

<u>Information Sheet</u>	Advocate Health Care Institutional Review Board
IRB Application & Protocol Status Terminology	205 W. Touhy, Suite 203, Park Ridge, IL 60068-4202 Voice: 847-384-3534; Fax: 847-384-3537 E-Mail: IRBMail@AdvocateHealth.com
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The Advocate Health Care Institutional Review Board (AHC IRB) office is providing the following terminology and guidelines to facilitate communication and completion of the AHC IRB application, forms and other regulatory requirements.

NOTE

- 1) A person who participates in a research study is called a “subject.”
- 2) The terms are presented as the actions occur, not in alphabetical order.

IRB Application

The packet of materials required for IRB review. This includes the “AHC IRB Protocol Review Form,” research protocol, consent form, investigator’s brochure, recruitment materials, subject questionnaires and diaries, etc.

Submitted

Receipt of IRB application acknowledged by AHC IRB office staff by assigning IRB protocol number, but not scheduled for action by the Board (full review protocols) or IRB Chair and/or designated IRB member (expedited and exempt protocols), due to incomplete submission, e.g., departmental or local oversight signatures not obtained, no literature review, consent form not in Advocate template, human subject research ethics training for relevant research team members not submitted.

Pending

IRB application submitted to AHC IRB office, acknowledged as complete, and scheduled for review by Board (full review protocols) or IRB Chair and/or designated IRB member (expedited and exempt protocols).

Withdrawn

Submitted or pending IRB application withdrawn by principal investigator and/or study sponsor prior to IRB review and action. Withdrawal should be requested in writing whereupon no further reporting to the IRB is required. Withdrawn protocols may be resubmitted at a future date.

IRB Action

Refers to determinations made by the full Board and/or the IRB chair or designee as authorized by law. AHC IRB actions regarding IRB applications include: approved, conditionally approved, tabled, and disapproved. These and other IRB actions are recorded and/or reported in formal IRB meeting minutes. Actions of the Board and Chair are distinct from pre-review, support, education, audits, and other activities conducted by IRB staff in the IRB office.

Approved

IRB application reviewed and approved by IRB without any concerns and/or changes to protocol, consent, and/or other documents.

Conditionally Approved

IRB application reviewed and approved by the Board pending response by the investigator or study staff to Board’s concerns and/or changes to protocol, consent, etc. Substantive concerns and/or revisions required by the Board must be resolved during the meeting. Non-substantive issues (e.g. editorial changes to consent) identified during the meeting may be resolved afterwards. The revised IRB application does not have to be re-reviewed at a future IRB meeting. The IRB staff communicates and assists in fulfilling conditions of the Board’s approval.

Tabled

The Board is unable to approve, conditionally approve, or disapprove an IRB application due to one or more of the following: 1) insufficient information; 2) substantive concerns and/or revisions required by the Board are not resolved during the meeting; or 3) IRB primary reviewer assigned to a particular protocol is absent and his/her review has not been forwarded to the IRB Chair. The tabled IRB application maybe re-reviewed at a future IRB meeting.

Disapproved

IRB application reviewed by Board and deemed by the Board to lack scientific merit, to pose significant risks to subjects with little or no benefit, or to otherwise present serious deficiencies in human subject protection.

Final Approval

All conditions of Board and/or IRB Chair or designated IRB member are met and final approval letter is generated. Final approval triggers activation of the study.

NOTE

Final approval from the IRB should not be confused with authorization from other institutional/organizational offices whose requirements must be met in order to conduct research. Final approval from the IRB means that the proposed research has been approved as ethically and scientifically sound and is appropriate to be conducted at Advocate. It is the investigator's responsibility to resolve any non-IRB issues (such as budgets, billing, and contracts) that remain outstanding at the time of final IRB approval. If, after IRB approval, resolution of non-IRB issues changes information or material upon which IRB approval was based, such as the protocol, consent, etc., the investigator should file an amendment to that effect with the IRB.

Active/Ongoing – Open to enrollment

Final approval by the Board means that the investigator is authorized to begin subject enrollment. Investigators are forbidden by law from enrolling subjects prior to final IRB approval.

Enrollment

Includes activities such as active recruitment and eligibility screening (e.g. blood draws, physical exams, questionnaires, etc. to assess whether prospective subjects are appropriate candidates for inclusion in a study). No enrollment activities can occur prior to study final approval. A review of patient records in an investigator's practice to determine whether a sufficient number of cases exist to produce statistically valid research results would not constitute enrollment. If you have questions about whether particular activities constitute enrollment contact the IRB staff for clarification.

NOTE

The informed consent process and documentation must precede enrollment. While an investigator may discuss availability of studies and possible future enrollment with a prospective subject without obtaining consent, informed consent must be obtained prior to initiation of any procedures performed solely for the purpose of determining eligibility for research, including withdrawal from medication (wash-out).

Active/Ongoing - Closed to enrollment

No new subjects are being recruited but one or more of the following activities is occurring:

1. Subjects already enrolled receive investigational therapy;
2. Subjects already enrolled undergo periodic physical examinations/tests for research-related follow-up;
3. Subjects already enrolled are periodically contacted to obtain long-term follow-up information (e.g., survival rates);
4. All subjects have completed participation and follow-up in the study but data analysis continues.

On-hold (temporarily closed to enrollment)

No new subjects can be recruited into a study until resolution of a question or concern related to matters such as safety, data analysis, informed consent, or research noncompliance (e.g. delinquent continuing review). All other protocol-related activities such as treatment and follow-up of subjects already enrolled may continue. “On-hold” may be initiated by the principal investigator, study sponsor, the IRB, governmental agencies such as the FDA, and other authorized bodies.

Suspended (permanently closed to enrollment)

Same as “on-hold” except that prohibition of new subject enrollment is permanent, not temporary. All other protocol-related activities may continue.

Terminated

Same as “suspended” with the additional requirement that participation of subjects already enrolled must cease. The plan for study termination must be submitted in writing to and approved by the Board. It should include an explanation of how the safety and welfare of enrolled subjects will be protected. For example, what information will they receive about the reasons for termination? What opportunities for receiving and responding to subjects’ questions will be provided? What is the plan for monitoring subjects who may need to wean off study medication? What laboratory or other tests may be necessary in order to make sure that termination does not exacerbate or cause adverse events?

Completed

All clinical, regulatory, and data analysis activities on a protocol are concluded. Continuing review is no longer required, subjects are not being followed, and all data queries and analysis are finished. In order to access research-related information and/or perform any additional research-related activities (e.g., contacting subjects) the protocol must be re-opened by notifying the IRB and obtaining IRB approval. Determination of whether a new IRB application will be required is made on a case by case basis taking into consideration such factors as the reason for reactivating the research and how recently the study was closed.