HAWKE'S BAY
District Health Board

MEMO

To: **Principal Investigators Involved in Clinical Trials in HBDHB**

From: Dr John Gommans, Clinical Director, Clinical Trials Research Unit (CTRU)

Process for Obtaining HBDHB approval and Health & Disability Ethics Committee (HDEC) Locality Approval for Clinical Trials

Date: 13-July-2021

This is the agreed process for obtaining HBDHB approval and HDEC Locality Approval for Clinical Trials. Contact CTRU if any questions or concerns regarding this process.

1. Investigator or supporting staff access the following required Clinical trial (CT) forms from either the HBDHB External website or CTRU - contact Melissa Spooner, Research Coordinator Melissa.Spooner@hbdhb.govt.nz
   - CT Agreement Between Investigator and HBDHB
   - CT Application Process
   - CT Approval for Locality Assessment
   - CT Checklist for Site Agreements (not required for NZ template Indemnities & Agreements)
   - CT Documentation Checklist (Not Mandatory)
   - CT HDEC Checklist
   - CT Insurance Checklist
   - CT Maori Application Process
   - CT Peer/Management approval
2. Investigator/Staff return all the completed forms to CTRU
3. CTRU reviews the forms and forwards request for approval to COO
4. Approval is signed by the COO and returned to CTRU
5. Online HDEC locality approval completed by CTRU manager
6. Central register of clinical trials is updated
7. Copy of completed form sent back to the investigator

Signed  Dr John Gommans