

Part 7: Xenotransplantation Clinical Trial Section

To be completed if the research involves transplantation, implantation or infusion into a human recipient of tissues or organs from a non-human animal source, or human bodily fluids, cells, tissues or organs that have had ex-vivo contact with live non-human animal cells, tissues or organs.

GTAC approval will be required **before** an application will be considered for ethics approval.

Applicant responses to these questions may initiate a request from the Ethics Committee for more detailed information.

1. Have you read, and does your research comply with, the Guidelines for Preparation of Applications involving Clinical Trials of Xenotransplantation in New Zealand? Yes No

2. Are there any alternative procedures available and what are the advantages of the proposed procedure over the alternatives?

3. What are the possible risks of the proposed procedure to the xenotransplant recipient?

4. a. What are the risks of the proposed procedure to third parties or society?

- b. Please detail how you intend to address these risks.

5. What long-term monitoring will be done, and on whom?

6. Please include a copy of any information that will be provided to xenotransplant recipients in relation to long-term monitoring.

7. Please include a copy of any information that will be provided to third parties (eg, close contacts of the xenotransplant recipient). How will third parties be identified? By whom and how will the information be provided?

8. Please give details of any arrangements to facilitate compliance with long-term monitoring requirements (eg, travel arrangements, home visits).

9. Outline action that will be taken if anyone who is being monitored ceases to comply with long-term monitoring.