Information

- Updated format to the revised SOP template
- Added responsibilities section
- Included additional examples of reportable noncompliance events