Chapter 12

IRB Review of FDA-Regulated Research: Investigational Drugs, Devices, and Biologics

The Food and Drug Administration (FDA) is a component of the U.S. Department of Health and Human Service (DHHS) that is responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act to regulate the safety and efficacy of these products for human use.

The FDA regulates clinical investigations that are conducted on drugs, biologic, and devices. All such investigations must be conducted in accordance with the FDA requirements for informed consent and IRB review.

Clinical Trials involving an investigational drug, device, or biologic that are supported by DHHS fall under the jurisdiction of both the FDA and the DHHS Office for Human Research Protections (OHRP). Such trials must comply with both the FDA and the DHHS human subject regulations and the Common Rule.

a) FDA vs. Common Rule and DHHS Requirement

The human subject protection requirements found in FDA regulations and DHHS regulations are substantially the same as the Common Rule requirements. There are, however, important differences:

- FDA regulations contain no assurance requirements.
- Conditions for exemption, exception, and waiver of IRB review and Informed Consent requirements differ.
- FDA regulations require specific determinations for the IRB review of device studies (as outlined in this chapter).
- FDA regulations include specific requirements for reporting adverse events that are not found in the Common Rule or DHHS regulations.
- DHHS regulations include specific additional protections for vulnerable populations, such as those found for pregnant women, fetuses, and neonates (Subpart B) and prisoners (Subpart C) that are not contained in FDA requirements.
- FDA regulations define "human subject" and "clinical investigation" (research) differently.

b) Investigational Drugs, Devices, and Biologics

Applications are submitted to the FDA for approval of research involving investigational drugs, devices, and biologics. IRB approval is conditioned upon the receipt of this documentation.

c) Investigational New Drug Application (IND)

An IND is submitted so that an investigation can be conducted in support of a potential New Drug Application. The Investigator must make the determination if an IND is necessary. Investigators are also responsible for ensuring that the information included in the protocol is accurate.

The IRB staff will conduct the initial evaluation of the submitted study to determine if the application meets IND requirement exemptions. The convened IRB Committee will confirm and finalize this determination.

The research involves the use of a drug other than the use of a marketed drug in the course of medical practice and the protocol does not meet one if the FDA exemptions from the requirements to have an IND.

d) The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of an IND, if all the following apply:

i. the investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.

ii. if the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.

iii. the investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.

iv. the investigation is conducted in compliance with the requirements for review by an IRB (21CFR56) and the requirements for informed consent (21CFR 50); and

v. the investigation is conducted in compliance with the requirements of 21CFR312.7 (Promotion and sale of investigational drugs).

vi. **IND Exemption 2**

1. The clinical investigation for an *in vitro* diagnostic product that involves one or more of the following:
    - Blood grouping serum
    - Reagent red blood cells
    - Anti-human globulin
2. The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic produce or procedure.
3. The diagnostic test is shipped in compliance with 21 CFR 312.160

vii. **IND Exemption 4**

A clinical investigation involving use of a placebo is IND exempt if the investigation does not otherwise require submission of an IND.

viii. When the exemption criteria are not met and an IND application is required, the IND application and any FDA communication that an IND is in effect must be submitted with the IRB application for verification. The Prisma Health IRB will not review any submission requiring an IND without this information. Research cannot be initiated until the IND is verified and the protocol is IRB approved including recruitment, consenting, or screening activities for potential enrollment in the study.

ix. The IND will be in effect 30 days after the FDA receives the IND request, unless the sponsor receives earlier notification from the FDA.

e) Investigational Device Exemption (IDE)

i. An IDE supports research to be conducted for a Pre-Market Approval application. Devices that are substantially equivalent to other devices that are legally on the market are called 510(k) devices and can be marketed without clinical testing. Investigators are asked to make the initial determination of whether an IDE is necessary.

ii. Investigators should submit documentation of the applicable IND/IDE numbers for studies involving investigational drugs, devices, and biologics with their protocol applications to the IRB.

iii. Under FDA regulations, the Investigator of a clinical trial is responsible for the conduct of the study and for leading the team of individuals coordinating the study.

iv. Each clinical investigator must accept specific responsibilities that include the following:
    - Ensuring conduct of the research according to the investigator agreement, investigational plan (protocol), and all applicable regulations,
    - Protection the rights, safety, and welfare of the research subjects,
    - Training and supervising all members of the research team,
    - Controlling access to and use of the test article (drug/biologic/device),
    - Monitoring and reporting adverse events,
    - Maintaining and retaining accurate records.

f) Sponsor Responsibilities

The sponsor of a clinical investigation initiates and holds the IND or IDE for a clinical investigation but may not actually conduct the investigation. Although the sponsor is usually a pharmaceutical, biotech, or medical device company, an individual or group of individuals can also be considered a sponsor for an investigation. An investigator is referred to as the sponsor-investigator when the individual investigator is also the initiator of the clinical investigation.

The responsibilities of sponsors and sponsor-investigators include the following:

- Maintaining the IND, IDE, or Biologics License,
- Obtaining qualified investigators and monitors,
- Providing necessary information and training for Investigators,
- Monitoring the investigation,
- Controlling the investigational agent,
- Reporting significant Adverse Events to the FDA and IRB,
- Maintaining and retaining accurate records,
- Registering the study on **clinincaltrials.gov with responsibility for all reporting requirements.**
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1. IRB Review of Medical Devices

i. In accordance with FDA requirements, Prisma Health makes a Significant Risk (SR) or Non-Significant Risk (NSR) determination for a medical device by the convened IRB. The criteria for approval of device studies are consistent for any FDA regulated study.
    - **Significant Risk (SR) Device Defined.** A SR device study presents a potential for serious risk to health, safety, or welfare of a subject and:
        - Is intended as an implant;
        - Is used in supporting or sustaining human life;
        - Or is of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise prevents impairment of human life.

ii. The FDA considers studies of all SR devices to present more than minimal risk, therefore, full IRB Review for all studies involving SR devices is necessary. All devices with an IDE number require full Board approval.
    - **Nonsignificant Risk (NSR) Device Defined** Nonsignificant Risk (NSR) device study is one that does not meet the definition of a SR study.

2. Review Procedures of Medical Devices

If the IRB determines or concurs with the assessment of the sponsor that a device study involves a SR device, it would then be governed by the IDE regulations at 21 CFR 812. The determination of risk status of the device should be based on the proposed use of the device in the investigation. The IRB may review any of the following materials:

i. A description of the device,

ii. Reports of prior investigations conducted with the device,
iii. The proposed investigational plan,
iv. A description of subject selection criteria,
v. Monitoring procedures,
vi. The sponsor's risk assessment and the rationale use to make the sponsor's risk determination,
vii. The IRB may also request additional information, if necessary, from the sponsor or investigator or ask the FDA to provide a risk assessment.
viii. A device study that is deemed to involve a NSR may begin immediately following IRB approval as it would not require the submission of an application to the FDA.
ix. It is important to note that the terms "non-significant risk" and "minimal risk" are defined separately and are not synonymous.

3. Treatment IDE

i. Treatment use of an investigational device facilitate the availability of promising new devices to seriously ill patient as early as possible before general marketing begins. Such use may occur when:
   - The patient has a serious or immediate life-threatening condition
   - There is no comparable or satisfactory alternative available
   - The device is under investigation in a controlled trial for the same use, or such trial have been complete
   - The Sponsor is pursuing marketing approval / clearance
   - The Sponsor has submitted, and the FDA has approved an IDE under 21 CFR 812.36.

ii. Such use permits wide access to the device dependent upon patient needs. IRB review and approval and informed consent are required.

4. 510(k) Devices

The review requirements for 510(k) devices are somewhat different. If FDA agrees that a new device is substantially equivalent to a device already on the market, it can be marketed without clinical testing. If, however, clinical data are necessary to demonstrate equivalence, any clinical studies must be conducted in compliance with the requirements of the IDE, IRB review, and informed consent regulations. Because 510(k) devices fall under the IDE regulations, reporting of adverse or unanticipated 510(k) device effects follow the same requirements.

5. Radiology Devices and Radioactive Materials

FDA is responsible for regulating radiology devices and radioactive materials used in health care and research. Oversight of these devices is managed by the Institutions Radiation Safety Committee.

6. Investigators' Responsibilities for Reporting to the IRB

FDA IND regulations require that the investigator report promptly to the Sponsor any "adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the **adverse effect is alarming, the investigator shall report the adverse effect immediately" (21 CFR 312.64(b). The FDA IDE regulations require that the investigator notify the sponsor of any unanticipated adverse device effect within ten days (21 CFR 812.150(a)(1)).**

7. Investigators' Duty to Report Unanticipated Problems.

Investigators are required to report to the IRB using the appropriate form available in IRBNet, any unanticipated problem involving risks to subjects or other that occur in research conducted under the auspices of Prisma Health.

8. **Investigators' Duty to Report Serious Adverse Events.** (CFR 312.32(a) and 21 CFR 812.3(s))
    i. Investigators are required to report to the IRB using the appropriate forms available in IRBNet, any ***serious adverse event*** that occurs in research conducted at facilities of the Institution or by its employees.
    ii. A serious adverse event is defined as any adverse experience that results in any of the following outcomes:
        - Death.
        - A life-threatening experience, inpatient hospitalization, or prolongation of existing hospitalization.
        - A persistent or significant disability/ incapacity, or a congenital anomaly or birth defect.

9. **Investigators' Duty to Report all Protocol Deviations and Violations**
   Investigators are required to report all deviation or violations for approved protocol. This includes any change from the protocol that was implemented by the investigator to respond to immediate safety concern.

10. **Investigators' Duty to Forward Sponsor or Cooperative Group Safety Reports**
    Investigators are required to forward safety reports or other information concerning adverse events issued by sponsors or cooperative groups to the IRB within five working days of receipt. Each report should be accompanied by the appropriate cover sheet provided in IRBNet.

11. **Investigators' Duty to Forward Data and Safety Monitoring Committee (DSMC) Reports and Data Safety Monitoring Board (DSMB) Reports**
    Investigators are required to forward DSMB reports to the IRB within five working days of receipt when they indicate serious and/or continuing non-compliance and/or unanticipated problem involving risks to subjects or others. Routine DSMC and DSMB reports are submitted to the IRB at the time of continuing review.

    When DSMCS and DSMBs are employed, the IRBs conducting continuing review of research may rely on a current statement from the DSMC or DSMB indicating that it has reviewed study-wide adverse events, interim findings, and any recent literature that may be relevant to the research. The IRB must still receive and review reports of local, on-site unanticipated problems involving risks to subjects or others and any other information needed to make its continuing review substantive and meaningful.

12. **Duty to Notify the IRB of Serious or Continuing Non-compliance**
    Whether involved in research or not, all employees of this Institution are required to notify the IRB if they become aware of any serious or continuing non-compliance with human subject regulatory requirements or with the determinations of the IRB.

    i. **Non-Compliance** is a failure to adhere to federal, state, or local regulations governing human subjects research, organizational policies related to human subjects research, or the determination of the IRB. Noncompliance may be minor or sporadic, or it may be serious and continuing.
    ii. **Serious Non-Compliance** is noncompliance that in the determination of a convened IRB, creates an increase in risks to subjects, adversely affects the rights, welfare, or safety of subjects or adversely affects the scientific integrity of the study. Willful violations of regulations and/or policies may also constitute serious noncompliance.
    iii. **Continuing Non-Compliance** is a pattern of non-compliance that, in the judgement of the convened IRB, suggests a likelihood that instances of noncompliance will continue unless the IRB or organization intervenes.

13. Other Reporting Responsibilities

Investigators and sponsor-investigators have the following additional reporting responsibilities under FDA regulations:

i. FDA IND regulations require the clinical investigator to notify the sponsor of any adverse effect that may reasonably be regarded as caused by, or probably cause by the drug.

ii. FDA IND regulations require that the Sponsor notify the FDA and all participating investigators of any adverse experience associated with the use of a drug or biologic that is both serious and unexpected as soon as possible but in no event later than fifteen (15) calendar days after the sponsor determines the event to be reportable. The FDA should be notified by telephone, or in writing as soon as possible but, in no event, later than seven (7) calendar days of the sponsor's receipt of the information of any unexpected fatal or life-threatening experience.

iii. The Sponsor is required to evaluate the event and report serious, unexpected adverse device effects to the FDA, to all participating investigators, and to the IRB within ten (10) working days of the sponsor's receipt of the information.

14. Off-Label (Unapproved) Use of FDA-Regulated Products in Medical Practice

Good medical practice and the best interested of the patient require that physicians use legally available, marketed drugs, biologics, and devices according to their best knowledge and judgement. If a physician decides to use a product for an indication not included in the approved labeling (off label), they are responsible to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects.

Off-label use of a marketed product in this manner when the intent is solely within the context of the practice of medicine it does not require IRB review or the submission of an IND, IDE, or IRB approval. It should also not be reported as research.

Off-label use of a marketed product in research (as part of a systematic investigations designed to develop or contribute to generalizable knowledge) **does require IRB review.**

15. Treatment IND's and IDEs

The treatment IND is a mechanism for providing eligible subjects with investigational drugs for the treatment of serious and life-threatening illness for which there are no satisfactory alternative treatments. Where necessary, the mechanism can be used even for providing such drugs to a single patient. The Treatment IDE is a comparable mechanism for providing investigational devices to such patients.

The FDA regulations at 21 CFR Part 312, Subpart I, specify the requirements for the expanded access use of an investigational drug to diagnose, monitor or treat a patient's disease or condition.

The FDA regulations at 21 CFR 812, 36 specify the requirements that must be satisfied before a Treatment IDE can be issued.

16. Treatment IND

During the clinical investigation of a drug, it may be appropriate to use the drug in treatment of patients not in the clinical trials. Such use requires FDA approval under 21 CFR 312.305, as well as IRB approval and informed consent.

17. Single Patient Treatment IND

The Single-Patient Treatment IND as added to the law under the FDA Modernization Act (FDAMA) in 1997. Investigators must obtain FDA approval as well as satisfy the requirements set fort at 21 CFR 312.305 and 21 CFR 312.310.

18. Group C Treatment IND

Group C drugs are Phase 3 study drugs that have shown evidence of efficacy in a specific tumor type. Group C drugs are distributed by the National Cancer Institute (NCI) with a Guideline Protocol and an informed consent document. Informed consent is required, and although FDA and NCI permit the use of Group C drugs without local IRB review, local IRB review may be required.

Investigators that are considering use of Group C drugs should contact the IRB Chair or the HRPP Director for guidance.

19. Orphan Drugs

The term "orphan drug" refers to a product that treats a rare disease affecting fewer than 200,000 Americans. The treatment use of orphan drugs required prospective IRB review and approval and informed consent (21 CFR 316.40).

20. Gene Transfer Research

i. Gene transfer research involve the administration of genetic material to alter the biological properties of living cells for therapeutic use. Gene transfer activities in humans are investigational and are regulated by the FDA.
ii. FDA regulations required the submission of an IND for human gene transfer research.
iii. DHHS regulations specify that no individual may be enrolled in human gene transfer research until:
   - Review has been completed by the Recombinant DAN advisory Committee (RAC) at the NIH,
   - Approval of relevant Institutional Component-Designated Committee(s) has been obtained,
   - Component IRB approval has been obtained,
   - And the investigator has obtained all other regulatory authorizations, such as any consent required by regulations form the subject (65 FR, October 2000).

21. Emergency Use of a Test Article without IRB Review

i. An exemption under FDA regulations at 21 CFR 56.10(c) permits the emergency use of an investigational drug, device, or biologic on a one-time basis per institution without IRB review and approval. Subsequent use of the investigational drug, device, or biologic must be prospectively reviewed by the IRB.
ii. The emergency use of a test article, other than a medical device, is a clinical investigation, the patient is a subject, and the FDA may require data from an emergency use to be reported in a marketing application.
iii. DHHS regulations do not permit data obtained from patients to be classified as human subject's research, nor permit the outcome of such care to be included in any report or a research activity subject to DHHS regulations,
iv. Informed consent is sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 21 CFR 50 and informed consent is appropriately documented in accordance with and to the extent required by 12 CFR 50,27.

22. Institutional Requirement Emergency Use of a Test Article without IRB Review

If possible, Prisma Health policy requires that investigators consult the IRB Chair, or medically qualified designee for guidance when considering the emergency use of drugs or medical devices.

Required Conditions:

Before the use of the test article, investigators must certify in writing that all the following conditions have been met for this type of emergency use for a

human subject in a life-threatening situation:

- No standard acceptable treatment is available,
- There is insufficient time to obtain IRB approval,
- The emergency use must be reported to the IRB within five working days (such reporting must not be construed as IRB approval for emergency use). The IRB will review the report of the emergency was compliant with the required FDA conditions set forth above.
- Ordinarily, the investigator must obtain the informed consent of the subject for such an emergency use, except as described below.

23. Emergency Use of a Test Article without Informed Consent

An exception under FDA regulations at 21 CFR 50.23 permits the emergency use of an investigational drug, device, or biologic without informed consent before the use of the test article both the investigator and an independent physician who is not otherwise participating in the clinical investigation certify in writing all the specific conditions described below.

24. Institutional Requirements for Emergency Use of a Test Article without Informed Consent

If possible, Prisma Health policy required the investigator consult the IRB Chair for guidance when considering the emergency use of drugs or medical devices. When consulted, the IRB Chair shall evaluate and confirm that the required conditions are satisfied.

Required Conditions: Before use of the test article, the investigator and another physician who is not otherwise participating in the clinical investigation, must certify in writing that all the following conditions have been met for this type of emergency use without informed consent:

- The subject is in a life-threatening situation necessitating the use of the test article and the immediate use of the test article is, in the investigator's opinion required to preserve the life of the subject
- Informed consent cannot be obtained because of the inability to communicate with, or obtain legally effective consent from the subject
- There is not sufficient time to obtain consent from the subject's legally authorized representative
- No alternative method of approved or generally recognized therapy is available that provided an equal or greater likelihood of saving the subject's life
- The emergency use must be reported to the IRB within five working days. Such reporting must not be construed as IRB approval for the emergency use.

Note: if time is not sufficient to obtain the independent physician determination before use of the test article, the actions of the investigator must be reviewed and evaluated in writing by an independent physician within five working days from the use of the test article.

25. IRB Review of Report of Emergency Use without Informed Consent.

The IRB will review the report of the emergency use and will confirm that the emergency use was compliant with the required conditions set for in the previous section.

26. Expanded Access to Investigational Drugs and Devices

i. "Compassionate Use" is not a term that appears in the FDA or DHHS regulations or the Common Rule.
ii. Studies involving investigational drugs, "Compassionate Use" is often meant to refer to the

emergency use situations discussed above.

iii. Studies involving investigational devices, compassionate use may occur when a device that is being tested in a clinical trial is the only options available for a patient with a serious condition who does not qualify for the trial. Such uses require prior FDA approval of a protocol deviation under 21 CFR 812.35(a). Prior FDA approval for compassionate use should be obtained before the device is used.

iv. On occasion, compassionate use may occur even it here is no IDED for the device. Under this situation, the physician would submit the compassionate use request directly to the FDA.

v. Compassionate use of an unapproved device also required as many of the following protections as possible:
   - Informed consent
   - Clearance from the institution
   - Concurrence of the IRB Chair (which does not constitute IRB approval)
   - An independent assessment of an uninvolved physician
   - Authorization of the IDE sponsor
   - Follow-up reports should be / may be required to the Sponsor
   - Such use may involve an individual or a small group of patients

27. Institutional Requirements

Prisma Health requires that investigators consult the IRB Chair or HRPP Director for guidance when considering such "compassionate use".

28. Humanitarian Device Exemption

[*Should not be confused with Expanded Access or Compassionate Use]*

***A Humanitarian Use Device (HUD*)** is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 8,000 individuals in the United States per year. FDA developed this regulation to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations.

Humanitarian Device Exemption (HDE) is a marketing application for an HUD. An HDE is exempt from the effectiveness requirements when used in accordance with FDA-approved indication(s) and is subject to certain profit and use restrictions.

i. An HUD is a legally marketed device, and its use within approved indications does not constitute a clinical investigation. However, IRB appropriate committee approval is required before an HUD can be used at a facility for clinical care, with the exception of emergency use.

ii. The reviewing IRB will apply the same approval criteria at 21CFR46.111 when it performs an initial review of an HUD as it does for any other FDA-regulated product. FDA approval of the HDE is based on safety and probably benefit and does not provide assurance of effectiveness.

iii. IRB reviewers should consider:
   - Risks are minimized by using procedures that not unnecessarily expose patients to risk, and if risks are reasonable in relation to the device being used and its probable benefit,
   - Whether there are adequate provisions to protect the privacy of patients and confidentiality of data collected,
   - If the device is being used with the scope of the FDA HDE approval order,
   - Whether the patient or legally authorized representative (LAR) is given sufficient opportunity to consent to the use of the device for their disease/condition,
   - If consent is applicable, it is appropriately documented and contains the necessary information (See Chapter 11 for informed consent requirements.)
   - If no written consent is being required, patients or their LAR is provided with

device brochure, or labelling information.

iv. To effectively review the HUD submission, the IRB must be provided:
   - A copy of the FDA HDE approval order,
   - A description of the device,
   - Device labelling,
   - Any patient information packet or brochure that might be available,
   - A summary of; device use, patient population, patient screening, overall treatment plan, as well as required unanticipated event reporting requirements.
   - Should a consent form be required, it should make not reference to research, nor is HIPAA authorization required.

v. The IRB may use the FDA expedited review of the HUD for continuing review (21 CFR 56.110), because the use of an HUD approved under the HDE is not considered research.

vi. A physician in an emergency situation may use an HUD within its approved indication(s) prior to IRB review, only if approval cannot be obtained in time to prevent serious harm or death to the patient. The physician is obligated to report that use to the IRB within 5 days to the IRB. The report must be provided in writing and include the patient information, reason for use, and the HUD was used (FDA,2019b).

29. Right to Try Legislation

i. Right to Try (RTT) laws vary from state to state. A Federal Right to Try Bill was signed into law in May 2018. The FDA has published an information sheet: https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try, however the law has not been enacted through regulations.

ii. Prior to the enactment of the Federal Law, South Carolina passed state Right to Try Law:https://www.scstatehouse.gov/code/t44c137.php. (South Carolina Code of Law Section 44- 137).

iii. Any physician or investigator receiving such as request to access a drug in this manner should contact the IRB Chair or HRPP Director for assistance in managing this request. ***This request will accommodate support and guidance through the process. IRB review and approval of such requests is not required.***

iv. The right to try pathway is limited to treatment for a single patient and is not intended to treat cohorts, nor treatment with investigational devices. Under this law, companies are under no legal obligation to provide access to their investigational agents and the liability of physicians and manufacturers is limited.

v. Under the RTT law an investigational drug eligible for request must fulfill certain requirements contiguous with current federal law, including:
   - That it is the subject of an application filed with the FDA (pursuant to 505(b), or 351(a) of the Public Health Services Act).
   - Investigational drugs are only eligible if they have already completed a Phase I Clinical Trial.
   - Are not FDA approved for any indication.
   - Are part of either a pending FDA drug approval application or a current trial whose data will be submitted to FDA as part of an application.
   - Have not during development been placed on a clinical hold.
   - The clinical outcomes associated with the use of an eligible investigational drug typically cannot be used to adversely affect the review or approval of that drug.
   - Any known serious adverse events (SAEs) must be summarized and reported annually and submitted with the new drug application for the drug.

Participations should be informed that accessing treatment through this process may impact their existing health insurance and they should obtain clarification of that potential impact prior to proceeding in this

process.

30. Planned Emergency Research

An exception under FDA regulations at 21 CFR 50.24 permits planned research in an emergency setting without the informed consent of subjects. The exception applies to a limited class of research involving human subjects who are in need of emergency medical intervention. ***At present Prisma Health does not conduct planned emergency research.*** Prior to consideration of any such research, the investigator may must contact the HRPP Director to discuss the resources, processes, and requirements for implementing such a protocol.