



May 7, 2021

Daniel Tsze  
752140X - EMD PED Emergency Medicine

Protocol Number: IRB-AAAT0121

Title: Pediatric Sedation Research Consortium

Acknowledgement Date: 05/07/2021      Next Annual/Progress Report Due: 05/06/2022

Event Identifier: Annual Report(Y02M00)

The above-referenced event was reviewed by Human Research Protection Office (HRPO) staff.

Level of review and outcome: Acknowledged by HRPO Administrative Staff

To view a list of documents that were included in this approval (if applicable) and all other currently approved documents for this study, please refer to the Print Menu for this Event in Rascal. It is important to confirm the status of each document, e.g., active, stamped, etc. Only stamped, active documents can be used with research participants.

Consent Requirements: (as previously approved) A waiver of some or all elements of informed consent has been granted

Please Note:

1. Impact of COVID-19: For current information regarding the ramp up of human subjects research activities, please consult the frequently asked questions available at: [https://research.columbia.edu/COVID-19\\_Research/Ramp-up/HS](https://research.columbia.edu/COVID-19_Research/Ramp-up/HS). Any questions regarding ramp up, as it pertains to human subjects research should be directed to [irboffice@columbia.edu](mailto:irboffice@columbia.edu).

Electronically signed by: Collazo, Yaritza

**Researcher Responsibilities:**

Any proposed changes to the protocol or other study-related documents or procedures must be immediately submitted to the IRB for review and approval prior to implementation, unless such a change is necessary to avoid immediate harm to the participants.

Any unanticipated problems that involve risks to subjects must be reported to the IRB in accordance with the Unanticipated Problems: Reporting to the IRB of Unanticipated Problems Involving Risks policy. All submissions for modifications and unanticipated problems must be submitted through Rascal.

Studies that require renewal applications must have the renewal submitted 60 days before the expiration date through Rascal. Failure to obtain renewal of your study prior to the expiration date will require discontinuance of all research activities for this study, including enrollment of new subjects.

Studies that require an annual/progress report must have the report submitted in Rascal prior to the due date noted on the first page of this approval correspondence.

A Closure Report must be submitted in Rascal when this study has been completed.