

Section 17 Records

1. The Responsible Official must maintain an up-to-date, accurate list of the individuals approved under §73.10 for access to select agents and toxins.
2. Each Principal Investigator must maintain an up-to-date, accurate list of the individuals approved under §73.10 for access to the select agents and toxins under their control.
3. The Responsible Official must maintain an up-to-date, accurate list of each select agent and toxin held at the University.
4. Each Principal Investigator must maintain an accurate, current inventory of the select agents and toxins under their control. The inventory records must include the following information
 - a. For each select agent:
 - The name, characteristics, and source data;
 - The quantity acquired, the source, and date of acquisition
 - Where stored (building, room, freezer)
 - The select agent used and purpose of use
 - The quantity, volume, or mass destroyed or otherwise disposed of and the date of each such action;
 - The quantity transferred, the date of transfer, and individual to whom it was transferred (this includes transfers within an entity when the sender and the recipient are covered by the same certificate of registration);
 - Any select agent lost, stolen, or otherwise unaccounted for; and
 - A written explanation of any discrepancies.
 - b. For each select toxin:
 - The name, characteristics, and source data;
 - The toxin used and purpose of use, quantity, date of use, and by whom;
 - Where stored (building, room, freezer)
 - When moved from storage and by whom and when returned to storage and by whom including quantity amount
 - The initial and current quantity amount;
 - The quantity acquired, the source, and date of acquisition;
 - The quantity, volume, or mass destroyed or otherwise disposed of and the date of each such action;
 - The toxin transferred, quantity transferred, the date of transfer, the sender, and recipient (this includes transfers within an entity when the sender and the recipient are covered by the same certificate of registration);

- Any select toxin lost, stolen, or otherwise unaccounted for; and
 - A written explanation of any discrepancies.
5. Each Principal Investigator must maintain the following records for each select agent and toxin under their control:
- (a) For access to the select agents or toxins:
- The name of each individual who has accessed any select agent or toxin;
 - The select agent or toxin used;
 - The date when the select agent or toxin was removed, if removed from long-term storage or holdings for stock cultures;
 - The quantity removed (toxins only);
 - The date the select agent or toxin was returned to the long-term storage or holdings for stock cultures; and
 - The quantity returned (toxins only).
- (b) For access to the area where select agents or toxins are used or stored:
- The name of each individual who has accessed the area;
 - The date and time the individual entered the area;
 - The date and time the individual left the area; and
 - For individuals not approved under §73.10, the individual approved under §73.10 who accompanied the unapproved individual into the area.
6. The Responsible Official must conduct regular inspection of the records required under this section in order to ensure that all records and databases are accurate, have controlled access, and that the authenticity of records may be verified.
7. The Responsible Official must maintain copies of all inspection reports conducted by the Responsible Official, including the annual inspection and any other inspections conducted during the year.
8. Each Principal Investigator must maintain their copy of the following:
- Inspection reports, including those conducted by outside agencies, the Principal Investigator, and the Responsible Official;
 - Biosafety, security, and incident response plans;
 - Training records;
 - Transfer documents (CDC Form 2) and permits; and
 - Biosafety and security incident reports.
- 9. All records created under this part must be maintained for three years.**