Chapter 3

Conduct of the Investigation

I. **Scope.** This chapter sets forth the policies and procedures the Investigator must follow during the course of a discrimination investigation. It does not attempt to cover all aspects of a thorough discrimination investigation. It must be understood that due to the extreme diversity of cases that may be encountered, professional discretion must be exercised in situations that are not covered by these policies. To the extent that statutes and their rules mandate specific procedures, those procedures must be followed if there is any conflict with the procedures in this chapter. The investigator should consult with the IA when additional guidance is needed.

II. **General Principles.**

The investigator should make clear to all parties that IOSHA does not represent either the complainant or respondent, and that both the complainant’s allegation(s) and the respondent’s proffered non-retaliatory reason(s) for the alleged adverse action must be investigated. On this basis, relevant and sufficient evidence should be identified and collected in order to reach an appropriate determination of the case.

The investigator must bear in mind during all phases of the investigation that he or she, not the complainant or respondent, is the expert regarding the information required to satisfy the elements of a violation of the statutes administered by IOSHA. This applies not only to complainants and respondents but to other witnesses as well; quite often witnesses are unaware that they have knowledge that would help resolve a jurisdictional issue or establish an element. Framing the issues and obtaining information relevant to the investigation are the responsibilities of the investigator, although the investigator will need the cooperation of the complainant, respondent and witnesses.

The standard that applies to IOSHA whistleblower investigations is whether IOSHA has reasonable cause to believe that a violation occurred. This standard applies to all elements of a violation. When IOSHA believes that there may be reasonable cause to believe that a violation occurred, IOSHA should consult informally with the Legal Section, if it has not already done so, to ensure that the investigation captures as much relevant information as possible so that Legal can evaluate whether it is likely to prevail at trial.

III. **Case File.**

The investigator must prepare a standard case file containing the Whistleblower Case Activity Worksheet (OSHA-87) form, all documents received or created during the intake
and evaluation process, copies of all required opening letters, and any original evidentiary material initially supplied by the complainant. All evidence, records, administrative material, photos, recordings and notes collected or created during an investigation must be maintained in a case file and cannot be destroyed, unless they are duplicates. Further detailed guidance regarding proper case file organization may be found in Chapter 5, Report Writing and Case File Documentation.

IV. Preliminary Investigation.

A. Intake and Evaluation.

When initially receiving the discrimination case, it is important to confirm that the complaint is valid and is covered under Iowa Code 88.9(3). This initial review should confirm that the complaint is timely filed, that a prima facie allegation is present, if possible, and that the case has been properly logged.

B. Early Resolution.

OSHA must make every effort to accommodate an early resolution of complaints in which both parties seek resolution prior to the completion of the investigation. At any point the investigator may explore how an appropriate settlement may be negotiated and the case concluded. (See Chapter 6 regarding settlement techniques and agreements.) An early resolution is often beneficial to all parties, since potential losses are at their minimum when the complaint is first filed. Consequently, if the investigator believes that an early resolution may be possible, he or she is encouraged to contact the respondent immediately after completing the intake interview and docketing the complaint. However, the investigator must first determine whether an enforcement action is pending with OSHA prior to any contact with a respondent. Additionally, any resolution reached must be memorialized in a written settlement agreement that complies with the requirements set forth in Chapter 6.

C. Additional Case Information.

The investigator may also check on prior or current discrimination or safety and health cases related to either the complainant or employer. Such information normally will be available from the IMIS, Discrimination Log or safety and health inspection records. This enables the investigator to coordinate related investigations and to obtain additional background data pertinent to the case at hand.

Examples of information to be sought during the pre-investigation research phase include, but are not limited to:
1. Copies of IOSHA safety and health actions including phone/fax complaints, or any complaint filed with other State or Federal agencies or entities. This would include inspection reports, investigator’s notes, etc.

2. Interviews and signed statements

3. Information on previous discrimination complaints

D. Coordination with Other Agencies.

If information received during the investigation indicates that the complainant has filed a concurrent whistleblower charge or a safety and health or environmental complaint with another government agency (such as DOT, NLRB, EPA, NRC, FAA, DOE, etc.), the investigator may wish to contact such agency to determine the nature, status, or results of that complaint. This coordination may discover valuable information pertinent to the discrimination complaint, and may, in certain cases, also preclude unnecessary duplication of governmental investigative efforts.

V. Weighing the Evidence.

The investigative standard for Iowa Code 88.9(3) is whether there is reasonable cause to believe that a violation occurred. This standard applies to each element of a violation.

A. Investigative Standard.

Under the reasonable cause standard, IOSHA must believe, after evaluating all of the evidence gathered from the respondent, the complainant, and other witnesses or sources, that a reasonable judge could rule in favor of the complainant. The threshold that IOSHA must meet to find reasonable cause that a complaint has merit requires evidence in support of each element of a violation and consideration of the evidence provided by both sides or otherwise gathered during the investigation, but does not generally require as much evidence as would be required at trial. Because IOSHA makes a reasonable cause determination prior to a hearing, the reasonable cause standard is somewhat lower than the preponderance of the evidence standard that applies following a hearing. Accordingly, IOSHA’s investigation must reach an objective conclusion – after consideration of the relevant law and facts – that a reasonable judge could believe a violation occurred. The evidence does not need to establish conclusively that a violation did occur.

IOSHA’s responsibility to determine whether there is reasonable cause to believe a violation occurred is greater than the complainant’s initial burden to demonstrate a prima facie allegation that is enough to trigger the investigation.
However, a reasonable cause finding does not necessarily require as much evidence as would be required at trial to establish unlawful retaliation by a preponderance of the evidence. Although IOSHA will need to make credibility determinations to evaluate whether a reasonable judge could find in the complainant’s favor, IOSHA does not necessarily need to resolve all possible conflicts in the evidence or make conclusive credibility determinations to find reasonable cause to believe that a violation occurred. Rather, when IOSHA believes, after considering all of the evidence gathered during the investigations, that the complainant could succeed in proving a violation, it is appropriate to issue a merit finding or to consult with Legal.

**B. Causation Standards.**

Iowa Code Chapter 88.9(3) simply uses the word “because” to express the causation element. The Supreme Court has ruled that the anti-retaliation provision of Title VII, which simply uses the term “because” to express the causation element, requires the plaintiff to prove that the employer would not have taken adverse action but for the protected activity and that the plaintiff always has the burden of proof on this element. University of Texas Southwestern Medical Center v. Nassar, _U.S._, 133 S. Ct. 2517 (2013). A fuller explanation of but-for causation and examples can be found in Burrage v. United States, _U.S._, 133 S. Ct. 881 (2014). Since the district court statutes also simply use the term “because” to express the causation element, likewise before IOSHA informally consults with legal staff to suggest a possible merit determination IOSHA must have reasonable cause to believe that the employer would not have carried out the adverse action but for the protected activity. The but-for causation test is more stringent than the contributing factor or the motivating factor tests, but it does not require a showing that the protected activity was the sole reason for the adverse action.

**C. Gatekeeping Provisions.**

Iowa Code Chapter 88 also contains “gatekeeping” provisions, which provide that the investigation must be discontinued and the complaint dismissed if no prima facie allegation is made. That is, the complaint supplemented as appropriate by interviews of the complainant, must allege the existence of facts and either direct or circumstantial evidence that:

1. The complainant engaged in protected activity;
2. The respondent knew or suspected that the complainant engaged in protected activity;
3. The complainant suffered an adverse action; and
4. The circumstances are sufficient to raise an inference that protected activity was a contributing factor (or a motivating factor under the environmental statutes) in the adverse action. For example, the adverse action happened soon after the protected activity.
These gatekeeping provisions help stem frivolous complaints and simply codify the commonsense principle that no investigation should continue beyond the point at which enough evidence has been gathered to reach a determination.

VI. The Field Investigation.

The investigator ordinarily will be assigned several complaints to be investigated concurrently. Efficient use of time and resources demand that investigations be carefully planned in advance.

A. The Elements of a Violation.

An illegal retaliation is an adverse action taken against an employee by a covered entity or individual in reprisal for the employee’s engagement in protected activity. An effective investigation focuses on the elements of a violation and the burden of proof required. If the investigation does not establish by preponderance of the evidence that all of the elements of a violation exist the case should be dismissed. Therefore, the investigator should search for evidence that would help resolve each of the following elements of a violation:

1. Protected Activity.

The evidence must establish that the complainant engaged in activity protected by 88.9(3).

2. Employer Knowledge.

The investigation must show that a person involved in the decision to take the adverse action was aware, or suspected, that the complainant engaged in protected activity. The investigation need not show that the person who made the decision to take the adverse action had knowledge of the protected activity, only that someone who provided input that led to the decision had knowledge of the protected activity. If the respondent does not know, but could reasonably deduce that the complainant filed a complaint, it is referred to as inferred knowledge.

3. Adverse Action.

The evidence must demonstrate that the complainant suffered some form of adverse action initiated by the employer. An adverse action may occur at work; or, in certain circumstances, outside of work. Some examples of adverse actions include, but are not limited to:

● Discharge
● Demotion
- Reprimand
- Harassment - unwelcome conduct that can take the form of slurs, graffiti, offensive or derogatory comments, or other verbal or physical conduct. This type of conduct becomes unlawful when it is severe or pervasive enough to create a work environment that a reasonable person would consider intimidating, hostile, or abusive.
- Hostile work environment - separate adverse actions that occur over a period of time, may together constitute a hostile work environment, even though each act, taken alone, may not constitute a materially adverse action. Courts have defined a hostile work environment as an ongoing practice, which, as a whole, creates a work environment that would be intimidating, hostile, or offensive to a reasonable person. A complaint need only be filed within the statutory timeframe of any act that is part of the hostile work environment, which may be ongoing.
- Lay-off
- Failure to hire
- Failure to promote
- Blacklisting
- Failure to recall
- Transfer to different job
- Change in duties or responsibilities
- Denial of overtime
- Reduction in pay
- Denial of benefits
- Making a threat
- Intimidation
- Constructive discharge - the employer deliberately created working conditions that were so difficult or unpleasant that a reasonable person in similar circumstances would have felt compelled to resign

It may not always be clear whether the complainant suffered an adverse action. The employer may have taken certain actions against the complainant that do not qualify as “adverse,” in that they do not cause the complainant to suffer any material harm or injury. To qualify as an adverse action, the evidence must show that a reasonable employee would have found the challenged action “materially adverse.” Specifically, the evidence must show that the action at issue might have dissuaded a
reasonable worker from making or supporting a charge of retaliation. The investigator can test for material adversity by interviewing co-workers to determine whether the action taken by the employer would likely have dissuaded other employees from engaging in protected activity.

4. **Nexus.**

There must be reasonable cause to believe that there is a causal link between the protected activity and the adverse action. That causal link will be that the adverse action would not have occurred but for the protected activity. Nexus can be demonstrated by direct or circumstantial evidence, such as timing (proximity in the time between the protected activity and the adverse action), disparate treatment of the complainant in comparison to other similarly situated employees or in comparison to how the complainant was treated prior to engaging in protected activity, and/or animus (ill will towards the complainant).

**B. Contact with Complainant.**

The initial contact with the complainant must be made as soon as possible after receipt of the case assignment. Contact must be made even if the investigator's caseload is such that the actual field investigation will be delayed.

1. **Telephone Log.**

All telephone calls made, messages received, and exchange of written or electronic correspondence during the course of an investigation must be accurately documented in the activity/telephone log. Not only will this be a helpful chronology and reference for the investigator or any other reader of the file, but the log may also be helpful to resolve any difference of opinion concerning the course of events during the processing of the case. If a telephone conversation with the complainant is lengthy and includes a significant amount of pertinent information, the investigator should document the substance of this contact in a “Memo to File” to be included as an exhibit in the case file. In this instance or when written correspondence is noted, the activity/telephone log may simply indicate the nature and date of the contact and the comment “See Memo/Document - Exhibit #.”

2. **Amended Complaints.**

After filing a retaliation complaint with IOSHA, a complainant may wish to amend the complaint to add additional allegations and/or additional respondents. It is IOSHA’s policy to permit the liberal amendment of
complaints, provided that the original complaint was timely, and the investigation has not yet concluded.

a. **Form of Amendment.** No particular form of amendment is required. A complaint may be amended orally or in writing. Oral amendments will be reduced to writing by IOSHA. If the complainant is unable to file the amendment in English, IOSHA will accept the amendment in any language.

b. **Amendments Filed within Statute of Limitations.** At any time prior to the expiration of the statutory filing period for the original complaint, a complainant may amend the complaint to add additional allegations and/or additional respondents.

c. **Amendments Filed After Statute of Limitations Has Expired.** For amendments received after the statute of limitations for the original complaint has run, the investigator must evaluate whether the proposed amendment (adding subsequent alleged adverse actions and/or additional respondents) reasonably falls within the scope of the original complaint. If the amendment reasonably relates to the original complaint, then it must be accepted as an amendment, provided that the investigation remains open. If the amendment is determined to be unrelated to the original complaint, then it may be handled as a new complaint of retaliation and processed in accordance with 88.9(3).

d. **Processing of Amended Complaints.** Regardless of the statute, any amended complaint must be processed in the same manner as any original complaint. This means that all parties must be provided with a copy of the amended complaint; that this notification must be documented in the case file; and that the respondent(s) must be afforded an opportunity to respond. Investigators must review every amendment to ensure that a *prima facie* allegation is present. The investigator must ensure that all parties have been notified of the amendment in accordance with 88.9(3). See the chapter related to the implicated statute for specific information on processing complaints.

3. **Amended Complaints Distinguished from New Complaints.**

The mere fact that the named parties are the same as those involved in a current or ongoing investigation does not necessarily mean that new allegations should be considered an amendment. If the alleged retaliation involves a new or separate adverse action that is unrelated to the active investigation, then the complaint may be docketed with its own unique case number and processed as a new case.

4. **Early Dismissal.**

If the investigator determines that the complainant does not have allegations which are appropriate for investigation under the statute, but
may have a *prima facie* case under the jurisdiction of another State or Federal agency, the investigator can terminate the investigation and take proper steps to close the case and refer the complainant to the other agency as appropriate for possible assistance.

5. **Inability to Locate Complainant.**

In situations where the investigator is having difficulty locating the complainant to initiate or continue the investigation, the following steps must be taken:

a. Telephone the complainant at different hours during normal work hours and at other times of the day.

b. Mail a certified, return-receipt-requested letter to the complainant's last known address requesting that the investigator be contacted within 5 days of the receipt of the letter or the case will be dismissed. If no response is received within 5 days, the investigator may terminate the investigation and dismiss the complaint.

C. **Field Investigation.**

Personal interviews and collection of documentary evidence must be conducted on-site whenever practicable. Investigations should be planned in such a manner as to personally interview all appropriate witnesses during a single site visit. The respondent’s designated representative has the right to be present for all interviews with currently-employed managers, but interviews of non-management employees are to be conducted in private. The witness may, of course, request that an attorney or other personal representative be present at any time. In limited circumstances, witness statements and evidence may be obtained by telephone, mail, or electronically.

If a conversation is recorded electronically, the investigator must be a party to the conversation, and the witness give prior consent to the recording. This does not apply to other tape recordings supplied by the complainant or witnesses; however, all electronically recorded interviews or other voice recordings may be transcribed if they are to be used as evidence.

D. **Complainant Interview.**

The investigator will arrange to meet with the complainant as soon as possible in order to interview and obtain a signed statement detailing the complainant's allegations. Such a record is highly desirable and useful for purposes of case review, subsequent changes in the complainant's status, possible later variations
in testimony, and documentation for potential litigation. The complainant may, of course, have an attorney or other personal representative present at any time.

The investigator must attempt to obtain from the complainant all documentation in his or her possession that is relevant to the case. Relevant records may include, but are not limited to:

- Copies of any termination notices, reprimands, warnings or personnel actions
- Performance appraisals
- Earnings and benefits statements
- Grievances
- Unemployment benefits, claims and determinations
- Job position descriptions
- Company employee and policy handbooks
- Copies of any charges or claims filed with other agencies
- Collective bargaining agreements
- Arbitration agreements
- Medical records

The restitution sought by the complainant should be ascertained during the interview. If discharged or laid off by the respondent, the complainant should be advised of his or her obligation to seek other employment and to maintain records of interim earnings. Failure to do so could result in a reduction in the amount of the back pay to which the complainant might be entitled in the event of settlement, issuance of merit findings and order, or litigation. The complainant should be advised that the respondent’s back pay liability ordinarily ceases only when the complainant refuses a bona fide, unconditional offer of reinstatement. The complainant should also retain documentation supporting any other claimed losses resulting from the adverse action, such as medical bills, repossessed property, etc.

If the complainant is not personally interviewed and his or her statement is taken by telephone, a detailed Interview Summary will be prepared relating the complainant’s testimony.

E. Contact Respondent.

1. The respondent notification letter will normally be delivered in person by the Investigator without prior notice. The investigator will hand deliver the respondent notification letter which will be marked as “HAND
DELIVERED”. The respondent shall be advised of the protection provided to employees under Iowa Code 88.9(3). The investigator may then immediately commence with the investigation. The investigator will attempt to identify and interview respondent’s witnesses, neutral witnesses, etc. that the respondent feels are important to the case. In some instances, at the discretion of the Investigator, notification to respondent can be sent by certified mail.

2. In many cases the respondent will forward a written position statement, which may or may not include supporting evidence. In some instances, the material submitted may be sufficient to adequately document the company’s official position. Assertions made in the respondent’s position statement do not constitute evidence. The investigator will still need to talk with the respondent; interview respondent’s witnesses; review records and obtain documentary evidence; and to further test respondent’s stated defense.

3. The ideal arrangement is to make the respondent contact unannounced and complete as much of the respondent’s investigation as possible, excluding the complainant interview and complainant witness interviews.

4. If the respondent requests time to consult legal counsel or a designated representative, and they cannot be reached at the time of the investigation, the investigator will request that the respondent or counsel/designated representative contact them in a reasonable time limit. The investigator will obtain counsel/designated representative’s name, address, telephone number and e-mail address. The investigator will advise that future contact in the matter will be through such representative.

5. In the absence of counsel/designated representative, the investigator is not bound or limited to making contacts with the respondent through any one individual or other designated representative (e.g., safety director). If a position letter was received from the respondent, the investigator will contact the person who signed the letter.

   a. The investigator should interview all company officials who have known direct involvement in the case, and attempt to identify other persons (witnesses) at the employer’s facility who may have knowledge of the situation. Witnesses must be interviewed individually to obtain the best testimony.

   b. If the respondent has designated an attorney to represent the company, interviews with management and supervisory officials should ordinarily be scheduled through the
attorney, who may be present during any interviews of the management and supervisory witnesses.

c. Respondent’s attorney does not, however, have the right to be present, and should not be present, during interviews of non-management or non-supervisory employees.

d. Any respondent or other witness may, of course, have a personal representative or attorney present at any time. If respondent’s attorney indicates that he/she represents the non-management witness, a signed Designation of Representative form should be completed by respondent’s attorney memorializing that he/she represents the non-management witness.

e. There may be circumstances where there is reason to interview management or supervisory officials outside of the presence of counsel or other officials of the company, such as where the official has information helpful to the complainant and does not wish the company to know he or she is speaking with the investigator. In such event, an interview should ordinarily be scheduled away from the premises.

6. While at the respondent's establishment, the investigator should make every effort to obtain copies of, or at least review and make notes on, all pertinent data and documentary evidence which respondent offers, and which the investigator construes as being relevant to the case.

7. If at any time during the initial (or subsequent) meeting with respondent, management officials, or counsel, respondent suggests the possibility of an early resolution to the matter, the investigator should immediately and thoroughly explore how an appropriate settlement may be negotiated and the case concluded. (See Chapter 6 regarding settlement techniques and adequate agreements.)

8. If necessary, subpoenas may be obtained for testimony or records when conducting an investigation under 88.9(3). Subpoenas should be obtained following procedures established by the legal staff.

9. If the respondent fails to cooperate or refuses to respond, the investigator will evaluate the case and make a determination based on the information gathered during the investigation.
F. **Uncooperative Respondent.**

When dealing with a nonresponsive or uncooperative respondent it will frequently be appropriate for the investigator, in consultation with the IA and/or legal staff, to draft a letter informing the respondent of the possible consequences of failing to provide the requested information in a timely manner. Specifically, the respondent may be advised that its continued failure to cooperate with the investigation may lead IOSHA to reach a determination without the respondent’s input. Additionally, the respondent may be advised that IOSHA may draw an adverse inference against it based on its refusal to cooperate with specific investigative requests.

G. **Early Joint Review with Legal Staff.**

If in the early stages of the investigation of a case (where preliminary reinstatement may be ordered), and in other cases where the IA or the investigator may recommend that legal staff participate in the case, where the investigator and the IA believes there is evidence that the complainant's allegation has merit and may not be easily settled, legal staff should be contacted and briefed on the case.

H. **Further Interviews and Documentation.**

It is the investigator's responsibility to fairly pursue all appropriate investigative leads which develop during the course of the investigation, with respect to both the complainant's and the respondent's positions. Contact must be made whenever possible with all relevant witnesses, and every attempt must be made to gather all pertinent data and materials from all available sources.

1. The investigator must attempt to obtain a signed statement from each relevant witness. Witnesses will be interviewed separately and privately to avoid confusion and biased testimony, and to maintain confidentiality. The respondent has no right to have a representative present during the interview of a non-managerial employee. Only on rare occasions will the complainant's witnesses be interviewed in the workplace. If witnesses appear to be "rehearsed," intimidated, or reluctant to speak in the workplace, the investigator may decide to simply get their names and home telephone numbers and contact these witnesses later, outside of the workplace. The witness may, of course, have an attorney or other personal representative present at any time.

2. In the event that a signed statement cannot be obtained from a
witness, interview notes should be taken and a memorandum to the file subsequently prepared by the investigator setting forth all pertinent information obtained verbally from the witness.

3. The investigator will attempt to obtain copies of appropriate records and other pertinent documentary materials as required. If this is not possible, the investigator will review the documents, taking notes or at least obtaining a description of the documents in sufficient detail so that they may be subpoenaed or later produced during proceedings.

4. In cases where the complainant is covered by a collective bargaining agreement, the investigator should interview the appropriate union officials, and obtain copies of grievance proceedings or arbitration decisions specifically related to the discrimination case in question.

5. When interviewing potential witnesses (other than officials representing the respondent), the investigator should specifically ask if they request confidentiality. In each case a notation should be made on the interview form as to whether confidentiality is desired. Where confidentiality is requested, the investigator should explain to potential witnesses that their identity will be kept in confidence to the extent allowed by law, but that if they are going to testify in a proceeding, the statement will need to be disclosed.

I. Resolve Discrepancies.

After completing the respondent’s side of the investigation, the investigator will again contact the complainant and other witnesses as necessary to resolve any discrepancies or counter allegations resulting from contact with the respondent.

J. Analysis.

After having gathered all relevant evidence available, the investigator must evaluate the evidence and draw conclusions based on the evidence and the law using the guidance given in VI. A.

K. Closing Conferences.

Upon completion of the field investigation, the investigator will conduct a closing conference with the complainant. This conference may be conducted with the complainant in person or by telephone. The investigator should bear in mind that a thorough, tactful closing conference is considered a very important
and valuable step to achieve a successful conclusion to the investigation.
Assuring the complainant that his or her concerns have been fully explored and
the investigative findings impartially evaluated will minimize the likelihood of
appeals or objections, even though the complainant may not be totally satisfied
or in agreement with the determination.

1. During the conference, the investigator will discuss the case with the
complainant, allowing time for questions and explaining how the
recommended determination of the case was reached and what actions
may be taken in the future.

2. It is unnecessary to reveal the identity of witnesses interviewed. If the
complainant feels that certain witnesses should have been interviewed
but were not, the investigator will explain why the witnesses may not
have been interviewed.

3. If the complainant attempts to offer any new evidence or witnesses, this
should be discussed in detail to ascertain whether such information is
relevant or might change the recommended determination; and, if so,
what further investigation might be necessary prior to final closing of the
case. Should the investigator decide that the potential new evidence or
witnesses are irrelevant or would not be of value in reaching a fair
decision on the case’s merits, this should be explained to the complainant
along with an explanation of why additional investigation does not
appear warranted.

4. During the closing conference, the investigator must inform the
complainant of his/her rights to appeal, as well as the time limitation for
filing the appeal or objection.

5. The investigator will also send a closing letter, by certified mail, which
contains the procedure for appealing.

6. The closing conference will be documented in the case file either by an
entry in the telephone log or a separate Memo to File.

L Document File.

With respect to any and all activities associated with the investigation of a case,
the investigator must continually bear in mind the importance of documenting
the file to support his/her findings. Time spent carefully taking notes and writing
memoranda to file is considered productive time and can save hours, days, and
dollars later when memories fade and issues become unclear. To aid clarity,
documentation should be arranged chronologically where feasible.
The Report of Investigation (ROI) must be signed by the investigator and reviewed and approved by the supervisor.