



University of Pittsburgh

Case Studies in Suitability and Application to the Research Community

Kathryn Board, MS, RBP, Alternate Responsible Official for Select Agents

Jay Frerotte, MBA, EH&S Director and Responsible Official for Select Agents

Molly S. Stitt-Fischer, PhD, CPH, CBSP, SM(NRCM), Alternate Responsible Official for Select Agents



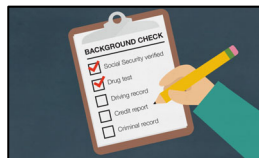
University of Pittsburgh

Environmental Health & Safety

Select Agent Program

Approval requires two background checks for Tier 1 registered facilities:

SRA approval
Tier 1 Suitability





Suitability Program

Must include:

- A “whole person” assessment.
- Mechanisms in place for both self- and peer- reporting.
- Enhanced security.
- Ongoing training, including that for insider threats.
- An Occupational Health Program.
- *Ongoing assessment for continued suitability.*



Suitability Program

Should Include

- A culture of safety supported at every level of the entity
- Free communication, interdepartmentally, to conduct Suitability Assessments.
- Support from entity leadership to commit to decisions of the RO and, if applicable, the Suitability Panel



Case Study: Personality Conflicts

Scenario: Two individuals, both approved for access to Tier 1 registered spaces, have a volatile relationship. They are required to work together, both inside and outside of registered space. Already, they have several altercations and reported each other to their respective supervisors



Is this a Suitability Issue?

It Depends.



Case Study: Personality Conflicts

Things to Consider:

- Can this be addressed through the individuals' supervisors?
- Are these two individuals a threat for theft/loss/release of a Select Agent?
- Are these two individuals a threat to the entity Select Agent program?



Case Study: Personality Conflicts

Potential Outcomes

- *(A culture of safety supported at every level of the entity)* Concerns can be brought to supervisors, with the expectation that they will support a culture of safety.
 - Can one or both of the individuals be assigned to different locations?
- Should the Suitability Panel be consulted?





Case Study: Personality Conflicts

Additional Considerations

- Does it matter if these individuals do not directly work with Select Agent?
- Has one individual has demonstrated a pattern of aggression?
- Is there a No Contact Order in place?



Case Study: Personality Conflicts

No-Contact orders at Universities

- Do you know what a “No Contact Order” means at your institution?
- Differs from university to university

Months of stalking end with 2 dead at UW

Originally published April 3, 2007 at 12:00 am | Updated April 3, 2007 at 7:18 pm



Rebecca Jane Grigo (1981-2007)

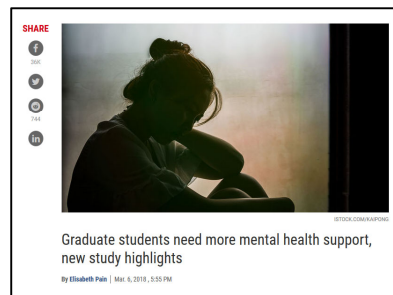


Jonathan Brown (1966-2007), photo sent by Rebecca Grigo to an unknown identity for stalkin



Case Study: Attempts or Threats of Self-harm

Scenario: A graduate student, with approval to work with and access to Select Agent, has been hospitalized because they made a credible threat of self-harm.



Science, July 2018



Case Study: Attempts or Threats of Self-harm

Is this a Suitability issue.....?

.... or a health issue?

Yes.



Case Study: Attempts or Threats of Self-harm

Acute concerns may require action that can be reversed.

- Temporary or permanent suspension of Suitability
- Temporary or permanent assignment to non-Select Agent registered spaces

If the suspension is considered temporary, what are the terms for regaining access?



Case Study: Attempts or Threats of Self-harm

Use of Your Occupational Health Program

- Potential in-house evaluation
- Ability to refer the individual to mental health care professionals outside of the university system
- Can speak to mental health care professionals outside of the university system without compromising medical confidentiality
- Can provide recommendations concerning Suitability without compromising medical confidentiality



Case Study: A Principle Investigator's Suitability is in question

Scenario: A Principal Investigator, who previously was found suitable for work with Select Agents, is demonstrating erratic behavior.



The Trials of Thomas Butler

Science, December 2003



Case Study: A Principle Investigator's Suitability is in question

**This isn't typically the result of a single event; but
An ongoing concern based on a pattern of behavior.**

**Amy Bishop, Ala. professor,
pleads guilty to shooting
and killing three colleagues
in 2010 faculty meeting**



CBS News 2012

**What issues must be considered if
a Select Agent PI is found unsuitable?**



Case Study: A Principle Investigator's Suitability is in question

Special Considerations

- Should the PI's lab personnel continue to have access to Select Agent registered spaces if their PI is found unsuitable?
- Who should communicate with personnel that report to a PI that has been found unsuitable?
- Does the PI have a Select Agent inventory?



Suitability and Wider Application to the Research Community

Tier 1 Suitability exists because of the high impact that misuse of Select Agent can have on the workers, the entity, and the general population.

What other program's misuse would have a high impact on workers, the entity, or the general population?



Suitability and Wider Application to the Research Community

Any BSL-3 Facility



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

HHS OIG Data Brief • May 2017 • (OEI-04-15-00430)

CDC Generally Met Its Inspection Goals for the Federal Select Agent Program; However, Opportunities Exist To Strengthen Oversight



Suitability and Wider Application to the Research Community

Animal Care Groups



Investigation Reveals Hell on Earth for Animals at California Dealer Warehouse

In 2012, a PETA investigator recorded abuse and neglect of thousands of rats and reptiles.

[READ MORE >](#)



Cruelty Revealed at University of Colorado Health Sciences Center

PETA received evidence of numerous potential violations of federal regulations at the University of Colorado Health Sciences Center from a whistleblower who worked inside.

[READ MORE >](#)



PETA Exposes Horrific Dog Testing Lab at Texas A&M

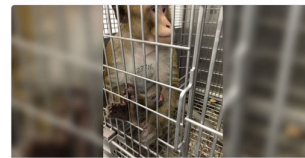
Video footage exposes the horrors of laboratories where dogs are bred to have muscular dystrophy and live a short and painful life.

[READ MORE >](#)



PETA @peta - May 29
Replying to @xoxoellamay

Help end the cruelty! Please demand that NIH put an immediate stop to funneling money into **NIH's** cruel experiments on animals.



VICTORY for Mice Suffering at Pitt Now Help More Animals
For more, see PETA.org.
investigations.peta.org



Dogs and Cats Suffer, Die at Liberty Research

A PETA eyewitness investigation reveals that dogs and cats were used in painful, invasive, and deadly experiments at a contract testing laboratory. Act now!

[READ MORE >](#)



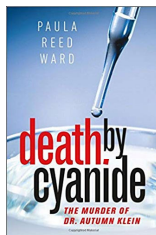
Suitability and Wider Application to the Research Community

Individuals ordering large amounts of
specific chemical agents

Nicotine



Ethylene
Glycol



Dimethylmercury



Arsenic



Sodium Cyanide



In Conclusion

- Suitability Assessments are a powerful tool in maintaining a culture of safety.
- Case studies in Suitability illustrate that there are multiple approaches to answering personnel concerns.
- The application of portions of the Suitability Assessment to sensitive departments and programs may enhance overall safety and security.



Thank you!

University of Pittsburgh EH&S

- Jay Frerotte
- Molly Stitt-Fischer
- Rebecca Lingenfelter

University of Pittsburgh Division of
Laboratory Animal Research (DLAR)

- Dave Schabdach
- Dennis Heflin
- Reagan Walker

University of Pittsburgh Suitability
Panel