

Novocure® partners with the Western Institutional Review Board (WIRB) to support the Humanitarian Use Device (HUD) submission for Optune Lua™

WIRB was the first independent review board, with over 3,000 partner institutions nationwide

- Pursuing IRB approval through WIRB offers the potential for a quicker review and seamless electronic submission
- Novocure will cover the fees for the HUD application IRB submission, review, and approval
 - *Novocure will pay these fees whether WIRB grants approval or not*

How to leverage WIRB for a HUD submission

STEP 1:

Contact your Novocure representative to confirm if your institution has an established partnership with WIRB

STEP 2:

Institutions with a WIRB partnership may begin registration and submission of the HUD application via Connexus® at connexus.wcgclinical.com

- Your Novocure representative will send you a partially pre-populated HRP-284 form to finish filling out and submit through Connexus

The institution will need to contact Client Services at (800) 562 4789 or clientservices@wirb.com with the study number to be added to the study.
HDE Study Number*: 20192265

Institutions without a WIRB partnership may need to establish a contract with WIRB. Your Novocure representative can provide information on next steps.

- Note: If you have a local IRB or Office of Human Research Protection, you will first need to notify them to complete any local requirements prior to submitting materials to WIRB
 - *If an institution has an IRB in place already, this IRB must first approve the use of WIRB*

*Optune Lua, formerly known as NovoTTF-100L.

If you have any questions about the WIRB partnership, please reach out to your Novocure representative for assistance

novocure®

OPTUNE
LUA™

Caution: Federal law restricts this device to sale by or on the order of a physician. Humanitarian Device. Authorized by Federal Law for use in the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma concurrently with pemetrexed and platinum-based chemotherapy. The effectiveness of this device for this use has not been demonstrated.

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