#### Organization and Functions

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## **Authority**

The Department of Health and Senior Services Institutional Review Board (hereafter referred to as the IRB) is established as required by regulations of the Department of Health and Human Services in [45 CFR 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

##### Institutional Responsibilities

All human subject activities of the Department of Health and Senior Services (DHSS), regardless of funding source, 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 federally supported human subject research will comply with [45 CFR 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) and/or any human subject regulations and policies of any relevant regulatory Department or Agency.

DHSS is responsible for complying with the terms of the Federalwide Assurance of Protection for Human Subjects ([FWA](http://ohrp.osophs.dhhs.gov/humansubjects/assurance/fwas.htm)). This includes the designation of a Human Protections Administrator and an Institutional Review Board, and development of and adherence to the required policies and procedures. Information provided to the [Office of Human Research Protections](http://www.hhs.gov/ohrp/) (OHRP) under the FWA will be updated every 36 months, even if no changes have occurred.

DHSS Division, Center, and Office Directors may not approve any project that the IRB has disapproved, but may disapprove projects that the IRB has approved (see [45 CFR 46.112).](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1112)

1. **Organization of the IRB**

The IRB is composed of not fewer than nine (9) members who are appointed by the DHSS director, and who represent a variety of professions and interest areas. The IRB shall be demographically diverse and shall include scientists, non-scientists, and at least one member who is not otherwise affiliated with DHSS. The Chair is appointed from the membership of the IRB by the DHSS director.

* 1. Terms of Service – Members, including the Chair, serve two-year terms and may be reappointed.
  2. Quorum – A simple majority of the IRB, including at least one non-scientist.
  3. Approval Action – Full Board approval requires a majority of those present. Any IRB member who has a conflicting interest in a project may not participate in reviewing that project, except to provide information as requested by the IRB.
  4. Consultants – Consultants may be called upon whenever their expertise is required. The advice of those who are not IRB members should be sought only after decision and approval by the IRB at a meeting or approval by the Chair.

1. **Duties of the Chair**
   1. Convenes and presides over all meetings of the IRB.
   2. Determines whether research projects are exempt from review pursuant to [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) within 30 days of the date the proposal and all appropriate forms are submitted to the IRB.
   3. Determines whether research projects are eligible for expedited review, using the most current guidance from OHRP, and coordinates expedited review when appropriate.
   4. Ensures that the IRB is apprised of all projects that have been exempted or approved by expedited review.
   5. Appoints an individual from the membership of the IRB to act in the Chair’s absence.
   6. Assures all necessary correspondence and the maintenance of records.
   7. Notifies principal investigators of IRB action on their projects.

1. Investigators will be notified as soon as possible following action by the IRB.

2. No subjects may be solicited or recruited by investigators before the date on which a project has been approved or exempted.

3. No change that would affect human subjects may be made in an approved project unless the change is submitted to and approved by the IRB.

1. **Duties of the iNSTITUTIONAL REVIEW bOARD**
   1. Reviews and/or oversees review of all research that involves a human subject that originates in or is the responsibility of DHSS, or that involves DHSS staff in any aspect of the research, or that is funded by DHSS.
   2. Except when an expedited review procedure is used, performs all reviews of non-exempt research at convened meetings.
   3. Performs all reviews within 60 days of the date the proposal and appropriate forms and consent documents are submitted to the IRB.
   4. Approves research proposals only if the following requirements are satisfied:
2. Risks to subjects are minimized.
3. 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.
4. Selection of subjects is equitable.
5. 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 46.116-117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116).
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. 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).
   1. Approves research proposals involving minors (persons under age 18) as subjects only if the risk to the subjects is no greater than minimal, as defined in [45 CFR 46.102 (i),](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 46.401-409](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1401), are met.
   2. Acts on all newly submitted research protocols and those submitted for reconsideration, that do not qualify for exemption, by:

1. Approving them as submitted or

2. Approving them subject to specific, stated minor revisions that require simple concurrence by the investigator(s) or

3. Returning them to the investigator for revision and resubmittal or

4. Disapproving the project.

* 1. Reviews all ongoing research activity, which does not qualify forexemption, at least annually or more often at the discretion of the IRB. This includes any project with continuing activity, even if the activity is limited to data analysis or long-term follow-up of subjects. Acts on these projects by:

1. Approving them for continuation or

2. Approving them for continuation subject to specific, stated minor revisions that require simple concurrence by the investigator(s) or

3. Determining whether the project should be terminated or suspended, and stating the reasons for this action.

* 1. The Chair shall represent the Board in conducting the review of projects that qualify for exemption.
  2. The Chair shall coordinate expedited review of projects that qualify for this procedure, with assistance from 2-3 other members, and shall inform the IRB members of protocols reviewed in this manner.
  3. Advises the DHSS director with regard to review procedures and activities.

##### RECORDS RETENTION

Records shall be retained by DHSS for three years after the research has ended. Records of exempt projects shall be retained for three years after determination of exempt status. See Information for Research Investigators, Section VII Record Keeping for more detail.