Yale

Human Research Protection Program
Institutional Review Boards
FWA00002571
25 Science Park – 3rd Fl., 150 Munson St.
New Haven CT 06520-8327

Telephone: 203-785-4688
http://www.yale.edu/hrpp

September 1, 2020

APPROVAL OF SUBMISSION VIA EXPEDITED REVIEW

Approval Date: 9/1/2020

Investigator:	Emily Christison-Lagay
Type of Review:	Initial Study
Title of Study:	Pediatric tumor surgery during the COVID-19 pandemic: an international, multicenter observational cohort study (COVIDPaedCancerSurg) – Yale New Haven Hospital branch
IRB Protocol ID:	2000028852
Submission ID:	2000028852

Research activities associated with this submission are approved and may begin consistent with the terms of IRB approval.

The IRB has determined that this protocol presents minimal risk to subjects.

This approval is for medical record review only. This approval does not authorize patient contact.

Please be advised that Yale-New Haven Hospital and Yale Medical Group have implemented a new reporting request process. Requests for medical records should be made through JDAT as described at http://medicine.yale.edu/ycci/oncore/availableservices/datarequests/datarequests.aspx.

YNHH and Yale University consider it a violation of patient privacy for research personnel to review medical records of patients who have opted out of research use of their records. All record review requests should therefore be through JDAT.

The IRB has determined that informed consent can be waived for this medical record review.

The IRB has granted a waiver of HIPAA authorization for access to and use of protected health information (PHI) as described in the approved protocol for this medical record review. This waiver does not authorize subject contact.

. *BMJ Open* 2022; 12:e054690. doi: 10.1136/bmjopen-2021-054690

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HIPAA regulations require that accounting logs be maintained when researchers access patient records under a waiver of authorization including those approved for recruitment purposes. You are thereby reminded of your obligation to create the log. For further information on maintaining logs and on the accounting of disclosures, please see hipaa.yale.edu.

IRB approval of research or proposed changes to previously approved research does NOT constitute institutional approval for initiating or resuming in-person research during a pandemic. It is your responsibility to comply with institutional, federal, state, and local requirements (including Centers for Disease Control (CDC) and State of Connecticut guidelines), and other applicable policies. Please review the Yale requirements for research reactivation on the Yale website: https://research.yale.edu/phase-2-research-reactivation.

See the next pages for important reminders and the list of IRB approved documents.

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IMPORTANT REMINDERS:

- This research does not require IRB continuing review.
- You are obligated to submit the following to the IRB:
    - **Modifications**: Changes must be submitted with a modification and approved by the IRB prior to implementation except to eliminate immediate hazards to participants. This includes changes to study procedures, informed consent documents, recruitment activities or study personnel.
    - **Reportable New Information:** Information that requires prompt reporting to the IRB must be done so within 5 days of the PI becoming aware of the event (see Policy 710: Reporting Unanticipated Problems Involving Risks to Subjects or Others, including Adverse Events). This includes potential serious noncompliance, continuing noncompliance, and unanticipated problems to subjects or others.
    - **Closure request** (to end the IRB's oversight) when:
        i. The protocol is permanently closed to enrollment,
        ii. All subjects have completed all protocol related interventions and interactions, and
        iii. Analysis of private identifiable information is completed.
- In conducting this activity, you should refer to and follow the Investigator Manual (HRP-103) as applicable, which can be found in the IRB Library within the IRB system.

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IRB APROVED DOCUMENTATION:

• Main Data Collection Form, Category: Study questionnaires, measures, focus groups/interview questions;
• YNHH Specific Data Collection Form, Category: Study questionnaires, measures, focus groups/interview questions;
• Concept Approval, Category: Ancillary Committee Approval;
• Medical Record Review Protocol, Category: IRB Protocol;

Please keep this letter with your copy of the approved protocol documents.

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