

# Insurance Controlled Environment Research Guide & Valuation Tools

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## Controlled Environment - Mitigated Requirements (Courtesy of Unimutual 2020)

For a Controlled Environment to be considered mitigated it must have:

1. A back to base alarm that is monitored 24 hours a day. The alarm must be capable of detecting a change in the environment and must be serviced to manufacturer specifications.
2. Back-up Power capable of providing power in the event of a loss of regular power to the environment. Back-up power must be serviced in accordance with manufacturer specifications.
3. The controlling mechanism, for example a minus 80-degree freezer, must be serviced to manufacturer specifications.
4. A documented and tested response plan for management of research contents in the event of a failure.
5. Valuation assessment in accordance with Unimutual Research Valuation Guidelines or a similar, approved methodology (this document)
6. A variation of the above that has been assessed and approved by Unimutual and noted within the Member's wording. Where the Controlled Environment does not meet the criteria of points 1-5 or the variation pre agreed by Unimutual (point 6), it will be considered Non-Mitigated for the purpose of claims assessment.

## Principals of Valuing Research (Courtesy of Unimutual 2020)

Determining the value of research samples for insurance purpose can be a complex task given the wide-ranging variety of research undertaken by Australian universities. Adopting the following 10 principles can assist to simplify the process. These principles are:

1. The nature of each research project is different
2. The value of samples cannot exceed the value of the projects total funding
3. There are administration costs associated with a research project
4. Primary samples must be collected or created.
5. Samples are analysed using many different techniques.
6. There are costs associated with lab space and the storage and maintenance of samples
7. Insurable value is a function of the time, effort and cost to replace samples
8. Samples do not increase in value over time
9. Not all samples can be replaced
10. Samples derived from multiple research projects may be kept in a single device or environment.

## Nature of Research and Value (Courtesy of Unimutual 2020)

Some forms of research incur greater cost to undertake than others due either to that fact that collecting or making the samples can be difficult and sample preparation and analysis is both time consuming and expensive due to the nature of the chemicals, assays and equipment used. For simplicity's sake, research that generate samples for Controlled Environment (CE) storage can be split into three broad categories including:

1. Medical samples
2. Biological samples
3. Plant, environmental and engineering samples.

Medical samples may be collected as a part of baseline or longitudinal human health studies, clinical trials, cancer or other human health research including infectious and lifestyle diseases. In some instances, these studies will involve the use of animals and involve the storage of primary tissue samples (human and animal), DNA, RNA, blood, urine and other samples.

Biological samples are mostly derived from non-human subjects in relation to the fields of biochemistry, cell biology, virology, bacteriology (infection and immunity) animal parasitology, and microbiology.

Plant, environmental and engineering samples are in general terms easier to obtain and may relate to a broad selection of research topics ranging to marine, estuarine and freshwater ecology and environmental biology wheat and barley breeding, grain quality, potato production and supply, molecular plant pathology, transgenic plants, gene discovery and functional genomics

## Limits to Sample Value (Courtesy of Unimutual 2020)

The total value of the combined grant/funding of a research project provides a strong indication of the likely cost of the samples generated. A rough indication of the costs expended on the generation of samples is in the order of 65% of the total grant funding.

Grant funding may involve contributions from a funding body such as the Australian Research Council (ARC) or the National Medical Health Research Council (NMHRC) and from corporate or philanthropic sources or funds contributed by the university. A research project will incorporate a range of costs and overheads including:

- Administrative costs
- Supplies and consumables
- Sample purchases and transport costs
- Staff costs
- Cost of animals
- Field research and travel costs
- Sample preparation and analysis
- Lab space and equipment costs
- Teaching relief costs
- Paper preparation

## Administration Costs (Courtesy of Unimutual 2020)

Research projects incur administration costs at each stage of their life cycle; from grant funding submissions, establishing and discharging any contractual obligations, various research integrity requirements (ethics, governance and compliance), recording results and publishing research findings and papers. In some cases, there may be costs associated with obtaining permits from government bodies, landowners, traditional owners, councils and land councils.

## Insurable Value (Courtesy of Unimutual 2020)

Whilst research projects have an intrinsic or broader "moral value or good", they are made up of elements, each of which has a cost associated with it, therefore, a monetary value can reasonably be assigned. This is supported by the fact the all research is funded from one source or another be that grants from the ARC, NMHRC, other government body, the university, philanthropic sources or by industry.

Ideally, grant applications document the detailed cost of each element that constitute grant funds applied for. Should research samples associated with a research project be damaged, spoilt or lost, in most cases, these can be replaced. Replacement will incur administration costs, consumable costs and researcher/staff time and effort. Each of these elements can be quantified and represent the "insurable value" of the research.

## Sample Value Over Time (Courtesy of Unimutual 2020)

Unlike real estate, the value of research samples does not necessarily increase in monetary value over time other than for consumer price index increases for wages and consumable items, should they need to be recreated; that is not to say that they may not become more intrinsically valuable for research purposes.

The value of research samples, after they have been analysed and the research paper has been written is, in some respects, a vexed issue. In general terms, they will have little value if kept for records purposes only, however instances where they will become "more intrinsically valuable" over time may include:

- Where the samples can be either analysed further or are crucial as part of another research project
- Historic samples are part of a base line or longitudinal study, or
- Part of a remote community health study; or
- New analysis techniques mean that further and better data can be extracted from primary or secondary (laboratory or test samples).

Whilst such samples may have an increased intrinsic value on the basis that they may not be able to be collected or created again, do they have an insurable value? Most probably not unless they can be replaced.

## Irreplaceable Samples (Courtesy of Unimutual 2020)

As mentioned in the previous section, not all samples can be replaced, particularly those taken from donors as part of a baseline or longitudinal study which commenced 20 years ago, and the sample donor is no longer alive. Some samples may be unique and there is only one in existence. These samples may be considered invaluable or priceless and, in some instances, may not be insurable. Take for example, the Mona Lisa, it is considered priceless and is not insured.

Notwithstanding this, unique or priceless samples should at least be given a nominal value that reflects their uniqueness or criticality and can help to justify risk mitigation measures necessary to ensure their protection.

## Valuing A Research Project – Overview (Courtesy of Unimutual 2020)

In general terms, research projects costs are detailed in a research grant proposal or submission. Recording in detail, the steps and costs associated with each element of the project, assists to more clearly identify the costs associated with those steps and ultimately, the creation of samples. Further, should research be lost, it facilitates a better understanding of the cost of sample recreation.

A detailed costing calculator is provided in [Appendix 1](#). It is designed to assist the user to identify and cost all the elements of a research project which contribute to sample creation which include:

- Administrative costs
- Supplies and consumables
- Sample purchases and transport costs
- Staff costs
- Cost of animals
- Field research and travel costs
- Sample preparation and analysis
- Lab space and equipment costs

## Valuing A Research Project – The 65% Method (Courtesy of Unimutual 2020)

A method for “estimating” the cost of samples generated by a project is known as the **65% rule**. Put simply, the cost of producing samples is approximately 65% of the total cost of a research grant, the other 35% being consumed by administrative, compliance and paper writing costs.

The formula is:

$$\text{\$value of grant} \times 0.65 = \text{\$value of samples}$$

## Valuing A Research Project – The Time & Consumables Method (Courtesy of Unimutual 2020)

A further “estimating” method is the **time and consumables method**. In broad terms, it involves the lead researcher estimating the amount of time (in years or months) to re-establish lost samples based on the wages costs of research assistants to undertake the required work and the cost of any consumables.

The formula is:

Number of Research Assistants x \$ cost per annum + \$ value of consumables = Cost to re-establish samples.

## Valuing Research Animals – Overview (Courtesy of Unimutual 2020)

Animals are an important part of the research puzzle, used primarily for medical research purposes but also for the study of populations and preservation of species diversity. Research animals may include, but not be limited to rats and mice, rabbits and guinea pigs, lizards, fish and other marine organisms. Valuation of primates has not been included in this guideline.

The elements to consider when valuing animals include the costs associated with:

- Amortised cost of construction or per metre floor space rental,
- Purchasing or collecting animals,
- Treatments or interventions,
- Food, bedding and general agistment,
- Staff and husbandry,
- Researcher time,
- Laboratory and storage costs.

## Valuing Research Animals – Rats & Mice (Courtesy of Unimutual 2020)

The term transgenic animal refers to an animal in which there has been a deliberate modification of the genome, the material responsible for inherited characteristics as opposed to spontaneous mutation. Transgenic rats and mice may have a range of human or non-human genes (DNA) inserted into their genome.

Pro-nuclear DNA microinjection is the oldest and most common method for mammalian transgenic creation. A solution of the transgene is injected into fertilized eggs with a micro syringe under a microscope. These microinjected eggs are then transplanted in a surrogate mother. At birth the newborn are tested for the transgene detection. After these tests, the positive animals (founders) are crossed to obtain the F1 and F2 generations (transgenic rat line).

Rats and mice are kept in purpose-built controlled environments or to a lesser extent, in locations which have been repurposed. The elements of the environments which are controlled include temperature, humidity and light cycles. Husbandry aspects of managing rats and mice involve feeding and watering, changing bedding and cleaning and monitoring environmental conditions and the equipment which controls those conditions.

## Valuing Research Animals – Lizards (Courtesy of Unimutual 2020)

Lizards and snakes are used for a range of environmental based research projects from the impacts of climate change to behavioural and evolutionary ecology. Lizards and snakes are kept in terrariums under controlled temperature, light and humidity conditions with temperature being one of the most important environmental controls. Husbandry aspects of managing lizards involve feeding and watering, periodic terrarium cleaning and monitoring of environmental conditions and the equipment which controls those conditions.

In general terms, lizards and snakes are relatively expensive to maintain and breed because individuals require larger areas than rats, mice or fish.

## Valuing Research Animals – Fish (Courtesy of Unimutual 2020)

Fish and marine organisms are commonly used for a range of medical, environmental, biological and ecological studies. The zebrafish is an important and widely used vertebrate model organism in scientific research, for example in drug development. They are also notable for their regenerative abilities and have been modified by researchers to produce many transgenic strains. They are generally hardy but can be susceptible to significant changes in water temperature and quality. Large numbers of fish can be kept in a single tank.

Native fish are more often used for ecological research, breeding and repopulation purposes. Many native freshwater fish are already considered extinct, endangered or seriously threatened with over 50% of freshwater species considered “under threat”. Research efforts are focussed on identifying genetic characteristics, reproductive cycle enablers and captive breeding. Due to small numbers of “wild” populations and difficulties associated with breeding, native fish tend to be more valuable “per head” in a research or captive breeding environment.

The key environmental controls for fish include water temperature, oxygen content and water quality. Equipment which maintain environmental controls include, pumps, heaters, filters and aerators.

## APPENDIX 1 - Research Project Cost Calculator - Administration Costs (Courtesy of Unimutual 2020)

Section 1 – Administration Costs				
Item	Comments/Observation	Units/Hours	Rate \$	Value/Cost \$
Preparation of a grant funding proposal	Proposition, outcomes, methods and costs			
Obtaining required permits	May involve permits to enter enclosed or restricted lands or permits to import certain products goods and products			
Contractual matters	Must contracts or agreements be prepared			
Ethics and governance submissions	Submissions to human and animal research ethics and governance committees involve researcher time to prepare			
Are there costs involved with securing financial or political support for grant funding?	Reports, submissions, meetings and interviews			
Research compliance requirements	Must compliance reports or submission be prepared			
Documenting results	Time to document results			
Preparing the research paper	Time to prepare a peer reviewed paper			
<b>Cost</b>			<b>\$</b>	

## Research Project Cost Calculator – Items to be Purchased (Courtesy of Unimutual 2020)

Section 2 - Items to be Purchased				
Item	Details	Units/Hours	Rate \$	Value/Cost \$
What reagents and other chemicals are required <ul style="list-style-type: none"> <li>• Reagents</li> <li>• Chemicals</li> <li>• Buffers</li> <li>• Enzymes</li> <li>• Assays</li> </ul>	Type and Volumes - - -			
What supplies, consumables or specialised equipment will need to be purchased in order to collect or analysis samples or specimens? These may include but not be limited to items such as collection jars, vials, pipettes, etc	List - - - -			
Can samples be purchased from another researcher or supplier? For example, specific knock out mice, specialised cell lines or other items	Sample type and Number/Volume - - -			
Is there a cost for the purchase of a specific licence for quarantine purposes or use of GMOs or for other reasons?	Type of licence required			
Are the transport costs for purchased samples?	Local, National, International Shipping			
<b>Cost</b>			<b>\$</b>	



## Research Project Cost Calculator – Items to be Made (Courtesy of Unimutual 2020)

Section 3 - Items to be Made				
Item	Comments/Observation/	Units/Hours	Rate	Value/Cost \$
What items need to be specifically made to undertake the research – such as plasmas, organisms, compounds, other items	Item and Volume or Number - - -			
Are there any other specific costs associated with importing or transporting materials or equipment to make samples?				
<b>Cost</b>			<b>\$</b>	

## Research Project Cost Calculator – Animals to be Bred (Courtesy of Unimutual 2020)

Section 4 - Animals to be bred				
Item	Comments/Observation/	Units/Hours	Rate	Value/Cost \$
Will animals need to be purchased or bred to create a specific gene characteristic for the research?	Type of animal and number of animals - - -			
Are there quarantine costs involved?	Describe			
Are there costs associated with additional housing requirements or modifications?	Explain the nature of the modifications or additional costs - -			
<b>Cost</b>			<b>\$</b>	

## Research Project Cost Calculator – Sample Collection / Fieldwork (Courtesy of Unimutual 2020)

Section 5 - Sample collection or Field Work				
Item	Comments/Observation/	Units/Hours	Rate	Value/Cost \$
What are the transport costs associated with gaining access to access field locations?	Airline tickets			
	Hire Cars			
	Fuel costs			
	Camping/Equipment Hire			
	Provision of meals			
	Specialised equipment			
	Research or transport vessel			
What staff costs will be incurred to collect samples in the field?	Number of junior staff			
	Number of senior staff			
	Students			
Are there any outsourcing costs to collect samples?	Contractor or third-party costs			
<b>Cost</b>			<b>\$</b>	

## Research Project Cost Calculator – Preparation and Analysis of Samples (Courtesy of Unimutual 2020)

Section 6 - Preparation and Analysis of Samples				
Item	Comments/Observation/	Units/Hours	Rate	Value/Cost \$
How many staff hours are required to prepare samples?	Number of staff			
	Hours per staff member			
How many staff hours are required to analyse the samples?	Number of staff			
	Hours per staff member			
Are there any outsourcing costs associated with preparing samples?	Describe:			
Are there any additional laboratory equipment purchases associated with preparing or analysing the samples?	Describe:			
Are there any additional hiring, leasing or usage fees associated with preparing or analysing the samples?	Describe:			
Are there any other costs associated with preparing or analysing samples?	Describe:			
<b>Cost</b>			<b>\$</b>	

**Research Project Cost Calculator – Summary Table** (Courtesy of Unimutual 2020)

Section 1	Administration Costs	\$
Section 2	Items to be Purchased	\$
Section 3	Items to be Made	\$
Section 4	Animals to be Bred	\$
Section 5	Sample Collection / Fieldwork	\$
Section 6	Preparation and Analysis of Samples	\$
	<b>Grand Total</b>	<b>\$</b>