Gastrointestinal & Liver Disorders Theme
NIHR Nottingham Biomedical Research Centre
at the Nottingham University Hospitals NHS Trust
and the University of Nottingham
E Floor, West Block
Queen's Medical Centre
Derby Road
Nottingham
NG7 2UH

Tel: 0115 823 1149
Email: guru.aithal@nottingham.ac.uk

27th July 2020

WAIVER OF INFORMED CONSENT:

Project Number: 19-551C

This project was registered as an audit/service evaluation within the trust hence informed consent is not required. The primary aim was to compare the performance in tissue acquisition for two commonly used Endoscopic ultrasound (EUS) fine needle aspiration (FNA)/fine needle biopsy (FNB) needles, 22G Procore (Cook) and 22G Acquire (Boston Scientific).

The proposed plan was to:

Review the medical records and pathology slides of all individuals who have undergone EUS FNA/FNB from January 2016 to February 2019.

Data collected:

Age, sex, presence of trainee, use of Sonovue contrast, needle type used, lesion location, lesion size, lesion nature, number of passes, Euro-cytology result and number of cell groups in specimens slides.

Reason for justification for IRB to approve a waiver of informed consent:

1. **The project was a retrospective study and was registered as audit within the trust**- It was only review of endoscopy records, Histopathology and cytology slides. Hence, informed consent was not required.
2. **The rights and welfare of the individual would not be adversely affected** as it is a retrospective review patient records.

Yours sincerely,

Professor Guruprasad P. Aithal
Theme Lead for Gastrointestinal and Liver Disorders
NIHR Nottingham Biomedical Research Centre
Professor of Hepatology, Head of Division of Nottingham Digestive Diseases Centre