

*Changes to Requirements for
Reporting Research Incidents
(VHA 1058.01; June 2015)*

Human Research

Lexington VAMC IRB
Educational Item (Nov. 2015)

Definitions are found in VHA Handbook 1058.01 Research Compliance Reporting Requirements

http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=3116

DEFINITIONS: The definitions found in the 1200 series of VHA Handbooks, notably including definitions related to human research, animal research, and research safety, also apply to this Handbook. In instances in which the definitions below differ from the definitions in the VHA 1200 series Handbooks, the definitions below shall apply to this Handbook only.

a. **Adverse Event.** An Adverse Event (AE) is any untoward physical or psychological occurrence in a human subject participating in research. **NOTE:** For more information, see VHA Handbook 1200.05.

b. **Assurance of Compliance.** An Assurance of Compliance is a written commitment to a Federal department or agency to ensure compliance with applicable requirements.

c. **Continuing Noncompliance.** Continuing noncompliance is the persistent failure to adhere to the legal and policy requirements governing human research.

d. **Exposure.** Exposure refers to a research-related contact with hazardous and/or toxic materials, including any biological material, infectious agent, hazardous chemical, toxin, radioactive materials, or radiation source.

e. **Institutional Official.** The Institutional Official (IO) is the legally authorized Signatory Official for a research program and provides all official communications to external agencies and ORO. Facility Directors are the IOs for VA facility research programs. The Principal Deputy Under Secretary for Health is the IO for the VHA Central Office (VHACO) Human Research Protection Program (HRPP). References to facility Directors in this Handbook also apply to the Principal Deputy Under Secretary for Health when acting as the IO for the VHACO HRPP.

f. **Investigator.** An investigator is any individual who conducts research. **NOTE:** For more information, see VHA Handbook 1200.01.

g. **Local.** Local means occurring at the reporting facility's own research site(s).

h. **Noncompliance.** Noncompliance is any failure to adhere to the requirements for conducting VA research covered by this Handbook.

i. **Protected Health Information.** Protected Health Information (PHI), as defined by the Health Insurance Portability and Accountability Act (HIPAA), is individually identifiable health information transmitted or maintained in any form or medium by a covered entity, such as VHA. **NOTE:** For more information, see VHA Handbook 1605.1.

j. **Related AE, Death, or Problem.** A related AE, death, or problem is an AE, death, or problem that may reasonably be regarded as caused by, or probably caused by, the research. **NOTE:** For more information, see 21 CFR 312.64.

k. **Reportable.** A reportable event is any situation that requires an official report to ORO or any other regulatory entity beyond the local level.

l. **Research.** Research is a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Research involves the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question. **NOTE:** For more information, see VHA Directive 1200.

m. **Research Compliance Officer.** A Research Compliance Officer (RCO) is an individual who reports directly to the facility Director and whose primary responsibilities are auditing documentation related to facility research projects and informing the facility Director and research review committees about compliance concerns.

n. **Research Misconduct.** Research Misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or reporting research results. **NOTE:** For more information, see VHA Handbook 1058.02.

o. **Research Review Committee.** A research review committee is any committee or subcommittee designated by a VA facility to ensure compliance with the requirements for research.

p. **Select Agents and Toxins.** Select agents and toxins are regulated biological agents or toxins that could pose a severe threat to public health and safety or to animal or plant health as determined by the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA). **NOTE:** For more information, see VHA Handbook 1200.06, as well as 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121.

q. **Serious Accident/Injury.** Serious accidents/injuries include those that require medical attention or treatment, other than basic first aid provided at the site where the accident/injury occurred; those that require extended medical surveillance of the affected individual(s) that may include sequential serology or other medical testing; and those that lead to a serious long term health complication or death.

r. **Serious Adverse Event.** A Serious Adverse Event (SAE) is an untoward occurrence in human research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome.

s. **Serious Noncompliance.** Serious noncompliance is any failure to adhere to requirements for conducting human research that may reasonably be regarded as:

(1) Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or

(2) Substantively compromising a facility's HRPP. **NOTE:** For examples, see the ORO SharePoint/Web sites at <http://vawww.vha.vaco.portal.va.gov/sites/ORO/RCO/default.aspx> and <http://www.va.gov/oro/>. The first link is to an internal Web site and is not available to the public.

t. **Serious Problem.** A serious problem is a problem in human research or research information security that may reasonably be regarded as:

(1) Presenting a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or

(2) Substantively compromising a facility's HRPP or research information security program.

NOTE: For examples of possible serious problems, see the ORO SharePoint/Web sites at <http://vawww.vha.vaco.portal.va.gov/sites/ORO/RCO/default.aspx> and <http://www.va.gov/oro/>. The first link is to an internal Web site and is not available to the public.

u. **Suspension (Animal Research).** In animal research, suspension refers to the withdrawal of Institutional Animal Care and Use Committee (IACUC) approval for use of animals in research (relative to a procedure, protocol, or program), as determined by a majority vote at a convened meeting. Suspension of an animal activity requires the IO, in consultation with the IACUC, to review the reasons for the suspension, implement appropriate corrective actions, and report the actions and the circumstances surrounding the suspension to relevant regulatory authorities in accordance with USDA regulations at 9 CFR 2.31(d)(6-7) and paragraph IV.C.7 of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. **NOTE:** For more information, see VHA Handbook 1200.07.

v. **Suspension (All Other Research).** Except in animal research (see paragraph 4.u.), suspension refers to a temporary interruption in selected research activities (e.g., new enrollments or specific interventions) due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, regardless of whether the action to suspend was taken by an investigator, facility official, research review committee, or external entity. Suspension does not refer to interruptions for other reasons, including the expiration of project approval periods.

w. **Termination.** Termination refers to a permanent halt in all research activities due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, or about the welfare of laboratory animals, regardless of whether the action to terminate was taken by an investigator, facility official, research review committee, or external entity. Termination does not refer to interruptions for other reasons, including the expiration of project approval periods.

x. **Systemic Deficiency.** A systemic deficiency is a fundamental, underlying problem that jeopardizes the effectiveness of the facility's research protection system(s).

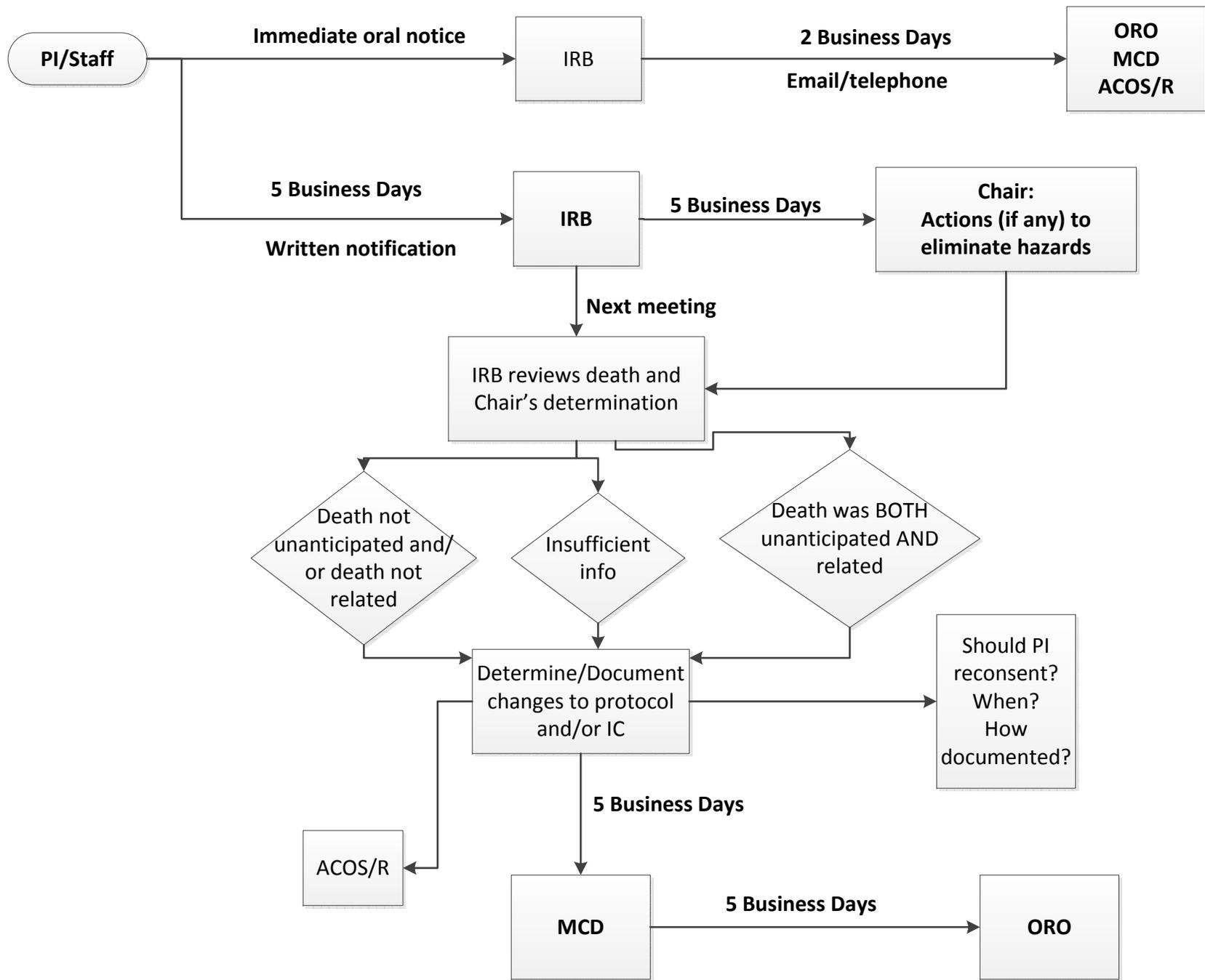
y. **Unanticipated and Unexpected.** Unanticipated and unexpected refer to an event or problem in human research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol documents and the characteristics of the study population.

z. **VA Research.** VA research is research conducted by an investigator under a VA appointment (i.e., a compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointment) on VA time. The research must be approved by

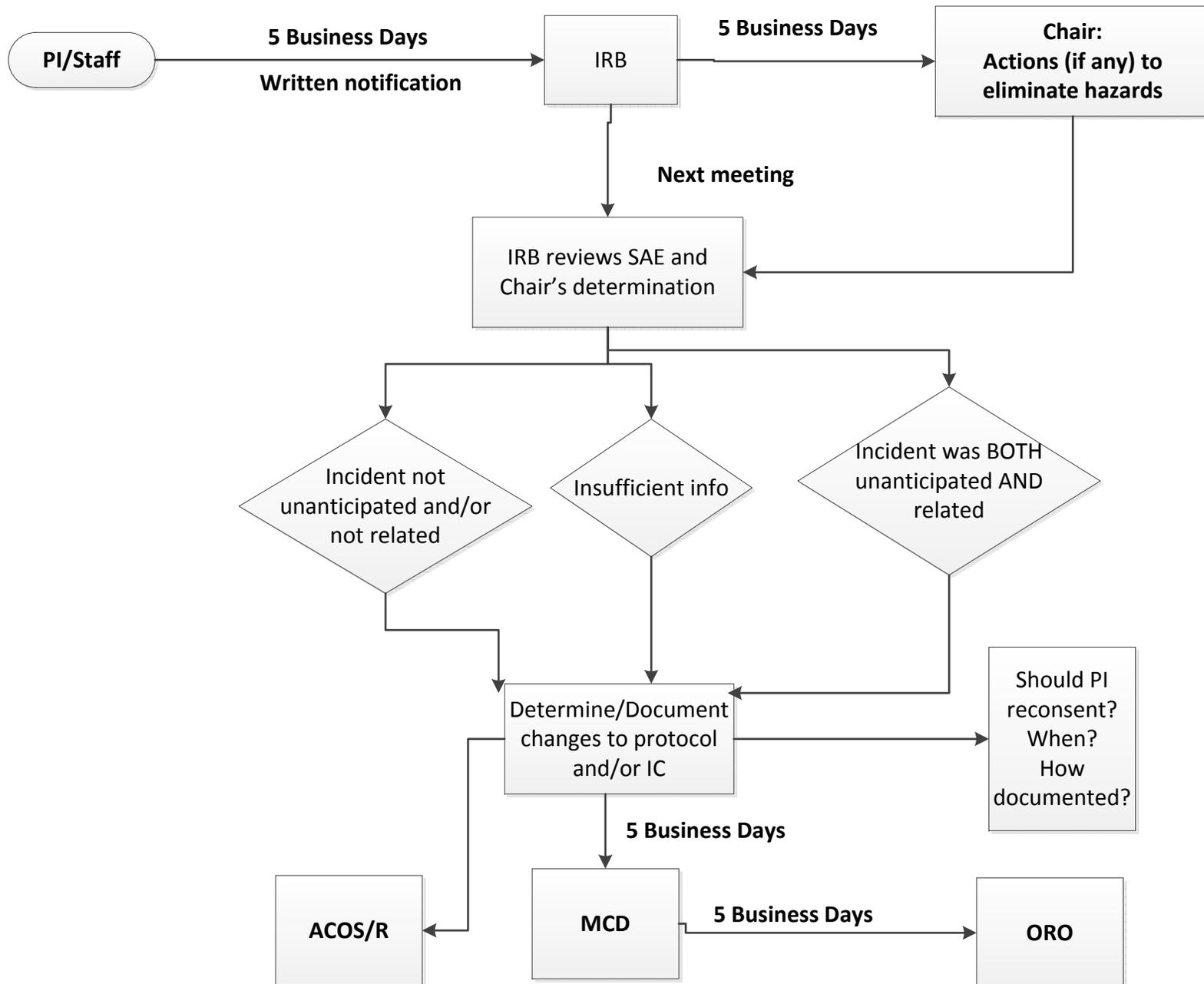
the Research and Development (R&D) Committee. **NOTE:** *For more information, see VHA Directive 1200 and the 1200 series of VHA Handbooks.*

aa. **Written or In Writing.** Written, or in writing, means conveyed on paper or electronically, including by e-mail, in a manner that creates a documented record.

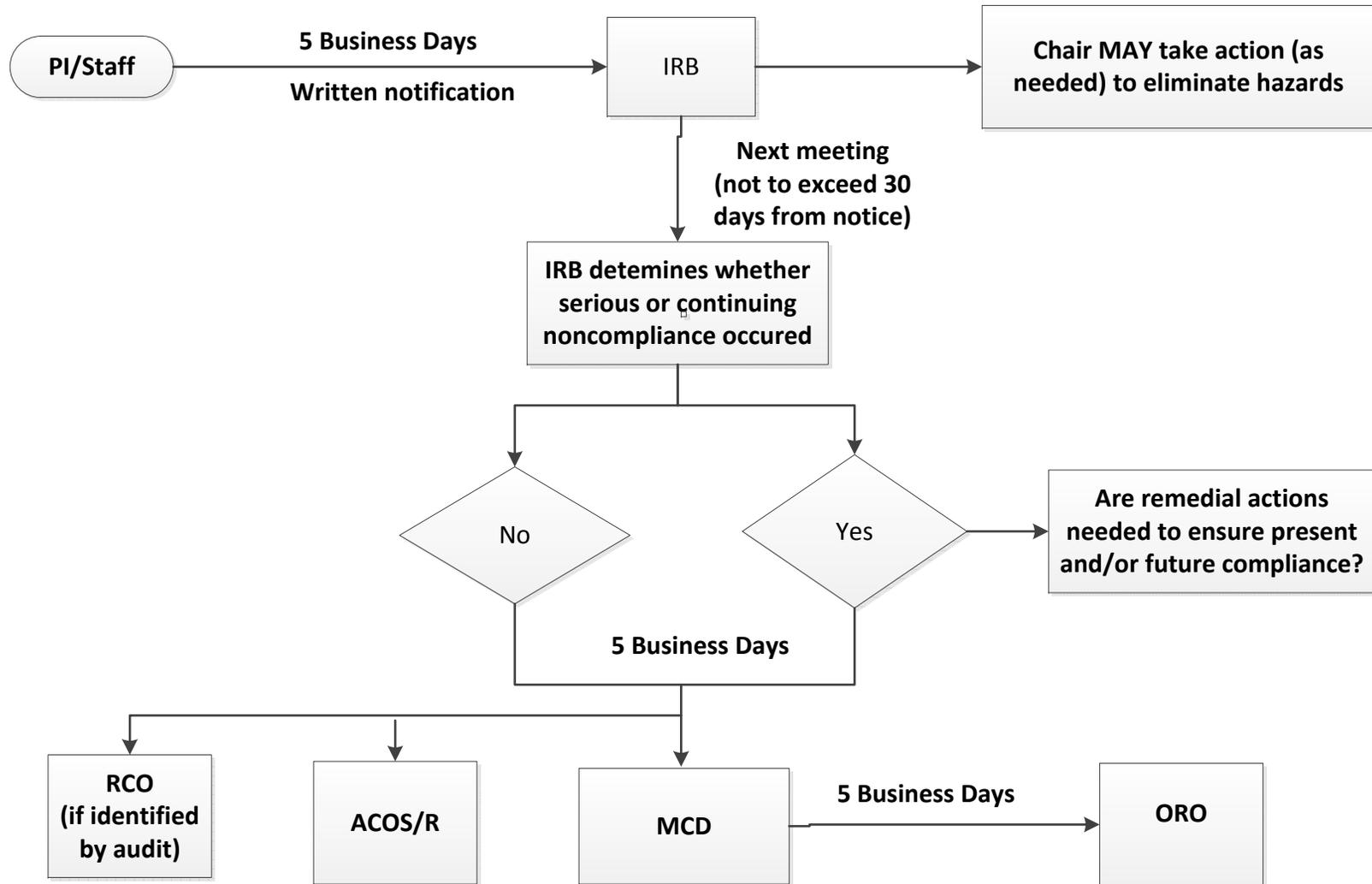
Local Research Deaths: Unanticipated AND Related to Research



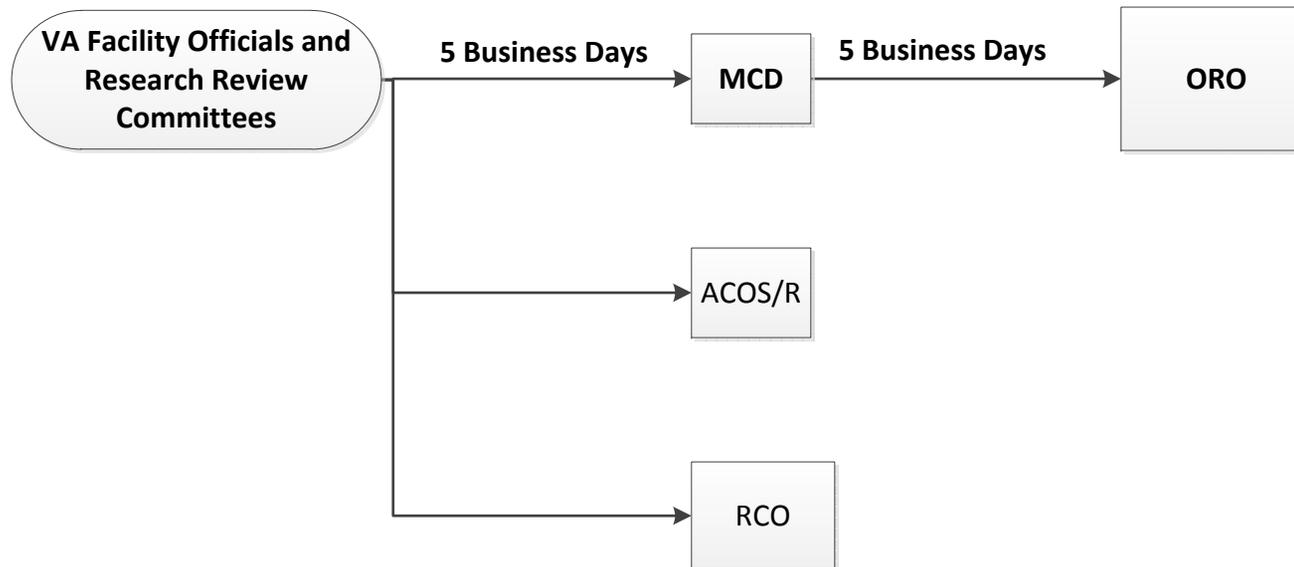
Local SAEs: Unanticipated AND Related to Research
Serious Problems: Unanticipated AND Related to Research



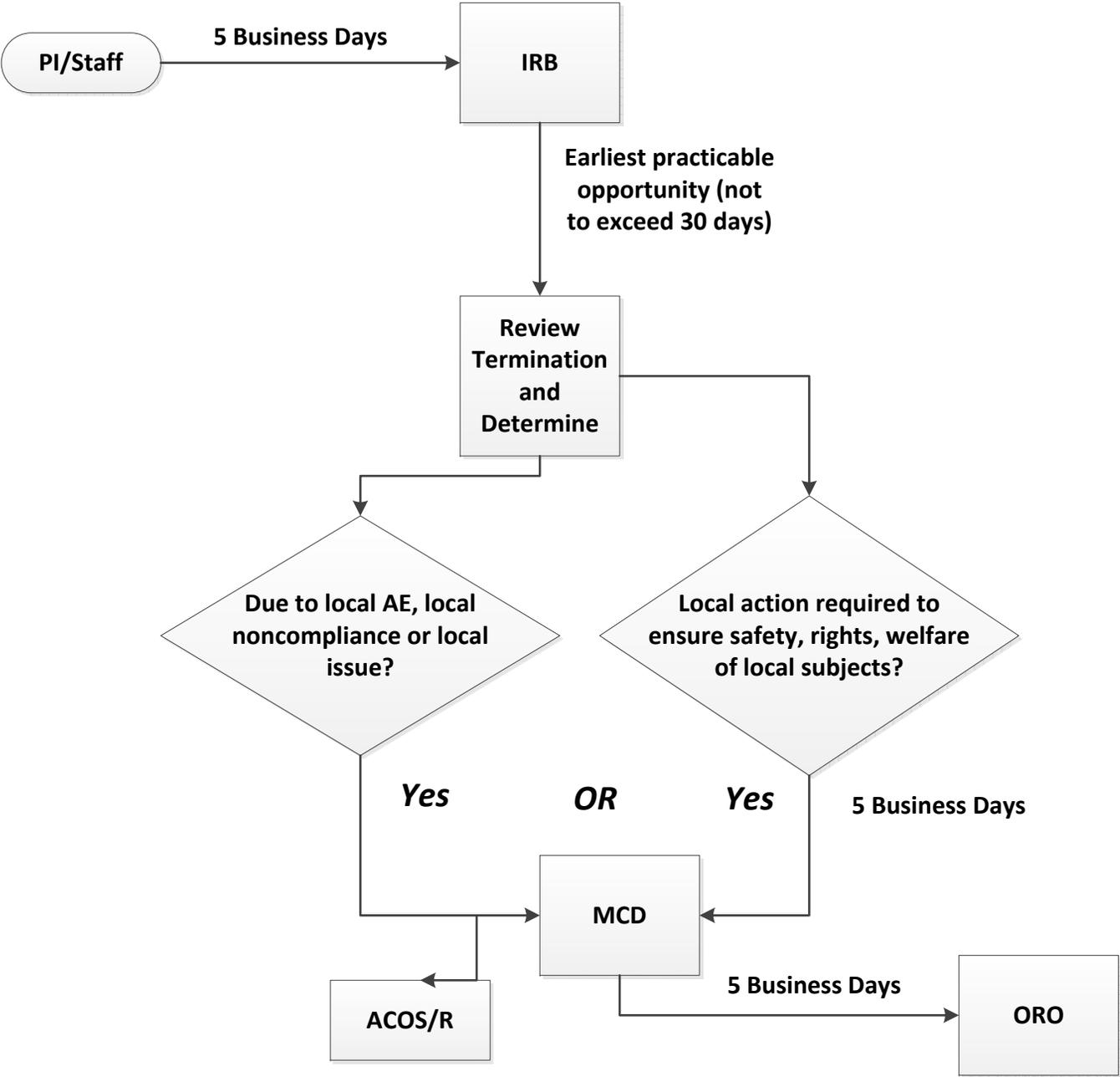
Apparent Serious or Continuing Noncompliance with IRB or other human research protection requirements



Suspensions/Terminations by VA



Suspensions/Terminations by External Entity



Program Changes

