

Biosafety and Biosecurity Policy

How Baxtra works with organisms that can kill the people who work with them.

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Owner	Institutional Biosafety Committee
Applies to	All Baxtra sites and all contracted laboratories

This policy describes the controls Baxtra Research Labs uses when research, clinical support, contracted work or waste handling may involve high-consequence pathogens. It is deliberately specific about authority and reporting, and deliberately limited about information that could increase misuse risk.

1. Scope and definitions

This policy applies to employees, visiting scientists, agency staff, couriers, service providers and contracted laboratories working for Baxtra Research Labs. It applies at discovery laboratories, containment-level-3 laboratories, the Palm Coast maximum-containment (BSL-4) suit laboratory, the surgical engineering facility where relevant, and any approved off-site location. A contract does not transfer Baxtra accountability: the contracting owner remains responsible for verifying that the laboratory can meet this policy and the work order.

Biosafety means controls that prevent unintentional exposure or release. Biosecurity means controls that prevent unauthorised access, removal, loss, diversion or misuse. Primary containment is the equipment or enclosure that directly contains an agent; secondary containment is the room, suite and building engineering that protects people outside primary containment. The Institutional Biosafety Committee (IBC) is the governance body that approves, conditions, suspends or withdraws work. The Biosafety Officer is the operational authority for implementation and immediate protective actions.

Operating principles

- No work begins without an approved protocol, named responsible investigator, trained personnel and a documented containment assessment.
- Containment is selected for the credible hazard, not for the convenience of the experiment. Where uncertainty remains, the higher control is used until the IBC resolves it.
- Records must be contemporaneous, attributable and reviewable. A missing record is treated as a control failure, not as evidence that a control occurred.
- Any person may stop work. Reporting a concern or using stop-work authority must not affect employment, training status, contract standing or future assignments.

This is a public policy. Site-specific room drawings, access lists, alarm set-points, quantities and other details that could weaken security are controlled records and are not published here.

2. The agents Baxtra works with

The following table is the controlled public description of the agent set associated with Baxtra programmes. Risk group and containment level are planning classifications; the approved protocol, material, procedure and current regulatory requirements determine the final controls. Select-agent registration is a legal and operational status, not a substitute for a risk assessment.

Agent	Risk group	Containment level	Select agent status	Which programme
Nipah	RG4	BSL-4	US select agent	BX-101 Nipavir
Marburg	RG4	BSL-4	US select agent	BX-204 Marburavir
CCHF	RG4	BSL-4	US select agent	BX-412 Cehafex
Lassa	RG4	BSL-4	US select agent	BX-515 Lassivar
Sudan ebolavirus	RG4	BSL-4	US select agent	BX-806 Sudanavir
Junín	RG4	BSL-4	US select agent	BX-1265 Arenavir
Machupo	RG4	BSL-4	US select agent	BX-1265 Arenavir
Sabiá	RG4	BSL-4	US select agent	BX-1265 Arenavir
Guanarito	RG4	BSL-4	US select agent	BX-1265 Arenavir
rabies virus	RG3	BSL-3	Not a Tier 1 select agent	BX-620 Rabivex
Andes/Sin Nombre orthohantavirus	RG3	BSL-3	US select agent; not Tier 1	BX-733 Hantrelvir
monkeypox virus	RG3	BSL-3	US select agent; not Tier 1	BX-1140 Poxavir
Rift Valley fever virus	RG3	BSL-3	US select agent; not Tier 1	BX-1330 Riftavir
Burkholderia pseudomallei	RG3	BSL-3	Tier 1 select agent	BX-1620 Meliovex

The public portfolio contains 12 disclosed Phase 1 programmes and one further clinical-stage programme whose designation and indication are withheld. The table names only the disclosed programme associations relevant to this policy. Discovery-stage candidates are not listed.

Reading the classifications

The BSL-4 entries are the seven targeted BSL-4 pathogens named by Baxtra, together with Sabiá and Guanarito, which are also RG4. The RG3 entries are the additional agents identified in the canonical programme description. Work involving a mixed sample, an unknown sample or a co-infection is controlled to the highest credible requirement until the sample is characterised and the IBC has documented the decision.

A programme association does not mean that every programme activity handles live agent. The responsible investigator must state what material is proposed, where it will be held, who may access it and how it will be accounted for.

3. Containment engineering: Palm Coast BSL-4 suit laboratory

Commissioning of the Palm Coast maximum-containment (BSL-4) suit laboratory was completed in July 2026. Its design intent is layered containment: the failure of one barrier must not become the failure of the system. The laboratory is operated only under approved procedures, with engineering controls maintained by qualified personnel and verified before the area is released for work.

Barriers and critical services

Control layer	Policy requirement
Airlocks	Personnel and materials pass through sequenced airlocks. Door interlocks, status indicators and access records are checked before entry, exit or transfer. Doors are never propped open or bypassed.
Positive-pressure suits	Personnel use the approved positive-pressure suit system with supply, connection and integrity checks before work. A suspected suit breach is an immediate stop-work event.
Chemical shower	Exit from suit operations includes the required chemical shower cycle and a documented release decision. A person does not leave the controlled area merely because the visible task is complete.
HEPA filtration	Exhaust and supply filtration are maintained, tested and changed under controlled maintenance. Filter work is itself a risk-assessed activity with a documented hand-off.
Effluent decontamination	Liquid effluent is held and decontaminated through the approved system before release. Any alarm, deviation or uncertain treatment status keeps the stream controlled.
Two-person rule	Suit-laboratory work uses the two-person rule. Personnel maintain direct or approved equivalent accountability for one another, and neither person works beyond the approved authorisation.
Redundant power	Critical containment, monitoring, communications and life-safety loads are supported by redundant power. Loss of normal power triggers the approved response and controlled suspension of work.

Engineering controls do not remove the need for disciplined behaviour. Operators verify alarms, communications, pressure indications, suit connections and decontamination status before proceeding. Maintenance, calibration and testing are scheduled work with their own permits and release criteria; they are not invisible exceptions to containment.

Release and re-entry

Re-entry after an alarm or suspected barrier failure requires documented assessment, compensating controls and a release decision with time and responsible role. Otherwise work remains stopped.

4. Governance, reliability and competence

Institutional Biosafety Committee authority

The IBC is independent of the project schedule and has authority over all work within the scope of this policy. It approves protocols and amendments; sets containment, personnel and monitoring conditions; reviews incidents and corrective actions; audits contracted laboratories; and suspends or withdraws approval. The IBC may require additional information, an independent review or a pause while facts are established. No commercial, clinical or scientific milestone overrides an IBC condition.

The chair of the IBC records decisions, dissent and conditions. The Biosafety Officer may take immediate protective action between meetings, including isolating material, restricting access and stopping work. Such action is reported to the IBC chair and the responsible investigator for formal review.

Personnel reliability and select-agent registration

Access to select agents is limited to people with a documented need, appropriate suitability determination, required training and current registration or approval under the applicable US select-agent framework. Access is removed when a person changes role, leaves the project, fails a competency check, is subject to a restriction, or no longer has a documented need. Contractors use the same decision standard; a badge or vendor relationship is not access authorisation.

Personnel reliability is maintained through identity control, escorted access where required, two-person accountability in the suit laboratory, inventory reconciliation, reporting of unexplained discrepancies and review of changes that could affect safe performance. The process is intended to protect people and materials, not to create a culture of surveillance. Concerns are handled confidentially and on a need-to-know basis.

Training and competency sign-off

1. Complete role-specific induction, agent hazard awareness, emergency communications, waste and transport instruction before unsupervised work.
2. Observe the approved procedure with a qualified trainer, then demonstrate the task under supervision, including the stop-work trigger and recovery path.
3. Pass the written and practical assessment recorded by name, role, date, scope and assessor. Training completion alone is not competency sign-off.
4. Requalify at the interval set by the IBC, after a material procedure change, after an extended absence, or after an incident or observed deviation indicates that reassessment is needed.

5. Occupational health and inventory accountability

Occupational health and immunisation

Occupational health provides a confidential fitness-for-task review before assignment and remains available throughout the work. The review covers relevant medical conditions, exposure response, work restrictions, respiratory or suit considerations and emergency contact arrangements. It is not a substitute for engineering controls or a reason to conceal symptoms.

For personnel assigned to relevant work, the occupational health programme includes rabies pre-exposure immunisation and orthopoxvirus pre-exposure immunisation when indicated by the agent, task and current public-health advice. Rabies and orthopoxvirus titre monitoring is scheduled according to the applicable immunisation protocol and individual risk assessment. Occupational health records the recommendation, consent, administration or declination, and follow-up; supervisors receive only the work-relevant clearance or restriction.

A possible exposure, illness compatible with the work, immunisation reaction or loss of titre is reported promptly to occupational health and the Biosafety Officer. Personnel must not self-clear or return to work on the basis of how they feel. Clinical care and public-health advice take priority over schedule or confidentiality concerns.

Tier 1 select-agent inventory accountability

Tier 1 select agents and materials containing them are maintained in a controlled inventory from receipt or creation through use, transfer, decontamination or destruction. The record identifies the responsible custodian, approved location, quantity or countable unit, transaction, date, time and independent verifier. Measurements use the approved unit and precision; estimates are not silently substituted for reconciliations.

- Every transfer between people or locations has a receiving and releasing custodian, with the container identity checked at both ends.
- Routine reconciliation is performed at the frequency set by the registration and protocol, and whenever a container is opened, moved, split, consumed or decontaminated.
- An unexplained difference is an incident immediately. Work involving the affected material stops while the custodian and Biosafety Officer secure the area and begin reconciliation.
- Inventory records are retained as controlled records and made available to authorised inspectors, the IBC and the independent reviewer where required.

6. Incidents, reporting and stop-work authority

An incident includes exposure or suspected exposure, containment loss, equipment or engineering failure, spill, injury, unaccounted inventory, unauthorised access, transport deviation or any condition in which the approved barrier may not have held. Protect life first, then protect containment, then preserve information. The operational standard BRL-BIO-2026-09 gives the first-fifteen-minutes actions.

Class	Examples	Required reporting timeline
Class 1 - observation	A near miss or unsafe condition with no exposure, release or inventory discrepancy.	Tell the supervisor before the end of the shift; enter the report within 24 hours.
Class 2 - controlled deviation	A procedural or engineering deviation contained within the approved barrier; no suspected exposure.	Notify the Biosafety Officer within 1 hour; written report within 24 hours.
Class 3 - exposure or containment event	Actual or suspected exposure, suit breach, spill outside primary containment, loss of negative pressure or material of uncertain status.	Stop work and notify the Biosafety Officer immediately; initial report within 1 hour; occupational health and IBC chair without delay.
Class 4 - critical event	Unaccounted Tier 1 inventory, unauthorised access, confirmed release beyond controlled containment, serious injury or event requiring emergency services.	Call emergency services when needed and notify the Biosafety Officer immediately; escalate to executive duty officer, IBC chair and required authorities within applicable legal time limits.

Stop-work authority

Any member of staff, contractor or visitor may stop an activity when they reasonably believe that a person, the public, the environment or the integrity of a controlled material may be at risk. There is no consequence for a good-faith stop-work decision. No seniority, title, permission from a supervisor or proof of harm is required. The person should state "stop work", move to a safe position if possible, and notify the nearest responsible role. The Biosafety Officer then controls the scene and decides what can safely continue.

A stop is a control, not an accusation. Work resumes only after the responsible authority documents the hazard review, corrective action and release decision.

7. Special reviews, movement and close-out

August 2026 containment event

Baxtra's public statement, 'Statement on a containment failure' (29 August 2026, ref BXRA-PS-2026-08), confirms only that an event occurred, was found by Baxtra's own staff, that work stopped, an independent review is open, and authorities were notified. It declines to name the programme, suite, material, quantities, dates or individuals, and states there is no identified risk outside the facility.

Dual-use research of concern review

Before approval and at each material amendment, the responsible investigator and IBC consider whether work could enable harmful enhancement, evasion of detection, increased transmissibility or host range, increased resistance, or more damaging dissemination. The review asks whether a safer design answers the question and how much information should be shared.

A concern is referred to the IBC chair and the Disclosure Review Board where public release, external communication or unusual access is involved. The IBC may add supervision, restrict dissemination, require independent review or decline the work.

Transport and shipping of specimens

Specimens move only under an approved transfer record. Classification, packaging, labelling, chain of custody, route, emergency contact and recipient authorisation are verified before dispatch. The shipper follows applicable US and international dangerous-goods requirements and uses an approved carrier. A damaged package, delay, misdelivery, broken seal or manifest mismatch is an incident; the carrier must not open or redistribute a suspect package.

Decommissioning and waste

Decommissioning is planned: freeze work, reconcile inventory, identify residues and equipment, validate decontamination, close records and document release of each area or item. Waste is segregated, labelled, rendered non-infectious by the approved method or transferred to an authorised provider, and tracked to final disposition.

Audit and external inspection

The IBC and Biosafety Officer audit training, access, engineering records, inventory, transfers, waste, incidents, corrective actions and contracted laboratories. Findings have an owner, due date, risk ranking and closure evidence. Baxtra cooperates with authorised regulators, public-health authorities, emergency responders and independent reviewers, subject to security controls, and does not conceal reportable events or delay required notification.

Important. Baxtra Research Labs develops investigational medicines and investigational medical devices. No Baxtra investigational medicine has been approved by any regulatory authority in any country, and the safety and efficacy of none of them has been established. This document is published for information. It is not medical advice, not biosafety or biosecurity guidance, not an offer to sell or a solicitation to buy securities, and not a forecast that any programme described in it will succeed. Forward-looking statements about timing, enrolment, regulatory interactions and intended indications are subject to change without notice.

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