STANDARD I-8

The organization works with public, industry, and private sponsors to apply the requirements of the Human Research Protection Program to all participants.

ELEMENT I.8.A.

The organization has a written agreement with the sponsor that addresses medical care for research participants with a research-related injury, when appropriate.

COMMENTARY

When appropriate, arrangements for medical care for research-related injury should be defined before the research starts and communicated to prospective participants. (See Element II.3.F.) This Element does not require any particular party, among the organization, sponsor or its agents, or participant to be responsible for such care; it requires that it be made clear to participants who will provide medical care and who will be responsible to pay for it.

This Element primarily applies only to the organization that conducts clinical research. If an organization conducts other types of research in addition to clinical research, this Element is generally not applicable, although there might be instances where research-related injury requiring medical care could occur. The organization should evaluate the risk of injury in the research conducted under its auspices and should make determinations whether medical care for research-related injury might be needed.

See AAHRPP Tip Sheet 25

REGULATORY AND GUIDANCE REFERENCES

- **DHHS**: 45 CFR 46.116(a)(6), 45 CFR 46.116(a)(7)
- **FDA**: 21 CFR 50.25(a)(6), 21 CFR 50.25(a)(7)

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

(a) Policies and procedures have contracts or other funding agreements indicate who will provide care and who is responsible to pay for it.

(b) For independent IRBs:

(i) If the organization contracts with sponsors or clinical research organizations, contracts or other funding agreements state that sponsors are required to indicate who will provide care and who is responsible to pay for it.

(ii) Policies and procedures include the process used to ensure that contracts with the researcher indicate who will provide care and who is responsible to pay for it, such as an attestation or other written statement from the researcher or clinical research organization, for examples master service agreement or work order.

COMMON TYPES OF MATERIALS THAT MAY BE USED TO MEET THE ELEMENT

- Contract template
- Reviewer checklist for contract language

OUTCOMES

- When appropriate, arrangements for medical care for research-related injury are defined before the research starts.
- For independent IRBs attestations or other written statements or agreements describe who will provide care and who is responsible to pay for it.

ELEMENT I.8.B. **In studies where sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the organization has a written agreement with the sponsor that the sponsor promptly reports to the organization findings that could affect the safety of participants or influence the conduct of the study.**

COMMENTARY

This Element does not apply when the sponsor is not responsible for monitoring the research. Monitoring of the research refers to overseeing the progress of a research study. An organization that works directly with a sponsor should require the sponsor or its agents to report to the organization findings of serious or continuing non-compliance detected during the monitoring process that could affect the safety of participants or influence the conduct of the study. If an independent IRB or EC or an organization does not work directly with the sponsor, the independent IRB or EC or organization should have a mechanism to ensure it receives copies of the monitoring reports that contain findings that could affect the safety of participants or influence the conduct of the study. An organization in this case should make the findings available to the IRB or EC.

See AAHRPP Tip Sheet 25

REGULATORY AND GUIDANCE REFERENCES

- None

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

(a) Policy and procedures have contracts or other funding agreements require the sponsor to promptly report to the organization any findings that could:

(i) Affect the safety of participants.

(ii) Influence the conduct of the study.

(b) For independent IRBs:

(i) If the organization contracts with sponsors or clinical research organizations, contracts or other funding agreements state that sponsors are required to promptly report to the IRB findings that could affect the safety of participants or influence the conduct of the study.

(ii) Policies and procedures include the process used to ensure that contracts with the researcher obligate the sponsor to promptly report any findings of study monitors that could affect the safety of participants or influence the conduct of the study to the researcher or organization conducting the research, such as an attestation or other written statement from the researcher or clinical research organization, for example a master service agreement or work order.

(iii) Policies and procedures require researchers or the organization conducting the research to promptly forward this information to the IRB.

COMMON TYPES OF MATERIALS THAT MAY BE USED TO MEET THE ELEMENT

- Contract template
- Reviewer checklist for contract language

OUTCOMES

- Contracts and other funding agreements require the sponsor to promptly report to the organization any findings that could:
    - Affect the safety of participants.
    - Influence the conduct of the study.
- An independent IRB or EC or an organization that does not work directly with the sponsor has a mechanism to receive findings that could affect the safety of participants or influence the conduct of the study. An organization in this case makes the findings available to the IRB or EC.

ELEMENT I.8.C. When the sponsor has the responsibility to conduct data and safety monitoring, the organization has a written agreement with the sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the organization.

COMMENTARY

IRB or ECs have the responsibility to ensure that provisions for data and safety monitoring are adequate and that results from data and safety monitoring justify the continuation of IRB or EC approval of the research study.

When the organization works directly with the sponsor, or its agent, and the sponsor, or its agents, has the responsibility for data and safety monitoring, the contract or funding agreement should include arrangements so that data and safety monitoring plans are provided to the organization, or provided to the researcher who provides them to the IRB or EC. Contracts and funding agreements should stipulate that reports from data and safety monitoring are provided to the researcher who provides them to the IRB or EC.

If an independent IRB does not work directly with the sponsor, it should have a mechanism to ensure it receives the data and safety monitoring plan in order to review the research study and results of the data and safety monitoring to ensure that continuation of IRB or EC approval of the research study is justified.

See AAHRPP Tip Sheet 25

REGULATORY AND GUIDANCE REFERENCES

- None

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

(a) Policies and procedures have contracts or other funding agreements require the sponsor to send data and safety monitoring reports to the organization.

(i) Contracts or other funding agreements specify the time frame for providing routine and urgent data and safety monitoring reports to the organization.

(b) For independent IRBs:

(i) If the organization contracts with sponsors or clinical research organizations, contracts or other funding agreements state that sponsors are required to send routine and urgent data and safety monitoring reports to the IRB.

(ii) Policies and procedures include the process used to ensure that contracts obligate the sponsor to send routine and urgent data and safety monitoring reports to the researcher or organization conducting the research, such as an attestation or other written statement from the researcher or clinical research organization, for example a master service agreement or work order.

(A) Policies and procedures require researchers or the organization conducting the research to forward this information to the IRB.

OUTCOMES

- Contracts or other funding agreements require the sponsor to provide reports of data and safety monitoring to the organization.
- The independent IRB or EC has a mechanism to ensure it receives data and safety monitoring plans prior to IRB or EC approval of the research.
- The independent IRB or EC has a mechanism to ensure it receives routine and urgent reports of data and safety monitoring.

ELEMENT I.8.D. Before initiating research, the organization has a written agreement with the sponsor about plans for disseminating findings from the research and the roles that researchers and sponsors will play in the publication or disclosure of results.

COMMENTARY

If the organization has a policy regarding the publication of findings from sponsored research and works directly with a sponsor or its agents, contracts or other funding agreements should require the sponsor to follow that policy and procedure.

This Element does not apply to the organization that does not directly work with sponsors or to the organization that has no policy regarding the dissemination of findings from sponsored research.

See AAHRPP Tip Sheet 25

REGULATORY AND GUIDANCE REFERENCES

- None

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

(a) Policies and procedures have contracts or other funding agreements require the sponsor to follow the organization's policies and procedures regarding the publication of findings from sponsored research.

OUTCOMES

- Contracts or other funding agreements require the sponsor to follow the organization's policies and procedures regarding the publication of findings from sponsored research.

ELEMENT I.8.E. When participant safety could be directly affected by study results after the study has ended, the organization has a written agreement with the sponsor that the researcher or organization will be notified of the results in order to consider informing participants.

COMMENTARY

In some cases, findings emerge after a research study has ended that directly affect the safety of past participants and were not anticipated at the time the study was designed or conducted. In such cases, past participants should be notified of the new findings. An organization that works directly with a sponsor or its agents should include in the contract or other agreement how such results will be communicated to the organization.

See AAHRPP Tip Sheet 25

REGULATORY AND GUIDANCE REFERENCES

- None

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

(a) Policies and procedures have contracts or other funding agreements describe the steps followed to communicate findings from a closed research study to the researcher or organization when those findings directly affect participant safety.

(i) Policies and procedures have contracts or other funding agreements specify a time frame after closure of the study during which the sponsor will communicate such findings.

(A) The time frame may be a specific time period (for example, two years).

(B) The time frame may be based on a specific triggering event (such as completion of data analysis)

(C) The time frame may be left open-ended or the requirement can be included or referred to in a survivor clause.

(b) For independent IRBs:

(i) If the organization contracts directly with sponsors or clinical research organizations, contracts or other funding agreements include a requirement that sponsors communicate findings from a closed research study to the IRB when those findings directly affect participant safety.

(A) Specify a time frame or triggering event after closure of the study during which the sponsor will communicate such findings (for example, two years; or after the close of data analysis), when appropriate.

(ii) Policies and procedures include the process used to ensure that contracts with the researcher obligate the sponsor to notify the researcher or organization conducting the research any study results after the study has ended that could directly affect participant safety, such as an attestation or other written statement from the researcher or clinical research organization, for example a master service agreement or work order.

(A) Specify a time frame or triggering event after closure of the study during which the sponsor will communicate such findings (for example, two years; or after the close of data analysis), when appropriate.

(B) Policies and procedures require researchers or the organization conducting the research to forward this information to the IRB.

OUTCOMES

- Contracts and other funding agreements describe the steps followed to communicate results from a research study to former participants when those results directly affect their safety or medical care.
- For independent IRBs attestations or other written statements or agreements describe the steps followed to communicate results from a research study to former participants when those results directly affect their safety or medical care, and to inform the IRB.