

Human Developmental Biology Resource (HDBR)
Institute of Genetic Medicine, Newcastle & UCL Institute of Child Health, London

Summary of operating principles, Sept 2018

Accountability. The HDBR is accountable to its funding bodies (Wellcome and MRC), the clinics that provide fetal material, the women who donate their products of conception and to the public which partly funds the activity. This accountability is achieved through scrutiny of HDBR working by the Joint Steering Committee (JSC) which has an independent scientific Chair, two independent senior scientists nominated by the funding bodies, administrative representatives of the funding bodies, one or more ethicist and lay representatives, and clinical representatives of the clinics where samples are collected. The HDBR is regulated by the National Research Ethics Service (NRES) and the Human Tissue Authority (HTA). Approvals are held by the HDBR at both its sites.

Tissue provision and charging. HDBR's core funding from Wellcome and MRC enables human embryonic and fetal material to be provided free of charge to registered projects. The only charge is an annual administrative fee, levied for each registered project. All projects are treated on an equal basis: that is, all projects have equal priority for receipt of tissue. The only proviso is that, if two or more projects require the same tissue/stage, then a rota system is applied to determine which project will receive the next batch of tissue. If projects have overlapping scientific goals, then the PIs are made aware by HDBR of a possible scientific conflict, and asked if they would like to be put in contact with each other: e.g. to encourage collaboration.

New projects. Registration of a new project involves completion of an electronic form that outlines the reasons for tissue request, the stages/tissues required, and the status of tissue (fresh, frozen, fixed, sectioned). Numbers of samples required for the project are agreed at this time, and once this number has been supplied the project ends. Availability of material varies with gestational age (e.g. very young embryos and older fetuses are less plentiful), and so HDBR cannot guarantee the time-frame over which requested material is supplied. New projects are formally approved by the JSC at its next 6-monthly meeting, but uncomplicated projects can usually begin within weeks of registration. An MTA must be set up between the supplying HDBR site(s) and the receiving institution before any tissue can be sent.

New projects with additional HDBR funding. The HDBR directors and managers feel strongly that the principle of equal access of all projects to human tissues should be maintained. Therefore, any projects that bring new funding to the HDBR will nevertheless be treated according to the equality-of-access principle. New funding sources will enable increased overall capacity within the HDBR, to allow the new sample requirements to be met, but will not mean that samples become 'ring-fenced' for particular projects; there will be no 'fast-track' arrangements for access to tissues.

Matching supply to demand. The HDBR has a finite capacity to collect new samples. Limiting factors are availability of clinic lists, and consenting of women for donation. Where new projects come on stream, HDBR will endeavour to increase collection to meet demand. New HDBR funding will be valuable in enabling additional staff to be recruited to the HDBR labs for consenting of patients, and for processing/dispatching the increased numbers of samples to receiving labs. Clinical staff time and equipment/consumables may also be needed. Nevertheless, HDBR must also work increasingly efficiently, and a primary goal is to maximise usage of each embryo/fetus. Tissues are usually dissected to generate a series of 'aliquots' which can then be dispatched to a number of different projects. Hence a single embryo/fetus can supply several research projects. This means that registered projects cannot often expect to receive whole embryos. Moreover, receiving labs cannot transfer tissues to 'secondary' labs without the express permission of the HDBR. In this case, the secondary lab must register a project and establish an MTA with the HDBR, and can only receive material up to the pre-set limit established at the time of project registration.