PROCEDURES

# DEPARTMENT OF HEALTH AND SENIOR SERVICES POLICIES

# APPOINTMENT OF IRB MEMBERS

# INFORMATION AND TRAINING

# CONFLICT OF INTEREST

1. **APPLICATION FOR REVIEW OF PROPOSALS**
2. **INITIAL REVIEW OF SUBMITTED PROTOCOLS**
3. **DETERMINATION OF EXEMPT STATUS**
4. **CRITERIA FOR APPROVAL OF A RESEARCH PROPOSAL**
5. **EXPEDITED REVIEW**
6. **FULL BOARD REVIEW**

### CHANGES IN APPROVED PROTOCOLS

1. **NOTIFICATION OF UNANTICIPATED PROBLEMS**
2. **PROCEDURES FOR CONTINUING REVIEW**
3. PROCEDURES FOR PROJECT CONCLUSION
4. COOPERATIVE RESEARCH PROJECTS
5. **COMMUNICATION**

###### MEETING MINUTES

###### RECORD KEEPING

# DEPARTMENT OF HEALTH AND SENIOR SERVICES POLICIES

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 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.

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. The following Administrative Policies relate to the Department of Health and Senior Services (DHSS) Institutional Review Board (IRB):

* 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.

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

# APPOINTMENT OF IRB MEMBERS

Refer to DHSS Administrative Policy 30.8: Human Subjects Protection and Institutional Review Board, Section IV. IRB members are initially appointed to a term of two years. At the end of the two-year term, a determination will be made about an additional reappointment period based on the current needs of the IRB. Committee members may be requested to accept reappointment to the IRB for an additional term of two years at the discretion of the Chair. The IRB Chair is responsible for selecting members to serve on the IRB. The selection process is conducted in consultation with the Institutional Officer, Division Directors, and Department Director. The Department Director will appoint the IRB members, IRB Chair, and IRB Institutional Official.

# INFORMATION AND TRAINING

**Information:** Key information is available to DHSS investigators and IRB members on the DHSS Internet at <https://health.mo.gov/data/irb/index.php> and on the DHSS Intranet at <https://dhssnet/irb/>.

**DHSS Submission Forms for IRB Review of Research/Study Protocols**

* Abstract of Protocol
* IRB Form 1 “Request for Review of Research Protocol”
* Protocol Template
* Checklist for Submission of Research/Study Protocols
* Cover Sheet for DHSS IRB Submissions (DHSS internal use only)
* IRB Form 2 “Information for Continuing Review of a Previously Reviewed Project”

##### **Information of Interest to Investigators**

##### DHSS IRB Organization and Functions

##### Definition of Terms

* Information for Research Investigators
* Informed Consent Guidelines
* Template of an Agreement for Reliance on Other Institution’s IRB
* Use of Cancer Registry, Behavioral Risk Factor Surveillance System (BRFSS), and County Level Study Data
* Use of Vital Statistics and Patient Abstract Data
* Public Health Practice or Research?

References and Related Documents

* [Department of Health and Human Services, Office of Human Research Protection](http://www.dhhs.gov/ohrp)
* [Code of Federal Regulations (CFR) including Title 45 Part 46 Protection of Human Subjects and listing of other agency CFR references](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html)
* [Institutional Assurance of Compliance (FWA) and IRB registration numbers](https://www.hhs.gov/ohrp/irbs-and-assurances.html)
* [Missouri Department of Health and Senior Services - Data, Surveillance Systems & Statistical Reports](https://health.mo.gov/data/)

**Training:** The DHSS requires all IRB Members, Principal Investigators, and Co-Investigators be adequately trained in the human subject protection prior to participation in any research related activities.

**IRB Members:** 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 Collaborative Institutional Training Initiative (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 and saved in the IRB secure folder. This training is valid for three years. Members are 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 subjects related training session per 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>. IRB members shall notify the IRB chair when they have completed training related to human subject research and protections.

**Investigators:** 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 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 also required to complete a reputable human subjects protection-training course and provide proof of completion within the past three (3) years.

# CONFLICT OF INTEREST

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.

# APPLICATION FOR REVIEW OF PROPOSALS

The following forms and documentation are required 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, is submitted to the DHSS staff working with the investigator on the project/study. This DHSS staff member will be assigned as the responsible DHSS Co-investigator.

**Initial Submission:**

* 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 study and/or who will have access to 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)

**Subsequent Submission(s), including Annual, Modification, or Close Out:**

* 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, when applicable
* Copy of current Consent Form, when 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

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.

# INITIAL REVIEW OF SUBMITTED PROTOCOLS

Initial review of protocols is performed by the IRB Chair to determine whether the project is exempt from review, meets the criteria for expedited review, or requires full board review.

# DETERMINATION OF EXEMPT STATUS

The Chair will apply the criteria stated 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) Exempt Research to determine whether a proposed project meets the conditions for exemption from IRB review. Research that involves pregnant women, fetuses, prisoners, children, or other vulnerable individuals can be exempted if meets the criteria listed under [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)(b).

If the project is exempt, the Chair will notify the investigator(s) in writing within 30 days of submission. If the project does not meet the criteria for exemption, the Chair will make arrangements for a full board review. During convened IRB meetings, the Chair will provide an overview of any Exempted Project that have occurred since the last convened meeting.

**Investigators shall report any changes in exempted protocols to the Chair before they are implemented.** 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. The IRB Chair will review the proposed changes to the project according to section XI below.

# CRITERIA FOR APPROVAL OF A RESEARCH PROPOSAL

The IRB may approve a research proposal only if:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, and appropriately documented, in accordance with and to the extent required by [45 CFR 46.116](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#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#se45.1.46_1117). If a waiver of written and/or verbal informed consent is requested, the criteria cited in this regulation must be met.
5. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
6. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
7. 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 have been included in the study to protect the rights and welfare of these subjects, as specified in 45 CFR 46, subparts [B](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.b), [C](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.c), and [D](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.d).
8. When minors (persons under age 18) will be subjects, the risk to the subjects is no greater than minimal, as defined in [45 CFR 46.102](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102)(j) and all requirements for parental permission and assent by children, as defined in [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), are met.
9. Each institution collaborating in the research has a Federalwide Assurance of Protection (FWA) for Human Subjects.
10. Each independent research investigator who is not acting as the employee or agent of an FWA institution, for example, a physician in private practice, must sign an Unaffiliated Investigator Agreement with DHSS.

In determining whether minors are capable of assenting to participate in a study, the IRB shall 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.

# EXPEDITED 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 the project is given expedited review, the information listed in Section V 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.

The following actions may be taken, based on expedited review:

* **Full approval**, if all reviewers approve the proposal as submitted; or
* **Contingent approval**, if all reviewers approve the proposal but one or more reviewers recommends minor revisions that require simple concurrence by the investigator(s); or
* **Deferral**, if one or more reviewers do not agree to approve the proposal without significant revisions. Deferred proposals may not be implemented without significant revision and resubmission for full IRB review.

The Chair will notify the investigators and the institutional official, in writing, regarding the results of expedited review within 45 days after submission of a complete application to the IRB. 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. During convened IRB meetings, the Chair will provide an overview of any Expedited Reviews that have occurred since the last convened meeting.

# FULL BOARD REVIEW

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 (see Section V above) 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.

Expert consultation may be needed in order to fully evaluate a research proposal. This may be proposed by any member and will be arranged upon approval by the Chair or by a vote of the members at a convened meeting.

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

* **Full approval** of the project 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; or
* **Contingent approval**, subject to specific, stated minor revisions that require simple concurrence by the investigator(s); or
* **Deferral**, deferred proposals may not be implemented without significant revision and resubmittal for full IRB review; or
* **Disapproval.**

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 and 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 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. If the project is deferred, the recommended changes must be made in the protocol application packet and resubmitted, which will require a full board review. The Chair will notify the investigators and the institutional official in writing when final approval is granted.

# CHANGES IN APPROVED PROTOCOLS

Investigators are required to report any changes in approved protocols to the Chair for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects, before they are implemented. 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. This responsibility will be emphasized in all correspondence with investigators. 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 chair will review the changes if they are minor (e.g., simple formatting or wording changes in a survey questionnaire or recruitment letter, or minor change in number of subjects to be recruited), and approve or disapprove. If the project was exempted from full board review, the Chair shall determine whether the proposed changes affect the exempt status of the project. If the changes are not minor or affect the exempt status of the project, then they will be subject to the same type of review as an initial proposal (expedited or full board review).

When approved, protocol changes must be incorporated into the written study protocol. Revision dates shall be noted on the first page and each revised page of the revised protocol. The Chair will notify the investigators in writing when changes are approved and changes to the project shall not be implemented until such approval has been given.

# NOTIFICATION 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.
* 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 to OHRP and the federal funding agency head or designee within five working days. 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.

# PROCEDURES FOR CONTINUING 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.

At least 45 days prior to the anniversary date of original IRB approval, or by a review date set by the IRB; the investigator(s) must submit IRB Form 2, Information for Continuing IRB Review. If the project is still active, even if activity is restricted to data analysis or long-term follow-up of subjects, the investigator(s) must submit a summary of the protocol and a report of the progress of the research that includes:

* The number of subjects accrued or withdrawn since last review.
* A description of any adverse events, complaints, or unanticipated problems.
* A summary of any recent literature, findings thus far, amendments or modifications to the research since the last review, and any new information about risks associated with the research.
* A copy of the current informed consent document.
* A copy of the Human Subject Protections training certificates, completed within the last 3 years, for the Principal Investigator and the DHSS Co-Investigator.

If the project is still active, even if activity is restricted to data analysis or long-term follow-up of subjects, then the project protocol will be reviewed by the IRB at a convened meeting. The project may be given expedited continuing review if:

* It was initially approved through expedited review.
* The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects.
* No subjects have been enrolled and no additional risks have been identified.
* The remaining research activities are limited to data analysis.
* The IRB determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The IRB may take the following actions, based on expedited or convened review:

* **Full approval** of continuation; or
* **Contingent approval** of continuation, subject to specific, stated minor revisions that require simple concurrence by the investigator(s); or
* **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 due to the need for major revisions, the full IRB must review the changes before it can resume.

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

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>.

# PROCEDURES FOR 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.

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 submit a final IRB Form 2, Information for Continuing IRB Review, and a 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. The Chair will notify the investigators and the institutional official, in writing, regarding the results of final IRB review within 30 days. IRB approval of a project close out does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

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>.

# COOPERATIVE RESEARCH PROJECTS

DHSS may choose to rely on another institution’s IRB for review of a specific project involving both institutions. The decision to do this will be made by the Chair after initial review of the application. The other institution shall have a valid IRB registration and Federalwide Assurance. The Federalwide Assurance is the only type of assurance accepted and approved by OHRP. The project application shall include a copy of the collaborating institution’s IRB approval that includes contact information (name, address, telephone number and e-mail address) for the other institution’s IRB office and signatory official. A Memorandum of Understanding for that protocol will be completed and signed by authorized officials of both institutions. 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.

# COMMUNICATION

The IRB Chair is responsible for communication with investigators and IRB members regarding applications, proposals, and IRB actions. Investigators will be notified of findings as soon as possible following IRB action. IRB members will be kept informed regarding the results of expedited reviews, and will receive summary information about exempted projects.

# MEETING MINUTES

IRBs must comply with HHS and FDA regulations when reviewing research. The DHSS IRB shall prepare and maintain adequate documentation of IRB activities, including minutes in sufficient detail to document the following:

1. Attendance at the meetings;
2. Actions taken by the IRB;
3. The vote on these actions, including the number of members voting for, against, and abstaining;
4. The basis for requiring changes in or disapproving research; and
5. A written summary of the discussion of controverted issues and their resolution.

Minutes are intended to provide a summary of what occurred during a convened meeting and provide information to persons not present at the meeting (e.g., investigators, institutional officials, regulators, IRB members who could not attend) about what the IRB reviewed and the actions taken by the IRB. Minutes should not include a verbatim transcription of what each member said during the course of the meeting.

The DHSS IRB assigned support staff is responsible for preparing and maintaining minutes at DHSS. Once the minutes are prepared, they must be reviewed and approved at a convened meeting. IRB minutes may also document and communicate announcements or other information to the IRB members and attendees at the meeting (e.g., upcoming meeting schedule, staff or membership changes). The DHSS IRB support staff may choose to record IRB meetings (e.g., video, audio tape) and use the recording as a tool to assist in the preparation of written minutes. However, retention of complete recordings of meetings is not required nor does it relieve the IRB of its obligation to keep written minutes.

**Attendance at the meeting:** Except when an expedited review procedure is used, the IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas (nonscientist). In order for the research to be approved, it must receive the approval of a majority of those members present at the meeting. For ease of review, the attendance information should be listed at the beginning of the minutes and include the full name and representative capacity (e.g., scientist, nonscientist, unaffiliated) of each IRB member present at the convened meeting. The minutes should make clear which members, if any, participated in the convened meeting via an alternative mechanism, such as telephone or video conferencing.

IRBs may invite consultants to assist in the review of a particular study when expertise is required beyond or in addition to that available on the IRB. If the IRB uses a consultant and the consultant is present at the convened meeting, the minutes must include the name of the consultant, and should include a brief description of the consultant's expertise. The consultant may not vote with the IRB on the study.

The DHSS IRB permits non-members and guests to attend a convened meeting (e.g., IRB support staff, the investigator whose study is being reviewed, study coordinator, human subjects protection administrator), then the minutes must record the name(s) of all such attendees.

A quorum is the minimum number and type of IRB members that must be present at a convened meeting. If a majority of the IRB membership is not present, or if a nonscientist is not present, then quorum has not been met. The attendance information in the minutes assists in determining whether enough IRB members were present to constitute a quorum, whether the nonscientist was present, and whether proposed research received enough votes (i.e., a majority of those present) to be approved. The DHSS IRB calculates the majority by taking half of the total number of IRB members, and rounding up to the next whole number (e.g. IRB membership is nine (9), then the majority is 5). A quorum must be maintained throughout the meeting. If quorum is lost during a meeting, then the IRB may not vote on proposed research. Because IRB members may occasionally enter or leave the room at various times during a convened meeting (e.g., arrive late, depart early, or leave the meeting temporarily), the minutes provide sufficient information to indicate that a quorum is maintained.

**Actions taken by the IRB**: Any IRB action to approve, require modifications in (to secure approval), or disapprove proposed research activities that occurs at a convened meeting must be documented in the minutes and provide sufficient information to identify the research activities being reviewed and voted on by the IRB at that meeting (e.g., initial review of protocol title/protocol number) and the basis for requiring changes in, or for disapproving the proposed research. In order to approve research, the IRB must determine that all of the criteria for IRB approval of research are satisfied (see Section VIII above). Meeting minutes, or other IRB records (e.g., correspondence with the investigator), must identify the effective date of approval and the approval period (continuing review interval) for any research approved by the IRB. IRBs must determine which projects, if any, require review more often than annually.

Any IRB action to suspend or terminate IRB approval that occurs at a convened meeting must be documented in the minutes. Any suspension or termination of approval must include a statement of the reasons for the IRB's action. Any decision to suspend or terminate the study that occurs outside of a convened IRB meeting (e.g., as determined by the IRB Chair or Institutional Official for subject safety reasons) should be reported to the convened IRB and the discussion summarized in the minutes. Any subsequent action taken by the convened IRB (e.g., to lift the suspension or to terminate the study) must also be documented in the minutes. When reviewing proposed research, there are other findings and determinations the IRB must make to fulfill other regulatory requirements that must be documented in the minutes, such as: Informed Consent; Studies Involving Children; Emergency Research; Studies Involving Pregnant Women, Human Fetuses, and Neonates; Studies Involving Prisoners; Reporting of Expedited Review Activities; and Unanticipated Problems, Serious or Continuing Noncompliance, Suspension or Termination of IRB Approval.

**The vote on these actions**: The minutes of IRB meetings must be in sufficient detail to show the vote on IRB actions as determined during the convened meeting, including the number of members voting for, against, and abstaining. Individual voting records by name are not required. An acceptable format for documenting the votes on actions taken by the IRB in the minutes would be as follows: Total Voting = 9; Vote: For = 7, Opposed = 1, Abstained = 1, Recused = 0. The minutes should identify any member who has a conflicting interest in a research study, and as such, is excluded (recused) from participation in the IRB's review of that particular research including the reason for the recusal. Members who are recused from voting on a specific study because of conflicting interests may not be counted toward the quorum. Their recusal may not be recorded as an abstention. IRB members who participate in a convened meeting via telephone or video conferencing may vote and be counted towards the quorum. The IRB must ensure that the votes of such members are recorded in the minutes. IRB members may not vote on proposed research outside of the convened meeting (e.g., via email prior to the convened meeting). IRB members who cannot attend a convened meeting may not send someone (e.g., from their department or office) to vote in their place. Opinions of absent members that are transmitted prior to the convened meeting by mail, telephone, telefax, or email may be considered by the attending IRB members but must not be counted as votes or towards the quorum for convened meetings.

**The basis for requiring changes in or disapproving research**: If the IRB requires that the investigator make specified changes to the research protocol or informed consent document(s) and resubmit such documents to the convened IRB for subsequent review, the IRB's action, along with the basis for requiring changes must be documented in the minutes. If the IRB disapproves a research activity, the IRB must include a statement of the reasons for its decision in the written notification to the investigator and the institution, and provide the investigator an opportunity to respond in person or in writing. The minutes must document the IRB's action along with the basis for disapproving the research.

**A written summary of the discussion of controverted issues and their resolution:** The minutes of IRB meetings must be in sufficient detail to show a written summary of the discussion of controverted issues and their resolution. Controverted issues are those that cause controversy and dispute among the IRB membership during a convened meeting. Controverted issues that arise during the convened meeting usually are the result of opposition to some aspect of the proposed research. During the review of proposed research, IRB members may express a difference of opinion, or raise issues, questions or concerns that cause debate among the IRB members, or even result in disagreement. Some research, by its very nature, is considered to be controversial (e.g., emergency research where informed consent may not be obtained for all subjects or some research involving vulnerable populations). IRB members may resolve controverted issues and concerns with continued discussion and deliberation, decide to seek further clarification from the investigator or sponsor of the proposed research, or decide to settle the issue by vote. The minutes must summarize the IRB's discussion and resolution of any controverted issues.

# 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#se45.1.46_1115)

The IRB Chair is responsible for retaining records regarding each proposal submitted to the IRB and all IRB actions. Records shall be retained for three years after the research has ended. Records of exempt projects shall 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 (e.g. correspondence issued to the investigators).
3. Minutes of IRB meetings. Many sets of minutes will have records of review of multiple studies. Relevant portions of the minutes must be retained with each study until the regulatory retention period for each study is satisfied.
4. Records of continuing review activities.
5. Copies of all IRB correspondence.
6. Current 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.

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:

* 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. Records of continuing review activities.
	3. 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#se45.1.46_1117).

If investigators have been designated to retain certain records (e.g., informed consent documents signed by subjects) on behalf of the institution as required by the 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#se45.1.46_1115), 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#se45.1.46_1115)). Retention of multiple copies of each record is not required. Investigators should follow the 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#se45.1.46_1115).

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