	STANDARD OPERATING PROCEDURES			
	RELEASE OF COMMERCIAL IRB HOLD ON INITIAL IRB REVIEW			
	NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-2109	Executive Director, ORS, LSUHSC	10.13.2022	Page 1 of 2	

PURPOSE

- 1.1 This procedure establishes the process releasing a institutional hold by a Commercial IRB for initial approval.
- 1.2 The process begins when the IRB staff receives an email that IRB approval has been granted by a Commercial IRB.
- 1.3 The process ends when the Commercial IRB releases the initial approval hold.

REVISIONS FROM PREVIOUS VERSION

- 2.1 None

POLICY

- 3.1 All initial applications submitted to a Commercial IRB have an institutional hold placed on the initial approval.
- 3.2 This hold must be released by the LSUHSC-NO IRB prior to study team receiving final, approved documents.

DEFINITIONS

- 4.1 None

RESPONSIBILITIES

- 5.1 Specific responsibilities for LSUHSC IRB Staff are described throughout this document.


PROCEDURES

6.1 Release of Hold for WCG IRB-Reviewed Studies

- 6.1.1 Upon receipt of an email from WCG IRB:
 - 6.1.1.1 Verify if the documents ready are for an Initial Review or an Outcome Document entitled “Hold Notice – Indefinite”
- 6.1.2 Verify that the study team has submitted a Reliance Request in Quali and that the request has been approved.
 - 6.1.2.1 The local reliance request should always be approved before release of the hold
- 6.1.3 Send an email to ClientServices@wirb.com requesting release of the hold.
 - 6.1.3.1 Example Language: *This email is to serve as the final institutional approval and release from LSUHSC-NO HRPP for the above study. The study may now be initiated.*
- 6.1.4 WCG IRB will take an average of 48 hours to release the hold. A second email will be sent, similar to the initial email, notifying the team that the hold has been released.

6.2 Release of Hold for ADVARRA-Reviewed Studies

- 6.2.1 Upon receipt of an email from CIRBI@advarra.com with the subject line “Institutional Sign-Off

	STANDARD OPERATING PROCEDURES			
	RELEASE OF COMMERCIAL IRB HOLD ON INITIAL IRB REVIEW			
	NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-2109	Executive Director, ORS, LSUHSC	10.13.2022	Page 2 of 2	

Required,” log into the Institutional CIRBI account (cirb@lsuhsc.edu).

6.2.2 Once logged in, click “Provide Institutional Sign-Off”

6.2.3 ADVARRA will take an average of 48 hours to release the hold. A second email will be sent, similar to the initial email, notifying the team that the hold has been released.

MATERIALS

7.1 None

REFERENCES

8.1 None