**Information for Research Investigators**

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##### INTRODUCTION

The Institutional Review Board (IRB) established by the Department of Health and Senior Services serves to assure that research on human subjects is planned and carried out in accordance with certain ethical principles and federal regulations.

Prior to initiation, all research that involves a human subject and that originates in or is the responsibility of DHSS, involves DHSS staff in any aspect of the research, or is funded by DHSS must be reviewed and approved by the IRB. This policy applies regardless of source of funding or location of the study.

##### GOVERNING PRINCIPLES AND REGULATIONS

All human subject activities of DHSS will be guided by the ethical principles in [*The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm). All human subject research will comply with 45 CFR Chapter 46 and/or any human subject regulations and policies of any relevant regulatory federal department or agency. The web site of the Office of Human Research Protection of the federal Department of Health and Human Services, <http://www.dhhs.gov/ohrp/>, includes valuable information for researchers.

The basis of these principles and regulations is humans should only be used as research subjects if:

* risks to them are minimized,
* the risks are reasonable in relation to anticipated benefits,
* selection of subjects is equitable,
* informed consent will be sought from each prospective subject, and appropriately documented
* data are monitored to ensure the safety of subjects (when applicable),
* adequate provisions are made to protect subjects’ privacy and maintain confidentiality, and
* additional safeguards are used to protect the rights and welfare of those who may be vulnerable to coercion, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

##### ROLES AND RESPONSIBILITIES

1. Investigators

Investigators are responsible for designing and carrying out research protocols that adhere to the basic principles stated above. To do this, attention must be given to the following points.

Risks: Design the study in such a way that physical and psychological risks to the subjects are minimized and are reasonable in relation to anticipated benefits. This means minimizing direct risks, and developing a good methodological design so the study results add reliable information to the body of knowledge. Even a low-risk study must have the substantial possibility of benefiting the subjects, society, or both.

Equity: Select subjects on an equitable basis. This is a justice issue if there are direct benefits from participation. It is also methodological--again, a poorly designed study cannot contribute to generalizable knowledge.

Informed Consent: Develop a fair procedure for requesting informed consent from all subjects (see details in Section V.A below and the “Informed Consent Guidelines”). [Informed Consent Guidelines](https://health.mo.gov/data/irb/doc/InformedConsentGuidelines.docx). This means, in part, assuring that they can understand the information provided to them about the study. Written information and consent forms should be at the sixth grade level or lower unless all subjects are drawn from a highly educated group, and should be written in the first languages of the subjects. Informed consent and/or written documentation of consent may only be waived if the criteria listed in [45 CFR 46.116](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116%23se45.1.46_1116#se45.1.46_1116) and [45 CFR 46.117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116#se45.1.46_1117) are met (see Section V.A below).

Protection of privacy and confidentiality: Develop procedures that effectively protect subjects’ privacy, especially when collecting information that could place the subjects at risk if released outside the research.

Reporting of unanticipated problems: Investigators are required to immediately report to the IRB Chair any:

* unanticipated problems involving risks to subjects or others (including injuries or death),
* serious or continuing noncompliance with Federal or DHSS IRB policies, requirements, or determinations, and
* untoward events such as complaints or lawsuits.

Procedures: Investigators are responsible for following DHSS procedures for submission of projects for initial and continuing review, and notifying the IRB of any protocol changes or unanticipated problems. These procedures are outlined in Section IV below.

The IRB chair shall be notified in writing if there is a change in the principal investigator. This written notification shall also be sent to DHSS units that have provided data or are involved in the study, including but not limited to the State Registrar/Designee and the Patient Abstract System Releasing Authority.

Training: All DHSS investigators and co-investigators who submit projects to the IRB shall review DHSS Administrative Policies 30.8, 30.8A, 30.11, and 30.17 and familiarize themselves with relevant federal regulations, OHRP guidance, state laws, and DHSS procedures. DHSS investigators and co-investigators are required to complete the Collaborative Institutional Training Initiative (CITI) Program training for investigator/co-investigators once every 3 years and print the certificate of completion to be included in any IRB review study packets. All external investigators are required to complete a reputable human subject’s protection training course and provide proof of completion within the past 3 years. Educational Resources for Investigators may be found at <https://www.hhs.gov/ohrp/sites/default/files/educational-resources-for-investigators.pdf>.

1. Institutional Review Board

The IRB is responsible for reviewing and/or overseeing the review of all research that involves a human subject and that originates in or is the responsibility of DHSS, involves DHSS staff in any aspect of the research, or is funded by DHSS.

The IRB is also responsible for:

* reviewing any changes in research protocols,
* receiving and investigating reports of any unanticipated problems related to a research project,
* continuing review of ongoing research activity, at least annually or more often at the discretion of the IRB,
* communicating with investigators and DHSS management, and
* providing consultation and human research protection training for DHSS investigators and co-investigators.

DHSS employees involved in research are subject to departmental administrative policies:

30.8 Human Subjects Protection and Institutional Review Board,

30.11 Procedures for Dealing with and Reporting Misconduct in Science, and

30.17 Scientific Study Approval Guidelines.

All new DHSS IRB members shall review DHSS Administrative Policies 30.8, 30.8A, 30.11, and 30.17 and are required to complete the CITI program training for IRB members within 45 days of appointment prior to participating in Board meetings. Certificates of completion shall be forwarded to the IRB Chair. This training is valid for three years. Members are also highly encouraged to view the training videos provided by OHRP that are available at <https://www.hhs.gov/ohrp/education-and-outreach/index.html> and <https://health.mo.gov/data/irb/index.php>. All IRB members are encouraged to attend at least one human subject’s related training session a year and maintain documentation of all training completed. Additional online trainings may be found at <https://www.hhs.gov/ohrp/education-and-outreach/online-education/index.html>.

Any IRB member who may have a conflict of interest with a research project may not participate in reviewing that project, except to provide information requested by other IRB members, and may not vote on the project. The IRB chair shall be notified of any such conflict prior to the vote on the project. Examples of conflicting interests include (but are not limited to) administrative responsibility for the project, supervision of one or more investigators, or a financial interest in the project.

1. **DHSS Responsibilities**

DHSS is responsible for assuring that all research that involves a human subject and that originates in or is the responsibility of DHSS, involves DHSS staff in any aspect of the research, or is funded by DHSS, adheres to the ethical principles in the Belmont Report and the applicable federal and state laws and regulations.

DHSS must maintain, and adhere to the terms of, a Federalwide Assurance of Protection for Human Subjects, administered by the federal [Office of Human Research Protections (OHRP](http://www.hhs.gov/ohrp)). This includes designating an Institutional Official, an IRB Chair, and a Human Subjects Protections Administrator, assuring that appropriate policies and procedures are in place, appointing members to the IRB, and enforcing policies related to human subjects’ protection.

##### REVIEW PROCEDURES

1. Initial Review of Submitted Protocols

The following forms and information are provided to facilitate the IRB review of research projects/studies submitted to DHSS. The forms are to be completed electronically. All external researchers are required to collaborate with a DHSS Co-Investigator. For external projects, the electronic application packet, which must include the signature of the principal investigator, are to be submitted to the DHSS staff person working with the investigator on the project/study. This DHSS staff member will be assigned as the responsible DHSS Co-investigator.

**Initial application submissions should include:**

* Checklist for Submission for IRB Review of Research/Study Protocols
* IRB Form 1 “Request for Review of Research Protocol”
* Copy of the Human Research Protection Training certificates, completed within the last 3 years, for all persons who will work on this project and/or who will have access to identifiable or potentially identifiable data
* Abstract of Protocol
* Protocol Template
* Copy of consent form, if applicable
* Copy of Memorandum of Understanding or Agreement, or other documentation that provides evidence that all collaborating institutions and investigators have agreed to collaborate on the project, if applicable
* Copy of the letter that includes the date of approval from another IRB, including any modifications, limitations or conditions required by that IRB, if applicable
* Copies of recruitment materials (media ads, notices, announcements, posters etc.), if applicable
* Copies of all research instruments (questionnaires, letters to institutions/subjects, material to be seen/read by subjects, etc.)
* Cover Sheet for DHSS IRB Submissions (completed by DHSS Investigator/Co-Investigator)

Incomplete applications will be returned to investigator(s). IRB review will begin only when all required documents are provided with signatures indicating approval by appropriate department staff. Substitutions for DHSS forms are not permitted.

The IRB members will convene and review all projects that are not exempt and do not qualify for expedited review. The Chair will convene the IRB, and full board review will be scheduled within 60 days of submission of the complete application to the IRB. A simple majority of members will comprise a quorum.

Copies of applications and all other relevant documents submitted by the investigators will be provided to the members at least one week in advance of the scheduled meeting. The investigator(s) will be given the opportunity to briefly present information about the protocol and answer questions from the IRB members. The investigator(s) will then be dismissed from the meeting.

IRB action requires a simple majority of members present that shall include at least one member whose primary concerns are in nonscientific areas. Any of the following actions may be taken by the IRB:

* **Full approval**—the project is approved as submitted indicating the project meets the regulatory requirements for the protection of human subjects. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.
* **Contingent approval**—the project is approved with minor revisions that require simple concurrence by the investigators.
* **Deferral**—the project is not approved and may not be implemented without significant revision and re-submittal for full IRB review.
* **Disapproval**—the project is disapproved and may not be implemented.

When the federal regulations require documentation of specific findings on the part of the IRB, for example to approve a waiver of informed consent or a signed consent form, or research involving pregnant women, prisoners, or children, those findings will be discussed, documented in the meeting minutes and the approval notice.

The Chair will notify the investigators and the Institutional Official, in writing, regarding the results of IRB review within 30 days of a convened meeting. If approval is contingent upon minor changes, these must be incorporated into the protocol and submitted to the IRB Chair before the project may be implemented. If the project is deferred, the recommended changes must be made in the protocol, which will require a full board review. The Chair will notify the investigators and the department Institutional Official in writing when final approval is granted.

1. **Request for Exemption**

An investigator may request exemption from review if all aspects of the project fit one or more exempt categories spelled out in detail in [45 CFR 46.104](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104).

Investigators may request exemption by checking the appropriate box on the first page of the IRB Form 1, “Request for Review of Research Protocol.” Requests for exemption are reviewed by the IRB Chair and the investigator will be notified within 30 days of submission of a completed application. If the project does not meet one of the criteria above, the Chair will arrange for a full board review.

Investigators shall report any changes in exempted projects by submitting a completed IRB Form 2 along with a written description of the proposed changes and copies of any proposed revisions to study protocols and forms to the Chair before they are implemented.

1. Request for Expedited Nonexempt Review

When a proposed project is not exempt from review, the Chair will determine whether it qualifies for expedited review according to 45 CFR 46.110 and 21 CFR 56.110 and the most current guidance from OHRP. If so, the Chair may coordinate expedited review or convene the IRB for full board review. If full board review is necessary, the investigators will be invited to briefly present the project to the IRB and answer any questions. If the project is given expedited review, the information listed in Section IV.A above may be reviewed by the Chair or by one or more experienced IRB members designated by the chair, who will provide written feedback to the Chair within 14 days.

Criteria for projects subject to expedited review may be found at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>.

Any of the following actions may be taken by the IRB:

* **Full approval**—the project is approved as submitted indicating the project meets the regulatory requirements for the protection of human subjects. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.
* **Contingent approval**—the project is approved with minor revisions that require simple concurrence by the investigators.
* **Deferral**—the project is not approved and may not be implemented without significant revision and re-submittal for full IRB review.
* **Disapproval**—the project is disapproved and may not be implemented.

Expedited review will be completed and the investigators informed of the results within 45 days after submission of a complete application. If contingent approval is granted, the project may not be implemented until the required information and minor revisions are provided to and approved by the Chair or another member designated by the Chair.

1. Continuing and Modification Review

Federal regulations require that the IRB re-approve research projects at intervals appropriate to the degree of risk, but no less than once per year. This process is called “continuing review.” Continuing review for non-exempt research is required to occur as long as the research remains active for long-term follow-up of research subjects, even when the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and to occur when the remaining research activities are limited to collection of private identifiable information. The IRB may decide that specific projects require more frequent review, based on greater than minimal risk or the collection of highly sensitive personal information. The IRB may also determine that a project requires verification from sources other than the investigators that no material changes have occurred since previous IRB review, if the project is complex and involves unusual levels or types of risk to subjects.

Any change in this research project or materials must be submitted to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards to subjects using the IRB Form 2. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

The investigator(s) must submit an IRB Form 2, “[Information for Continuing Review of a Previously Approved Project](https://health.mo.gov/data/irb/doc/IRBForm2.docx),” 45 days in advance of the annual or designated review date, along with the additional information stipulated on the form, see below for details on required documentation.

**Continuing or modification review submissions should include:**

* IRB Form 2 “Information for Continuing Review of a Previously Reviewed Project”
* Copy of Human Research Protection Training certificates, completed within the last 3 years, for the Principal Investigator and DHSS Co-Investigator
* Copy of current Consent Form, if applicable
* Written description of proposed changes and copies of any proposed revisions to study protocols and forms, when applicable
* Copy of progress or final report, when applicable

If the project is still active, even if activity is restricted to data analysis or long-term follow-up of subjects, then the project will be reviewed by the IRB. If the project received expedited review originally, it may receive expedited continuing review. The IRB may take any of the following actions upon continuing review:

* **Full approval** of continuation.
* **Contingent approval** of continuation, subject to specific, stated minor revisions that require simple concurrence by the investigator(s).
* **Suspension or termination.** The IRB may suspend or terminate research that is not being conducted in accordance with the IRB’s decisions, conditions, and requirements or that has been associated with unexpected serious harm to subjects. This is an unusual occurrence. If the project is suspended, the full IRB must review the protocol changes before it can resume.

If IRB approval for a federally funded research project is suspended or terminated, the Chair will notify the department Institutional Official, who will notify the Department Director, federal funding agency head or designee and the OHRP within five working days.

**Unanticipated Problems Involving Risks:** You must promptly report to the IRB any unexpected adverse experience, as defined in the IRB/HRPO policies and procedures, and any other unanticipated problems involving risks to subjects or others.

For further guidance regarding continuing review of human subject research, see the Office of Human Research Protections’ current Guidance on IRB Continuing Review of Research available at <http://www.hhs.gov/ohrp>.

1. Project Close Out / Final Review

If all research-related interventions or interactions with human subjects have been completed, and all data collection and analysis of identifiable private information described in the IRB-approved research plan have been finished, then the human subject research study has been completed. When a human subject research study has been completed, the investigators no longer are required to obtain continuing review and approval of that study by the IRB.

By no later than the current DHSS IRB approval end date, or a date set by the IRB, the principal investigator shall notify the IRB Chair in writing of the study’s completion and must submit a final IRB Form 2 and a copy of the final project report. The principal investigator’s signature on the IRB Form 2 for completed projects signifies all data has been properly destroyed as stated in the project protocol.

**Final Close Out submissions should include the following:**

* IRB Form 2 “Information for Continuing Review of a Previously Reviewed Project”
* Copy of final report, when applicable

For further guidance regarding completion of human subject research, see the Office of Human Research Protections’ current Guidance on IRB Continuing Review of Research available at <http://www.hhs.gov/ohrp>.

1. Cooperative Research Projects

If a specific project is conducted in collaboration with another institution, an investigator may request reliance on the other institution’s IRB for review. The decision to do this will be made by the Chair after initial review of the application. If this is approved, a Memorandum of Understanding for that protocol must be completed and signed by authorized officials of both institutions. The collaborating institution must have a valid IRB registration and Federalwide Assurance in place. The Federalwide Assurance is the only type of assurance accepted and approved by OHRP. If DHSS chooses to rely on another institution’s IRB, the DHSS shall be notified of any actions by the other institution’s IRB regarding the project.

DHSS may choose to allow a collaborating institution to rely on DHSS IRB review of a specific project. The decision to do this will be made by the Chair, only if requested by the DHSS principal investigator. The project application shall include a copy of the contact information (name, address, telephone number and e-mail address) for the other institution’s signatory official and a draft Memorandum of Understanding. The collaborating institution must have a valid IRB registration and Federalwide Assurance in place. The Federalwide Assurance is the only type of assurance accepted and approved by OHRP. A Memorandum of Understanding for that protocol will be completed and signed by authorized officials of both institutions. The DHSS IRB will notify the other institution of any actions taken regarding the project.

##### CRITICAL PROTOCOL ELEMENTS FOR IRB REVIEW

1. Informed Consent

The process of obtaining informed consent is critical to human subjects’ protection. Except in certain very specific situations discussed below, a researcher may not involve human subjects in research unless he/she has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. Usually, informed consent must be documented in writing, although under certain conditions written informed consent may be waived [45 CFR 46.117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116#se45.1.46_1117)

Key points are:

* The prospective subject (or representative) must have sufficient opportunity to consider whether, or not, to participate.
* The possibility of coercion or undue influence must be minimized.
* The information given to the subject about the study must be in language understandable to the subject.
* No language may be used that implies the subject is waiving any legal rights.
* No language may be used that releases the researcher or institution from liability for negligence.

The “[Informed Consent Guidelines](https://health.mo.gov/data/irb/doc/InformedConsentGuidelines.docx)” contain the basic elements that must be included in an informed consent document, as well as a suggested outline and sample form.

Waiver or alteration of informed consent. Under certain specific circumstances, the requirement of informed consent may be waived (see [45 CFR 46.116 (c and d)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116%23se45.1.46_1116#se45.1.46_1116). In brief, all the following conditions must be met:

* The research involves no more than minimal risk to the subjects;
* The waiver or alteration of informed consent will not adversely affect the subjects’ rights or welfare;
* The research could not practicably be carried out without the waiver or alteration; and
* When appropriate, the subjects will be given additional pertinent information after participating.

1. **Recruitment of Subjects**

Compensation may be offered to subjects for participation. However, the amount must be sufficient to compensate for time and inconvenience, but not so high as to constitute coercion or undue influence.

1. **Privacy and Confidentiality**

Adequate safeguards must be put in place to protect subjects’ privacy and confidentiality. Various methods may be used, including but not limited to:

* Record no identifying information (for example, from patient charts).
* Lock file cabinets.
* Limit the number of personnel with access to records.
* Purge identifying information from electronic records.
* Use assigned identifier numbers to link data, then destroy identifying information (such as name, address, etc.).
* Proof of completion of human research protection training, within the last 3 years, for all persons who will work on this study and/or who will have access to data.
* Obtain confidentiality agreements from participating institutions and staff.

1. **Research Involving Special Subject Populations**

When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons), additional safeguards must be included in the study protocol to protect the rights and welfare of these subjects, as specified in [45 CFR 46, subparts B, C, and D](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1207%23se45.1.46_1207%23se45.1.46_1207).

* 1. Subpart B [(45 CFR 46.201-207)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=%20&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1201) Research Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization.
  2. DHSS does not engage in research on fetuses or human in vitro fertilization. Pregnant women may be used as research subjects as long as the risk (to the mother and fetus) is minimal. If there is any potential impact of the research on the fetus, both the mother and father must give informed consent except under certain conditions listed in [45 CFR 46.207(b)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1207%23se45.1.46_1207%23se45.1.46_1207.#se45.1.46_1207).
  3. Subpart C [(45 CFR 46.301-306)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23sp45.1.46.c#se45.1.46_1301) Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.

The requirements pertaining to the use of prisoners as subjects are very specific and restrictive, and any investigator contemplating such research should study them thoroughly.

* 1. Subpart D [45 CFR 46.401-409](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.d) Additional DHHS Protections for Children Involved as Subjects in Research.

DHSS will not approve any research involving minors (persons under age 18) as subjects, unless:

* The risk to the subjects is no greater than minimal, as defined in [45 CFR 46.102 (j)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102), and
* All requirements for parental permission and assent by children, as defined in [45 CFR 46.408](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1408), are met.

In determining whether minors are capable of assenting to participate in a study, the investigator must take into account the nature of the research activity, and the ages, maturity and psychological state of the children involved.

As a guide, research findings suggest that:

* Children age 6-7 and below typically are unable to comprehend descriptions of research procedures;
* Children ages 8-13 typically comprehend concrete examples but are less successful in relating situations to a general principle; and
* Children 14 and older have the approximate decision-making capacity of adults.

##### IRB REPORTING REQUIREMENTS

The reporting requirements related to the IRB are summarized as follows:

1. **Proposed Research**

Projects that will involve human beings as subjects must be reviewed by the IRB and exempted or approved before the protocol is initiated. See Section IV.A-C above for details.

1. **Changes in Approved Protocols**

Any change in an approved protocol should be brought directly, before implementation, to the attention of the IRB chair. Investigators shall submit a completed IRB Form 2 along with a written description of the proposed changes and copies of any proposed revisions to study protocols and forms. See Section IV.D above for details.

1. **Periodic Review**

All ongoing research activity that was not determined to be exempt from IRB review must be reviewed at least annually. The IRB may decide that specific projects require more frequent review, based on greater than minimal risk or the collection of highly sensitive personal information. See Section IV.D above for details.

1. Reporting of Unanticipated Problems

Investigators are required to immediately report to the IRB Chair any:

* unanticipated problems involving risks to subjects or others (including injuries or death);
* serious or continuing noncompliance with Federal or DHSS IRB policies, requirements, or determinations;
* untoward events such as complaints or lawsuits;
* unauthorized disclosure of confidential information; and
* any suspension or termination of IRB approval.

In the event of such a report, or if the IRB detects serious or continuing noncompliance during continuing review, the Chair will request detailed information regarding the unanticipated problem and will then report immediately to the Institutional Official and Department Director. An initial report of the problem will be made within five working days to OHRP and the federal funding agency head or designee. The IRB and the Department Director will promptly investigate and take action. Action may include suspension or termination of the project, disciplinary action against departmental employees, and/or investigation of scientific misconduct if applicable under Administrative Policy 30.11.

1. Reporting of Significant New Findings

Any significant new findings developed during the course of the research that may relate to the subjects’ willingness to continue participation, must be reported to the subjects, with a copy sent to the IRB Chair.

1. Project Conclusion

If all research-related interventions or interactions with human subjects have been completed, and all data collection and analysis of identifiable private information described in the IRB-approved research plan have been finished, then the human subject research study has been completed. When a human subject research study has been completed, the investigators no longer are required to obtain continuing review and approval of that study by the IRB. See Section IV.E above for details.

##### RECORD KEEPING

The Health and Human Services protection of human subjects regulations require institutions to retain records of IRB activities and certain other records frequently held by investigators for at least three years after completion of the research ([45 CFR 46.115(b)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1115%23se45.1.46_1115%23se45.1.46_1115#se45.1.46_1115)).

1. IRB Responsibilities

The IRB Chair is responsible for retaining records regarding each proposal submitted to the IRB and all IRB actions. Records will be retained for three years after the research has ended. Records of exempt projects will be retained for three years after determination of exempt status. The following shall be retained:

1. Research proposals submitted to the IRB, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports, and reports of injuries to subjects.
2. All actions taken by the IRB, including those taken by designees who perform expedited review and who determine exempt status.
3. Minutes of IRB meetings.
4. Records of continuing review activities.
5. Copies of all IRB correspondence
6. List of IRB members.
7. Written procedures for the IRB.
8. Statements of significant new findings that would affect subjects’ willingness to continue and that have been given to subjects.

In addition, other regulations may apply and require retention of these records for a longer period of time. Documentation of the informed consent of the subjects - either the signed informed consent form or the short form and the written research summary - are records related to conducted research that are typically held by investigators and must be retained for at least three years after completion of the research, unless the IRB waived the requirement for informed consent or the requirement for documentation of informed consent ([45 CFR 46.117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116#se45.1.46_1117)).

1. Principal Investigator/Co-Investigator Responsibilities

The Principal Investigator and DHSS Co-Investigator shall also retain copies of records for three years after the research has ended or after determination of exempt status; or as described in the protocol if longer than three years; or as required by the funding source if longer than three years. The Principal Investigator and DHSS Co-Investigator shall retain at a minimum:

* + Research proposals submitted to the IRB, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports, and reports of injuries to subjects.
  + Records of continuing review activities.
  + Statements of significant new findings that would affect subjects’ willingness to continue and that have been given to subjects.

If investigators have been designated to retain certain records (e.g., informed consent documents signed by subjects) on behalf of their institution as required by the HHS regulations, they must retain the records in some form. .Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner ([45 CFR 46.115(b)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1115%23se45.1.46_1115%23se45.1.46_1115#se45.1.46_1115)). .Retention of multiple copies of each record is not required. .Investigators should follow their institution’s policies and procedures for retaining records. .If investigators who have been designated to retain records on behalf of the institution leave that institution, the investigators and the institution should identify the successor responsible for maintaining those institutional records, either at the original institution or wherever the records are relocated, for the period of time required under HHS regulations at [45 CFR 46.115 (b)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116%23se45.1.46_1115%23se45.1.46_1115#se45.1.46_1115).

Other regulations or policies may apply to the retention of records, including study data.