INVITATION TO PARTICIPATE

Dear Collaborators,

We are pleased to officially launch "PEACHY" – PATRN's 2018-2019 national research study investigating **PE**rioper**A**tive **CH**ildhood obesit**Y**. An overview of the study can be found in the summary attached.

Sponsor site: University Hospital Southampton NHS Foundation Trust

PEACHY has a webpage on the APAGBI website with all the relevant supporting information available including the full study protocol. This is also where the HRA document packs will be hosted:

http://www.apagbi.org.uk/professionals/trainee-section/research-network-patrn/peachy

PEACHY has been

- assigned IRAS number 248493
- approved by HRA Research Ethics Committee (REC 18/WM/0394)
- accepted as an NIHR Portfolio study (CPMS ID 40368)

PEACHY aims

1. To establish the proportion of overweight and obese children aged 2-16 years attending hospitals for surgery across the PEACHY registered centres.
2. To establish whether obese children are at increased risk of defined adverse perioperative events as compared to their healthy weight counterparts in this study population.
3. To assess variation in perioperative paracetamol dosing for overweight and obese children in the study population.

We would now like to invite you to participate in this study.

In contrast to previous PATRN audit projects, PEACHY is a multi-centre research study. Attached to this email is a study flowchart which details the main steps in signing up as a local site. Anaesthetists and Research & Development (R&D) departments will need to work closely in this process.

Expression of interest

Please send an email to uhs.PEACHY@nhs.net in order to express your interest in participating in PEACHY. This will ensure your receive all the relevant information.

Feasibility assessment

R&D departments and anaesthetists will need to work together in order to undertake a feasibility assessment at the local site in order to determine whether you are able to conduct the study.

Formal sign-up

In order to register formally, each local site will require:

- a named Local Lead Consultant Anaesthetist (with Good Clinical Practice training)
- a named contact in their R&D department

Please complete the online submission form which can be found on the study website or via this link

Sponsor approval

Your site will be approved by the sponsor (University Hospital Southampton) and you will receive an approval email from uhs.PEACHY@nhs.net

HRA document packs

HRA document packs will be available to download from the PEACHY website when each local site is ready. For R&D departments, the date of download will serve as the date of site selection.

Local approval

Each local site will begin their set-up process, anaesthetists working with their R&D departments. Approvals should be sought according to HRA document packs. The sponsor does not require confirmation of local approval or evidence of GCP training of the Local Lead. This will remain the duty of local R&D departments.

Site ready

Local site confirms readiness to recruit. Local trainee data collectors should be identified and sign up to facilitate data collection at their local site. Larger sites may appoint a Lead Trainee to oversee this process along with the Local Lead Consultant. A site specific poster is available to download for each anaesthetic department detailing the study overview and local contacts.

Recruitment (data collection)

This will occur between the dates **Monday 9th September** and **Sunday 6th October 2019**. The sponsor will issue the green light on Monday 9th September. Each local site can choose any consecutive 7-day period within this four-week data collection window. A case report form (CRF) should be completed for **all*** 2-16 year-olds undergoing general anaesthesia within the study period.

*Inclusion and exclusion criteria can be found in the study protocol/summary.

Data upload

All data collected must be uploaded onto the secure REDCap system by each local centre by **Friday 8th November 2019** to allow central analysis. A login for each site will be provided for this system.

Data analysis

This will start in December 2019 and we anticipate results will be published by winter 2020. All data collectors will be listed as collaborators in any publications. RAFT and any regional networks will also be acknowledged. Certificates of participation will be issued to all trainee data collectors by February 2020. Local Lead Consultants and Lead Trainee collaborators will be acknowledged as such on certificates.

Please do not hesitate to contact us if you have any questions and we look forward to collaborating with you on the first trainee led national research study in paediatric anaesthesia.

Yours sincerely,

The PEACHY Study Team
The PATRN Committee