Human Health Research Decision Tree:
HDEC Application – Key Pre-Submission Activities

Purpose of Decision Tree:

- Provides a guideline for PIs outlining the activities they need to undertake prior to submitting their application to HDEC, (e.g. obtaining Academic Head approval for the study, and requesting Sponsor Authorisation for the study etc) - it is not designed to be a checklist for all things that the PI must consider when establishing their study
- Assist in identifying if further insurance advice is required

ADDITIONAL NOTES

Please click on the hyperlinks in the Decision Tree for the following:

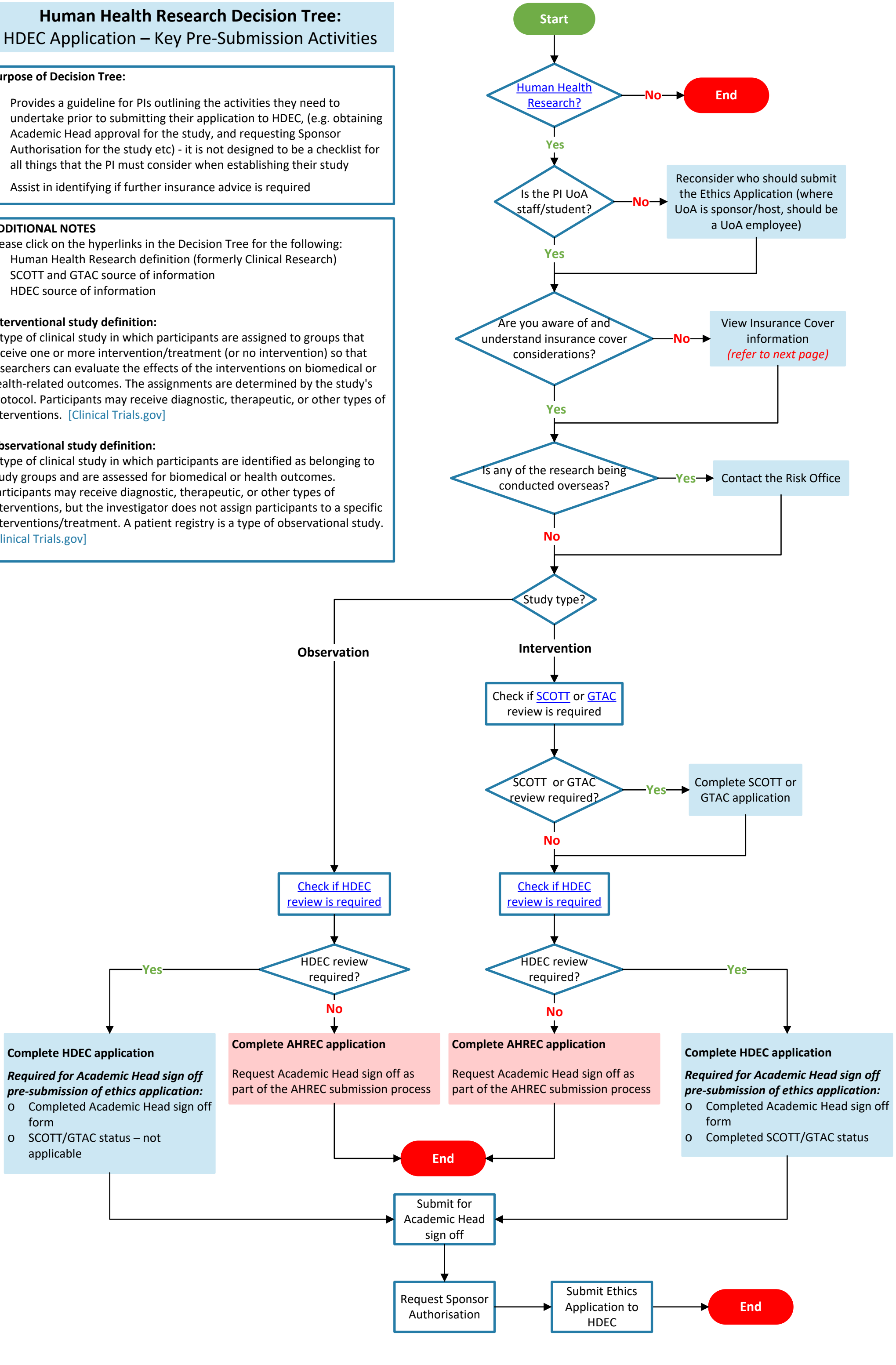
- Human Health Research definition (formerly Clinical Research)
- SCOTT and GTAC source of information
- HDEC source of information

Interventional study definition:

A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. [Clinical Trials.gov]

Observational study definition:

A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment. A patient registry is a type of observational study. [Clinical Trials.gov]



Insurance for Human Health Research

"What is in place to cover the study, researcher and participants in the event of damage or loss?"

- **ACC:** should provide relief to any subject of domestic public good research who suffers associated injury in accordance with the Accident Compensation Act 2001

Insurance responds in the event of legal liability of the Insured (the University of Auckland)
Where ACC does not respond, the UoA Human Health Research Insurance Policy provides the following cover:

- **No-fault:** Where the subject suffers harm or loss and makes a claim, regardless of the source or cause of the harm or loss

In addition, the following cover is in place regardless of the type of research:

- **Professional indemnity:** where there is an unintentional mistake in the trial design (and related)
- **Medical Malpractice:** where the medical practitioner makes an unintentional mistake

Further information on the UoA Human Health Research Insurance Policy is below:

- Total value of coverage: NZ$20m; standard excess: NZ$25k
- In place for:
  - Domestic clinical research i.e. in NZ
  - University of Auckland involvement as the Sponsor
  - University of Auckland involvement as the Host
  - Commercial research and Non-Commercial research
  - All types of Localities
  - University of Auckland involvement as a Trial Coordinating Centre
  - All research team members (whether UoA or non-UoA, whether domiciled in NZ or not)
  - UoA the organisation and Individual liability – for all persons the UoA wishes to be included under the insurance policy who are connected to the University research team.
  - A “new medicine”
  - All types of loss or damage associated with the clinical research are covered [noting that intentional/ deliberate acts of harm are never covered].
  - All subject types, including children [0 – 16 years] and pregnant women [noting a higher excess of NZ$50k for a claim involving a pregnant woman or child < 5 years]

Please contact Risk Office riskoffice@auckland.ac.nz in the following circumstances:

- Any aspect of your research is based in a country outside NZ, including Australia. Risk Office will confirm if you need additional insurance.
- If you have any insurance queries not answered by the above.