

## Memo to File

**Subject:** Form FDA 1572 – Updated IRB Registration (IORG) Information and Sabai IRB Oversight Acceptance

**Date:** January 26, 2026

**Sabai IRB Oversight Acceptance Start Date:** 02 FEB 2026

**To:** All Current and Legacy Castle Institutional Review Board, LLC and Alpha Independent Review Board, LLC Client Accounts

**From:** Sabai, LLC

**Re:** Guidance Regarding Statement of the Investigator Form (Form FDA 1572) Updates

### Purpose:

This memo provides clarification regarding recent updates to the Sabai, LLC (“Sabai”) Institutional Review Board (IRB) registration information with the Office for Human Research Protections (OHRP) and any associated implications for Form FDA 1572 (“Statement of Investigator”).

### Background:

Beginning 02 FEB 2026, Sabai will consolidate its two existing IRB operations under a unified registration:

New IRB Registration: Sabai IRB #1

IRB Organization #: IORG0012659

IRB Registration #: IRB00014968

This registration will supersede the following legacy IRB entities previously operated under Sabai Group LLC:

- Castle IRB:  
IRB Organization #: IORG0010151  
IRB Registration #: IRB00012054
- Alpha Independent Review Board, Inc. (“Alpha IRB”):  
IRB Organization #: IORG0005158  
IRB Registration #: IRB00006205

Sabai IRB will assume oversight of all studies previously under legacy Castle IRB and Alpha IRB oversight. All previously approved protocols, investigators, and sites will continue uninterrupted under Sabai IRB oversight.

For legacy Alpha IRB studies that have an active review underway at the time of the Sabai IRB Oversight Acceptance Date, oversight will transfer to Sabai IRB after the open review is completed. As such, IRB submission forms and/or determination letters may reflect the legacy Alpha IRB name until the transition is completed (anticipated no later than February 28, 2026).

To support a clear and orderly transition from the legacy IRB groups to Sabai IRB, the table below outlines the date on which Sabai IRB oversight begins, and how open study submissions will be managed during the transition period.

<b>Legacy IRB Group</b>	<b>Date of Sabai IRB Oversight Acceptance</b>	<b>Additional Transition Considerations (if applicable)</b>
Castle Institutional Review Board	02 FEB 2026	Includes any legacy Castle IRB study submissions in progress as of 02 FEB 2026
Alpha Independent Review Board	09 FEB 2026	
<i>Open</i> Legacy Alpha IRB Study Submissions as of 09 FEB 2026	Immediately upon Legacy IRB Review Completion Date	Open submissions remain under Alpha IRB until the review concludes, then transfer to Sabai IRB. Determination letters may reference the legacy Alpha IRB name through February 2026.

*Please note that all new study submissions not associated with a legacy IRB will be initiated with Sabai IRB starting 02 FEB 2026.*

*Once all studies have been completely transferred, both IORG0010151 and IORG0005158 will be deactivated.*



Guidance:

Per FDA's Frequently Asked Questions – Statement of Investigator (Form FDA 1572), a new Form 1572 is only required when:

- An investigator is participating in a new protocol added to the IND; or
- A new investigator is added to the study (21 CFR 312.53(c)).

See reference here: <https://www.fda.gov/media/78830/download>

Administrative updates such as a change in IRB name or address do not require submission of a new Form 1572. Sponsors may, however, document this memo in their regulatory files to reflect the IRB's updated registration information.

Recommended Actions:

- File this memo for each active protocol under Sabai IRB oversight.
- Update internal reference systems to reflect the new IORG, IRB Registration number, IRB name, and address.
- Studies with IND/IDE applications: Document this administrative change within the clinical study records and notify the sponsor as appropriate. The sponsor may then update the IND to reflect the new IRB information in accordance with FDA guidance—typically through inclusion in an information amendment or protocol amendment. A revised and newly signed Form FDA 1572 is not required for this administrative update.

*No submission of a new Form FDA 1572 is required unless otherwise dictated by sponsor procedures.*

Contact:

For any questions, please contact Sabai IRB at 888-442-2472 or [clientservices@sabaiglobal.com](mailto:clientservices@sabaiglobal.com),  
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