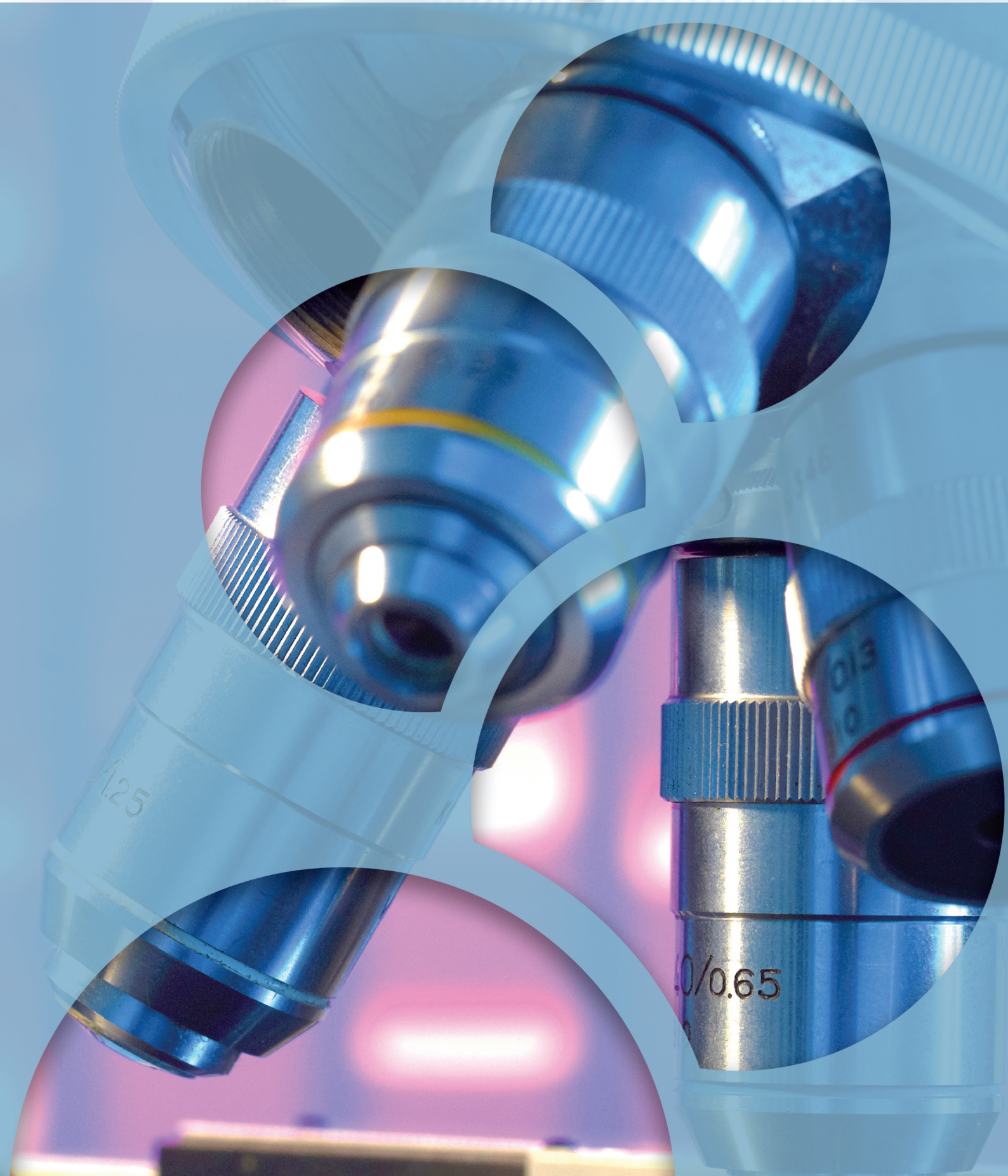
Research sector compliance updates report: 2017/18

HTA
Human Tissue Authority

A short summary of selected compliance update findings & learning points



Introduction

All establishments licensed in our Anatomy, Post-Mortem, Public Display and Research sectors are required to provide us with periodic updates of licensing information and to complete a compliance questionnaire. The data from this collection helps us to maintain oversight of the sectors we regulate, guide our regulatory approach for each sector, and inform the scheduling of site-visit inspections. We call these 'compliance updates' and we collect them every two years.

In October 2017, we completed a collection of compliance updates for the Research sector. Research sector establishments are organisations that store (and occasionally remove) human tissue for research in England, Wales and Northern Ireland, such as tissue and brain banks.

This report presents a snapshot of the key findings from the collection, identifying trends and themes we found from Research sector submissions. We hope that this report will be useful to people working in the sector, as well as to members of the public who have an interest in medical research.

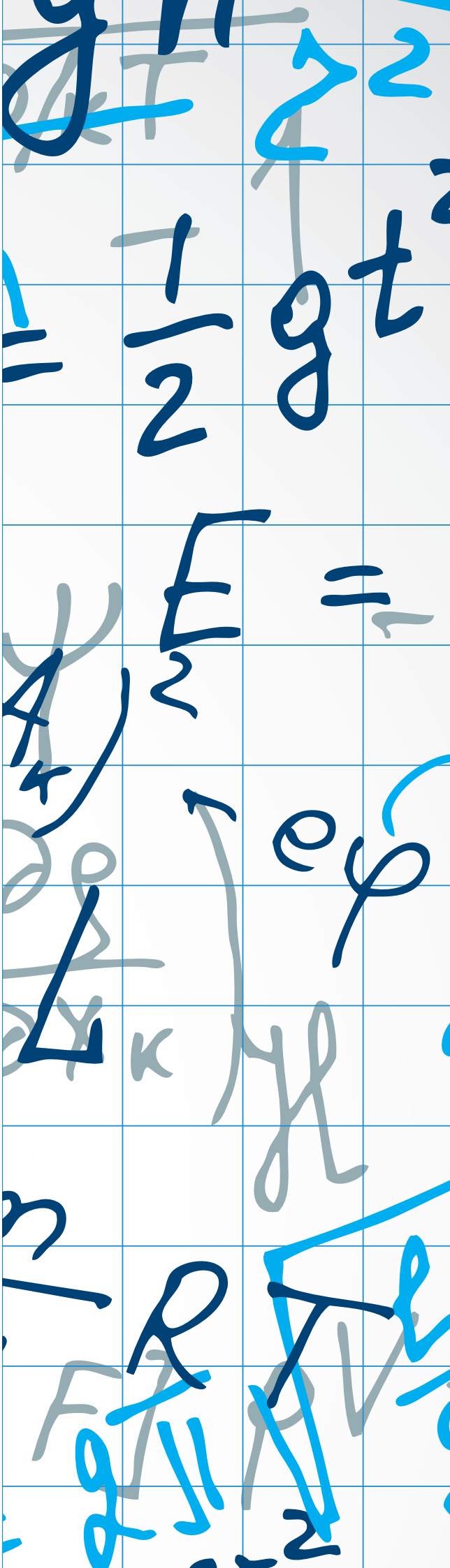
The data we collected in the 2017 round of compliance updates shows information from 165 establishments licensed in this sector. This includes two establishments newly licensed during the 2016/2017 period.

Research sector establishments reported high levels of compliance and good practice. This is consistent with our experiences of regulating the sector and supports our view of the sector as 'low risk'.

How we gather compliance data

We carefully analyse the data we receive from compliance updates. If we require further clarification on any aspects of the data, we follow these up with individual establishments. Compliance data is evaluated along with information such as the length of time since the last inspection. We use this information to prioritise establishments for future HTA inspections.

Compliance updates are submitted electronically, through the HTA Portal. As part of the submission, we ask establishments for feedback on the process. In 2017, all establishments found the instructions and communications from the HTA prior to submission clear. Furthermore, this year, the HTA chose to add accompanying guidance within the questions and all establishments found this to be useful. 97% of establishments found the submission process to be improved or similar to that of previous years.



Key findings

Profile of establishments

Out of 165 establishments, 43% (77) are classified as 'Academic', 37% (66) are 'Commercial', and 14% (25) are NHS-affiliated establishments. Four licensed establishments are charities and six consider themselves to be in the 'Other' category. The 'other' category includes government bodies and government funded research institutes.

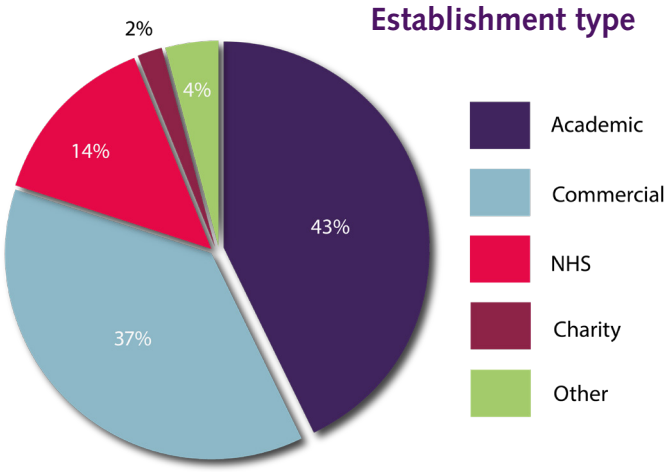


Figure 1 provides a breakdown of the types of establishments that hold HTA licences in the research sector.

To note: 13 establishments reported two or more types as best descriptors, demonstrating the importance

Research tissue banks

A research tissue bank (RTB) or biobank is a collection of human tissue or other biological material, which is stored for future research use. Some RTBs store samples in order to answer a very specific question about health, while others collect for future use without knowing exactly for what research projects the tissue will be used.

RTBs are usually found in hospitals, universities, charities and pharmaceutical companies. The compliance data tells us that 40% (66) of HTA-licensed Research establishments are either an RTB or contain at least one RTB.

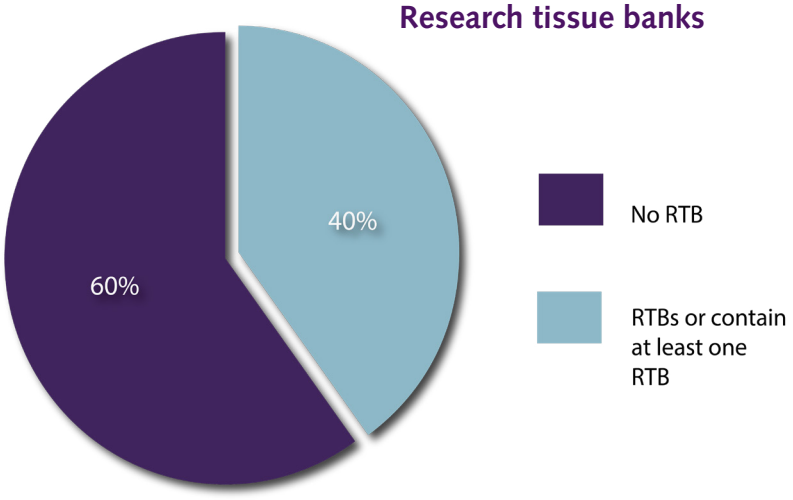


Figure 2. Proportion of research tissue banks (RTBs)

Key findings

Amount of samples

The number of samples of 'relevant material' varies greatly between establishments. The establishment with the largest collection holds over six million samples, while several establishments hold fewer than 100 samples.

Three quarters of establishments holding material under their HTA licence also hold material under ethical approval from recognised research ethics committees (RECs). RECs exist to safeguard the rights, safety, dignity and well-being of research participants.

The majority of establishments adopt a harmonised approach to sample management, with overarching governance for both material held under the HTA licence and material held for projects with qualifying REC approval. This is recommended by the HTA as inspection data has shown us that there are risks associated with varying practices where samples being stored for REC-approved projects are managed differently to samples subject to HTA licensing standards.

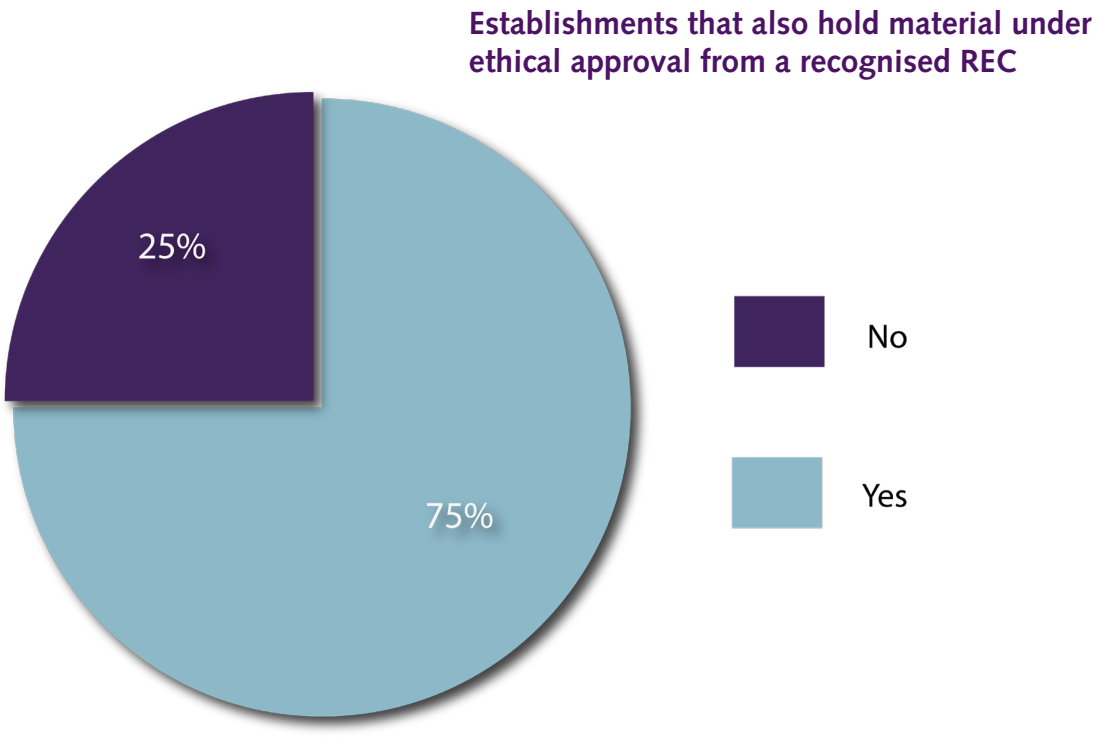


Figure 3: Proportion of establishments also holding material under ethical approval

Key findings

Storage arrangements

The types of 'relevant material' being stored varies between establishments. The data shows us that there are also many different storage conditions, ranging from room temperature storage to frozen storage conditions. All establishments that store relevant material under critical conditions have monitoring or alarm systems in place.

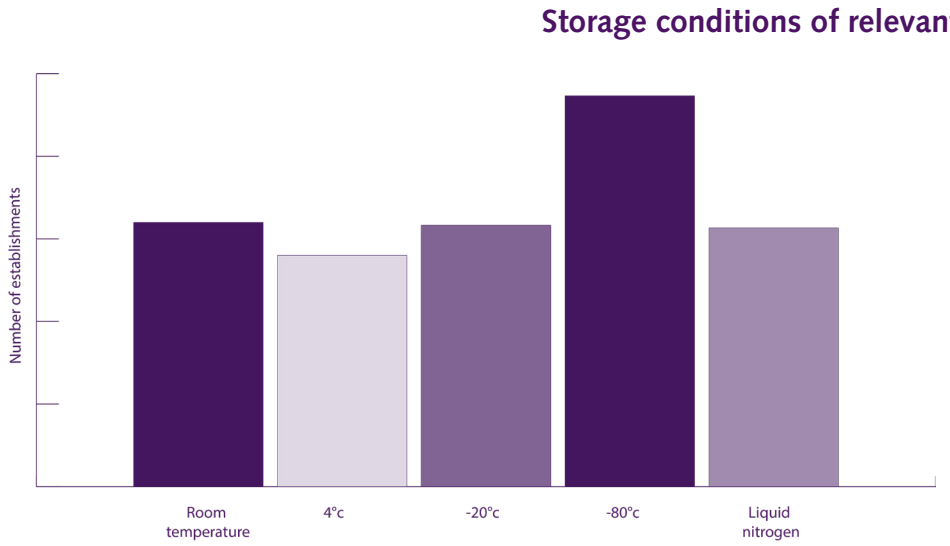


Figure 4: Storage conditions of relevant material

Types of donors

We asked establishments to provide us with details on the types of donors that participate in research. The data we received shows that NHS patients (27%), healthy volunteers (26%) and establishment staff (24%) make up the majority of the types of donors. Private patients make up 12% and 11% selected the 'Other' category. The other category included students, imported material and third party suppliers.

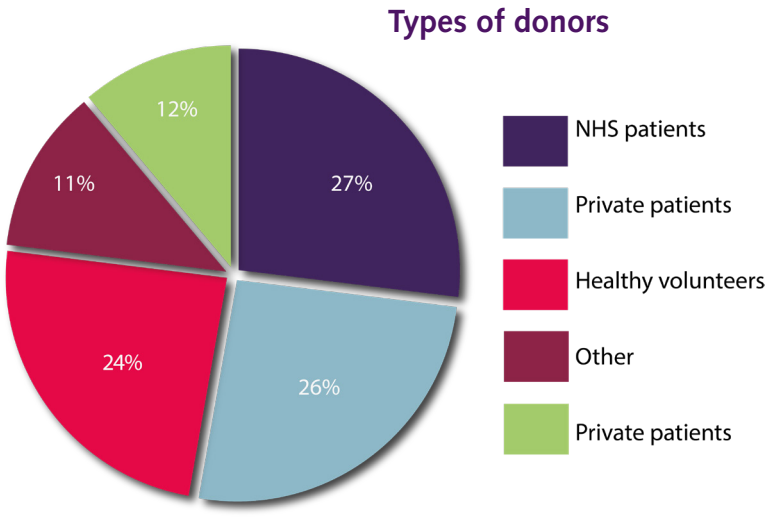


Figure 5 provides a breakdown of the types of donors that participate in the research at establishments.

Key findings

Compliance with consent standards

Research establishments reported that they comply with the HTA's licensing standards on consent. This indicates that Research establishments obtain consent from donors in accordance with the Human Tissue Act and our Codes of Practice, something that is also reflected in our inspection findings.

Out of 119 establishments that are directly involved with seeking consent, 83% (99) of them confirmed that staff have received consent training within the last two years. In total, 70% of licensed establishments have arrangements in place to seek specific consent for research involving genetic analysis.

Compliance with governance and quality system standards

The data we received in relation to governance and quality systems was positive. 98% of establishments reported having documented policies and procedures in place for all licensable activities.

All establishments have quality management and governance systems and the majority of these are overseen directly by the Designated Individual (DI).

Over 94% of all establishments have systems in place to deal with adverse events relating directly to licensable activities.

Types of adverse events that have been considered in governance systems

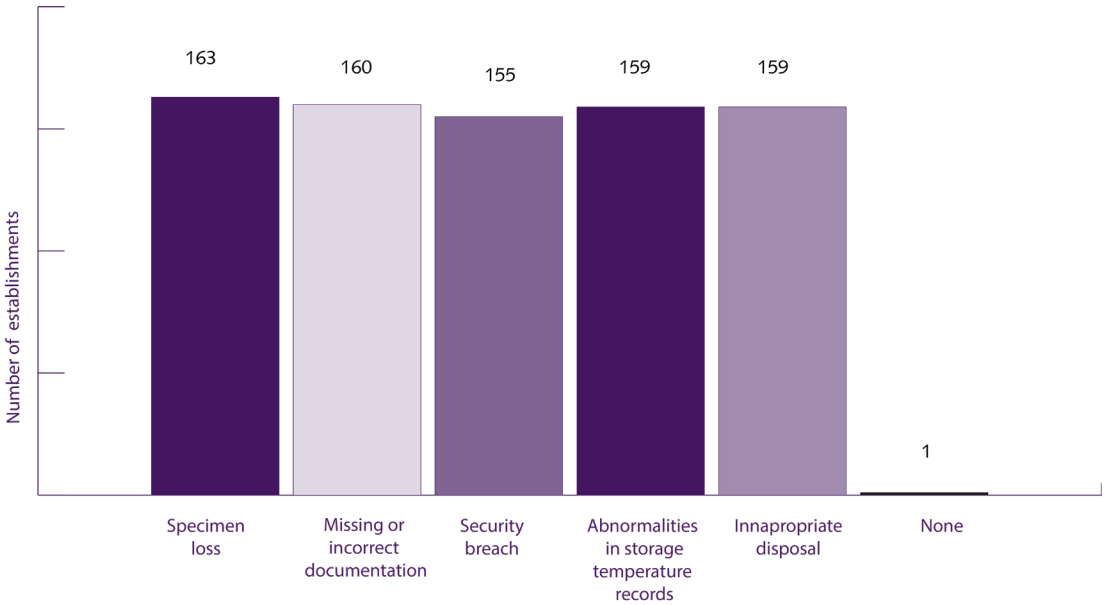


Figure 6: Types of adverse events that have been considered in governance systems

We hope you found this short report useful. The next round of compliance updates is being planned for 2019/20.

If you have any comments or questions, please contact us at enquiries@hta.gov.uk or visit our website.