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REVIEW

# Ethical, legal and practical issues of establishing an adipose stem cell bank for research



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## KEYWORDS

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**Summary** Access to human tissue is critical to medical research, however the laws and regulations surrounding gaining ethical and legal access to tissue are often poorly understood. Recently, there has been a huge increase in the interest surrounding the therapeutic application of adipose tissue, and adipose-derived stem cells. To facilitate our own research interests and possibly assist our local colleagues and collaborators, we established a Research Tissue Bank (RTB) to collect, store and distribute human adipose tissue derived cells with all the appropriate ethical approval for subsequent downstream research. Here we examine the legal, ethical and practical issues relating to the banking of adipose tissue for research in the UK, and discuss relevant international guidelines and policies. We also share our experiences of establishing an RTB including the necessary infrastructure and the submission of an application to a Research Ethics Committee (REC).

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## Introduction

Regenerative medicine is a rapidly expanding field of research, with many strategies currently being translated toward the clinic.<sup>1</sup> Regenerative medicine is defined as the “process of replacing or regenerating human cells, tissues or organs to restore or establish normal function”.<sup>2</sup> This definition is very similar to that of plastic surgery that aims to achieve the “restoration of form and function”. In combination, these two disciplines offer great promise for establishing novel therapies to effectively manage disease, degeneration and reconstruction.

Stem cells are central to regenerative medicine, and understanding these cells is fundamental to developing new treatments. One of the challenges facing regenerative medicine is finding suitable, safe and ethical sources of stem cells for both research and therapy. Native stem cells come in many forms from the totipotent and pluripotent cells found in the morula and blastocyst respectively,<sup>3</sup> through to multipotent, bipotent and unipotent stem cells found in adult organisms.<sup>4</sup> Embryonic Stem Cells (ES) are pluripotent cells found in the inner mass of early embryos, and offer huge promise in regenerative medicine. However their collection, storage and use raises many ethical concerns. In addition, their application is more strictly regulated in comparison to adult stem cells such as mesenchymal stem cells (MSCs). MSC are multipotent cells that are capable of differentiating into bone, cartilage, fat, muscle and tendon.<sup>5</sup> In addition, MSCs secrete many bioactive molecules that are immunomodulatory, anti-apoptotic, anti-fibrotic, angiogenic and mitotic therefore suggesting a general regenerative function not just limited to differentiation into cells of a mesenchymal lineage.<sup>6</sup> They were originally described by Friedenstein as a population of cells derived from rodent bone marrow that were capable of osteogenesis *in-vitro*,<sup>7,8</sup> and also when implanted in ectopic locations *in-vivo*.<sup>9</sup> Since this initial discovery, identical cells have been isolated from almost all foetal and adult tissues,<sup>10,11</sup> including fat.<sup>12</sup> This has resulted in our current understanding that the *in-vivo* precursors of MSCs reside in a perivascular niche in all vascularized tissues.<sup>13–15</sup>

Adipose tissue is easily accessible and frequently readily abundant even in individuals of healthy weight and therefore offers an excellent source of stem cells.<sup>16</sup> As plastic surgeons routinely remove large volumes of adipose tissue through reconstructive and cosmetic procedures, this has resulted in many surgeons being either directly or indirectly involved in research using adipose-derived stem/stromal cells (ASCs). In addition to ASCs, adipose tissue is also an excellent source of adipocytes, endothelial cells and vascular smooth muscle cells. In cases where there is excision of redundant skin there are also abundant dermal and epidermal cells.

To facilitate research interests, we established a Research Tissue Bank (RTB) to collect, store and distribute human adipose tissue derived cells with all the appropriate ethical approval for subsequent downstream research. Here we examine the legal, ethical and practical issues relating to the banking of human adipose tissue for research in the UK, with reference to international guidelines and

regulations. We also share our experiences of establishing an RTB, including the necessary infrastructure and the submission of an application to a Research Ethics Committee (REC).

## What is a tissue bank?

A tissue bank (or biobank) is a term applied to a broad and heterogenous range of facilities that share common features. This may include small collections of tissue with minimal associated data held by a single institution, through to population wide biobanks collecting a variety of tissue and specimen types along with comprehensive medical and epidemiological data.<sup>17,18</sup> An example of the latter is The UK Biobank that is a multisource funded initiative that has recruited over 500,000 participants and was opened to access by researchers in 2012.<sup>19</sup>

In their broadest context, they collect and store biological materials that may be accompanied with varying amounts of medical, demographic and epidemiological data. They are linked with current (planned) research, but also serve to facilitate future (unplanned) research. They are continuous projects where material and data is collected on a prospective and long term basis. They apply procedures to ensure anonymity, whilst under specific conditions allow clinically relevant information to be traced back to the donor and accessed by authorised parties. They serve to protect the rights of donors and the interests of researchers by incorporating relevant governance legislation (eg. ethical committee review) and procedures (eg. anonymity and consent).<sup>20</sup> It is this last feature that distinguishes a biobank – a facility that facilitates access to outsiders – from a research collection.<sup>21</sup> An adipose RTB bank that solely serves to provide cells, such as ASC, for research is unlikely to require significant medical and epidemiological data.

## The Human Tissue Act

The collection, storage and subsequent use of human tissue is regulated in England, Wales and Northern Ireland by The Human Tissue Act (2004),<sup>22</sup> and in Scotland by The Human Tissue (Scotland) Act 2006.<sup>23</sup> The legislation in Scotland focuses on three principal areas:

- 1 Organ/tissue donation for the purposes of transplantation, research, teaching and audit
- 2 Organ/tissue removal and storage as part of post mortem examination.
- 3 Donation of bodies/organs/tissues for use under The Anatomy Act 1984.

Although The Human Tissue (Scotland) Act 2006 aims to address the use of tissue for research, it does not directly address the issue of donation of surplus tissue from live donors for research – the most likely scenario in adipose tissue banking. However, it does refer to the use of human tissue from the deceased for research, and also the use of tissue from live donors for transplant. In each of these occasions it states that the stance of the Scotland Act is to

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