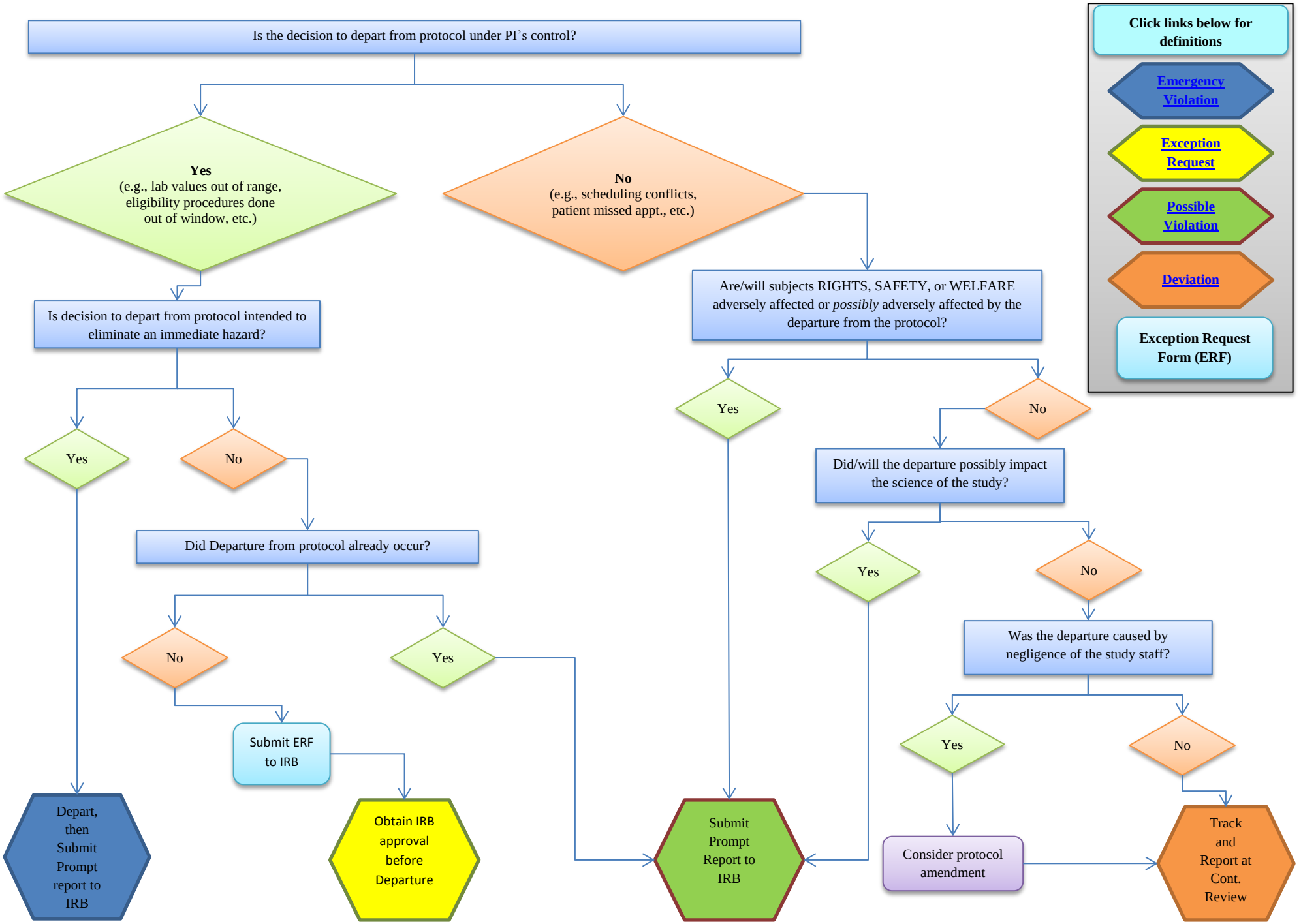
Decision Tree - Evaluating Departures

Deviations, Violations, Emergency Violations and Exceptions



DEFINITIONS:

Deviation:

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A departure from the approved study protocol without prior IRB approval that:

1. is generally noted or recognized after it occurs, or
2. if identified before it occurs cannot be prevented by the investigator (not an intentional deviation); and
3. has no potential substantive effect on the risks to research participants, and
4. has no potential substantive effect on the scientific integrity of the research plan or the value of the data collected, and
5. did not result from willful or knowing misconduct on the part of the investigator(s).

Examples when the deviation is recognized after it occurs include:

- An investigator's accidental failure to perform a protocol-required physical,
- A subject's failure to self-administer or incorrectly administer the test agent, or
- A coordinator's accidental failure to perform a protocol-required blood test on subjects.

An example when the deviation is identified before it occurs but it cannot be prevented includes

- A research subject who is on a business trip and calls the investigator to announce that she is stuck in a snow storm and cannot be at a study visit scheduled for the next day. The investigator knows in advance that the deviation will occur, but it is not under the investigator's control, and it is not the investigator's intent to deviate from the protocol.

Exception:

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A one-time, intentional action that departs from the IRB approved protocol for a single subject. An exception is identified before it occurs and is under the control of the investigator. Single subject exceptions may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.

Example includes (but not limited to):

- enrollment of a single subject who does not meet all eligibility criteria for a study, but the investigator and sponsor have agreed this subject should be enrolled.

Emergency Deviation:

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A departure from the approved study protocol without prior IRB approval that occurs in an emergency situation, such as when a departure from the protocol is required to eliminate apparent immediate hazard to the subject.

Examples include

- Withholding study drug in response to a serious adverse event (actual harm) or to avoid a serious harm (risk of harm).
- Emergency violations are considered Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) and require prompt reporting to the IRB

Violation:

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A departure (generally intentional on the part of the investigator) from the approved study protocol, and occurs without prior IRB approval that:

1. has the potential to cause harm or increase the risk of harm to one or more research participants or
2. has the potential to damage the scientific integrity of the data collected for the study; or
3. impacts a subject's safety, rights, or welfare

Examples include:

- Failure to obtain informed consent, use of an invalid consent form,
- enrollment of a subject who was ineligible for the study,
- performing a research procedure not in the approved protocol, changing an approved study procedure such as increasing the infusion rate

*Protocol violations require prompt reporting to the IRB and are summarized in the study progress report submitted during continuing review.