Emory University IRB Criteria for Approval Checklist

For VA research: See VA Criteria Checklist

Criterion	
(1) Physical, psychological, social, legal, and economic risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.	
(2) Physical, psychological, social, legal, and economic risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.	
(3) Physical, psychological, social, legal, and economic risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.	
(4) Selection of participants is equitable taking into account the following: (a) the purpose and setting of the research; (b) whether prospective participants will be vulnerable; (c) inclusion/exclusion criteria; (d) participant recruitment and enrollment procedures; and (e) the influence of payments to participants.	
The informed consent process will be waived or altered. **OR** Informed consent will be sought from each prospective participant or the participant's representative in accordance with the regulations as follows:	
(5)	(5a) The investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative.
	(5b) The circumstances of consent provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.
	(5c) The circumstances of consent minimize the possibility of coercion or undue influence.
	(5d) The information that will be given to the participant or the representative will be in language understandable to the participant or the representative.
	(5e) No information will be provided to the participant or the representative that waives or appears to waive any of the participant's legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
	(5f) All required and appropriate additional disclosures will be provided to the participant or the participant's representative. *(See Elements of Informed Consent)*
(6) The informed consent process will be waived. *(See Waiver of One or More Elements of IC Worksheet)* **OR** The requirement for written documentation will be waived. *(See Waiver of Documentation of IC Worksheet)* **OR** Informed consent will be documented in writing in accordance with the regulations. **Long form** The consent document embodies the basic and appropriate additional elements of disclosure. *(See Elements of Informed Consent)* The participant or the participant's legally authorized representative will sign <u>and date</u> the consent document.	

If the research is FDA-regulated, the participant or the participant's legally authorized representative will sign and date the consent document.

A copy of the signed and dated consent document will be given to the person signing the consent document.

The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed and dated.

Short form

The consent document states that the elements of disclosure required by regulations had been presented orally to the participant or the participant's legally authorized representative.

A written summary embodies the basic and appropriate additional elements of disclosure.

There will be a witness to the oral presentation.

For participants who do not speak English, the witness is conversant in both English and the language of the participant.

The participant or the participant's legally authorized representative will sign and date the consent document.

The witness will sign and date both the short form and a copy of the summary.

The person actually obtaining consent will sign and date a copy of the summary.

A copy of the signed and dated short form will be given to the participant or the representative.

A copy of the signed and dated summary will be given to the participant or the representative.

(7) The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants. *(Not applicable if the research involves no more than minimal risk.)*

(8) There are adequate provisions to protect the privacy of participants.

(9) There are adequate provisions to maintain the confidentiality of the data.

(10) Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence.

Additional considerations for **Initial Review**:

Should review be obtained more often than annually?

If this is multi-site research, is the management of information that might be relevant to the protection of subjects adequate?

Additional considerations for **Continuing Review:**

Should review be obtained more often than annually?

Should verification be obtained from sources other than the investigator that no material changes have taken place since prior IRB review?

Is the consent document is accurate and complete?

If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?

Additional considerations for **Review of Amendments:**

If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?