

**GENERAL APPROVAL
UNDER THE *HUMAN REPRODUCTIVE TECHNOLOGY ACT 1991*
OF
SOME REPRODUCTIVE TECHNOLOGY RESEARCH
INVOLVING PARTICIPANTS.**

The Reproductive Technology Council (Council) has by resolution granted general approval under s20(2)(b) of the *Human Reproductive Technology Act 1991* (Act) for licensees to carry out, authorize, facilitate or become involved in the following categories of reproductive technology research involving adult participants:

- Non invasive research relating to reproductive technology, such as surveys of participants during a current treatment cycle, subject to these being carried out with effective consent of participants and approval for the particular research project having been sought and gained from the relevant Institutional Ethics Committee (IEC).
- Research based on records (described in s44(1) of the Act and relating to artificial fertilisation (AF) procedures held by licensees), subject to compliance with confidentiality requirements of the Act (in particular s49 (2)(a); s46(4)(b)) and approval for the particular research project having been sought and gained from the relevant IEC, which should determine whether participant consent is required.
- Research involving additional testing of samples collected at time of the AF procedure, subject to the effective consent of participants for each purpose for which testing will occur and approval for the particular research project having been sought and gained from the relevant IEC. This research may involve some additional testing of samples or extra volumes (such as blood).

At no time shall research needs dictate clinical decision making.

Approval for any changes or additions to approved clinical or laboratory procedures remain subject to the current Directions, under which the person responsible must obtain the specific approval of the Council for any proposed research, or any clinical or laboratory procedure that may be considered innovative (Directions 9.3, 9.4). [Any proposed change or addition to approved routine clinical or laboratory procedures is to be notified by the person responsible to the Council prior to the introduction of the change in accordance with Direction 9.2.](#)

Agreed by resolution at a meeting of the Reproductive Technology Council, 6 February 2001.