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GUIDELINES FOR RISK TO BENEFIT RATIO CALCULATIONS

PREAMBLE:

It is accepted that all research, because it ventures into the unknown and pursues knowledge that may not as yet exist, contains an element of risk. The size, complexity, location and consequences of that risk need to be considered, for two fundamental reasons.

- Firstly, it can be safely assumed that, should the risk of the research far outweigh the benefits of such new knowledge, then it is not worth taking the risk.
- Secondly, if the benefits outweigh the potential risks, then it seems logical that one might want to curtail, reduce and contain the risk (in other words to control and minimize the risk factors in the research process).¹

The purpose, therefore, of this document is to offer an engagement with the risk-to-benefit ratios that research needs to consider, and which Research Ethics Committees will bring to bear in assessing the research ethical acceptability of the research that is to be undertaken. *In other words, these are guidelines to assist in the deliberations around risk-benefit ratios in research.*

One is reminded that research (or data collection and interpretation) will include the following domains (and therefore will contain the possibility of risk):

1. **Ideas** - and these would be found in texts, for example, and therefore the risk lies in duplicating other people's ideas without acknowledging the origins of the ideas but claiming the ideas as one's own – this is the domain of plagiarism and will not be addressed further.
2. **Humans** - Much of what follows will speak to this domain.
3. **Animals** - With Vaal University of Technology, any animal research specifically will have its research ethics considerations outsourced to registered Animal Research Ethics Committees. However, the one domain where animals might indeed come into play is where the environment in which the animals live is disturbed by the research. Here, the animals are not directly involved in data-gathering but are caught up in the data-gathering process.²
4. **The environment** - and this will include both the environment that is the subject of the research, as well as the environment in which the research is to be undertaken.

¹ In Animal Research, researchers speak of the 3Rs: *Reduce*, *Refine* the project, and, where possible, *replace* to avoid the risk. Animal Research does not use the term 'risk' but refers to 'harm' to the animals.

² It should also be noted that, except under unusual circumstances, standard Clinical Trials will also be outsourced.

FOUR GOLDEN RULES:

1. The benefit of the outcomes of the research **must** outweigh the risks that will be encountered in the research.
2. The risks **must be clearly identified and described** in the research proposal and accompanying documentation.
3. The benefits **must be clearly identified and described** in the research proposal and accompanying documentation.
4. In all cases, **the attempt to control and mitigate the risk** must be described in the research proposal and accompanying documentation.

DETERMINING RISK

Note - In all that follows on “risk,” it must be assumed that reference is being made to “risk in a research endeavour”. Therefore, the reader is asked to read “risk” in this way, unless otherwise declared.

It is perhaps useful to determine what constitutes no risk in research and then proceed from there.

No Risk - A no risk situation from a research point of view is where no research is taking place! This automatically assumes a clear definition and understanding of what constitutes a ‘research endeavour’ - this will not be defined here, and is taken as understood. As soon as a research endeavour enters the frame, risk becomes a factor.

Given this rather simplistic definition one can now conceive of risk on a continuum from the moment where there is no research taking place (in other words, the world carries on as usual) all the way along the continuum until there are world shattering, death inducing, cataclysmic effects on the world brought about by the research intervention. This is a long continuum and any research will position itself somewhere on that continuum. Thus, the critical analysis of poetry, for example, would be at the one extreme end of the continuum (very close to the “no research” beginning) and nuclear fusion, or anthrax bio-warfare, for example, might be at the other end.

Domains for risk

What follows are a number of domains where risk in research might be located. The list is by no means exhaustive. As one moves through each item on the list, it is worth remembering that notion of the continuum. At the end of the discussion of the domains a possible table for demarcating the extent of the risk is presented.

Risk - The “rules of thumb” defining risk might be the following:

- To what extent is the research **invasive** of a domain?
- To what extent is the research making that which is in the domain **vulnerable**?

The Physical (Human): this domain refers to where the data that is to be accessed is to be found in the human body as a physical or biological entity. Thus, if the data is to be extracted from what the body is, how it functions, what it does, how effectively it does it, or how this efficacy can be improved or protected, for example, one is in the domain of the physical and 'risks to life and limb' need to be considered, and actions taken to get permission to undertake the data extraction and to ameliorate the potential risk.

Working from the notion of the continuum, on the one side one might consider research that deals with automotive responses in the research about the difficulties of picking up tiddly-winks with the index and middle fingers, to the opposite end of running someone on a treadmill until they pass out, or submerging them in ice baths to determine the limits of conscious control over hyperthermia.

The Emotional and Psychological: - The two are difficult to separate but a separation might be clearer for specialists. Here the data lies in a person's feelings, opinions on, responses to and personal history (memories) of events or occurrences. Engaging in research that might trigger emotional responses or psychological reactions in participants needs careful control and response, particularly because such responses and the intensities of such responses are often difficult but not impossible to predict. (Literature does give guidance on this, however).

On the continuum of risk this might be a sense of melancholy based on a triggered memory, but it might also produce outburst of anger, despair or horror and may be seen as an attack on dignity and self-worth. At the other end of the continuum, one might find suicidal or revenge tendencies, or full-blown psychotic reactions. Thus, it becomes vital to determine the potential for such reactions and plan to mitigate, control or recover from such reactions.

The Economic (personal): In this situation the data lies in a person (or people) by virtue of the work that they do, and where and how they are employed. It is important to realise, therefore, that there is a relationship between the person and the place of work and therefore that relationship needs to be protected. In short, losing their employment by sharing data is a massive risk that needs control.

On the continuum for consideration, therefore, one end might suggest simply talking about the comfort of the working conditions (for example, noting that revelations of safety aberrations are riskier), but might range all the way across to revelations of international espionage or sabotage, that could lead to imprisonment or worse.

It should be noted that there are aspects that the law does not allow the researcher to pursue, and there are areas where the law demands that revelation of certain types of data must be reported to the police. It is important to determine these areas. It should also be noted that the Autonomy principle acknowledges the right of the employee not to be pressured by employers in any way. However, the employer also has rights, as outlined in the next section.

The Economic (business): In this situation, the data lies in the workings of a company/industry/ institution. This may vary, for example, across Human Resource management, supply chain management, working conditions, entrepreneurial enterprises, advertising and so forth. There are a number of key issues involved here: Preserving

competitive advantage, trade secret development, labour practices, customer engagement, leadership approaches and the like. Critically, therefore, a company must be made aware of the potential risks involved in sharing data with the researcher so that the company can make a calculated decision to supply the data or not. The risk might be minimal (for example, revealing the type of ergonomic office furniture that the company has found improves productivity), but it might also lead to prosecution, labour action, the company collapsing by losing competitive advantage, and so on, if the data is revealed. Care must therefore be taken by the researcher to identify such possible (or probable) risks, to alert the business to these risks, and to present ways of controlling the risk (or protecting the company).

Once again, the researcher needs to be aware of what he or she is compelled to report to the law, if discovered during the course of the research.

Furthermore, the researcher needs also to be aware that the information or data being provided might come from individuals within the company, and that, therefore, such individuals need also to be protected.

The Cultural: this particular area of risk is extremely wide. In very simplistic terms, and perhaps only to open up the areas of concern, a culture may be seen to contain the following dynamics:

- A group of people who *do things* in similar ways
- A group of people who *understand things* in the world in similar ways, and
- A group of people who *believe things* in similar ways, and accept things as being right or wrong, good or bad, positive or negative and so on, in similar ways (in other words, have a shared value system).

In short - a culture is a group of a people whose *actions, epistemologies and values* are shared by the people in the group. These may be different from the researcher's but they belong to the community and so the community and members of the community need to be treated with respect, not undermined, and the dignity of the community needs to be protected. One example of this is the "chain of command" in the community.

This definition of culture and cultural practices is wide enough to encompass all groups who share in this way. Although the definitions of culture are most often applied to an ethnic community, it might also apply to the culture of a university, for example, or a business, a football club, a political party, an academic discipline, the law, and so on. Therefore, it is important, before embarking on the research or data gathering process, for the researcher to have a clear idea of the shared actions, epistemologies and values of the particular community from whom data is to be gathered, and accepted protocols need to be put in place. (This understanding is very often captured in the proposal in the Literature Review section of the proposal).

Intellectual Property: One of the cornerstones of academic and research integrity is to give credit where credit is due, or, put another way, to acknowledge and protect the property of others. The section, below, that deals with the environment, will engage with physical property, but in this section the ownership of ideas, beliefs, creative work, solutions to

problems, and so forth needs to be protected and acknowledged (and paid for, where this is appropriate). The idea of plagiarism has already been raised, above, where data is collected from text-based sources, but where the data is collected from people, processes, businesses, companies and the like, this needs to be engaged with.

One of the risks is to determine what is in the public domain already (or in general use), and what is particular to a community, person or culture. Seen in this way, then, the risk consideration begins to overlap with what has been engaged with under peoples, cultures, economics and businesses, above.

A second type of risk when dealing with Intellectual Property (IP) is determined by the (financial or other) support provided to the research. Thus, for example, in most cases any IP that might emerge from research where the researcher is supported by (including being employed by, or registered at) a university (or firm, or company, for example) belongs to that supporting organisation. As such, the risk that might arise from the research is also carried by that supporting institution³.

Thus, in this domain one is considering the risk of loss of potential income through IP exploitation, but one is also considering the potential risks involved in carrying out the research, itself. Seen in this way, the risk of loss of IP might be minimal (in the cases of art work, for example, this is the situation) but in the case of loss of IP from major patents, or cures for world disease, climate change revolution or warfare development the risk of confidentiality breaches are massive and therefore the potential loss to the supporting institution is equally problematic.

Indigenous Knowledge Systems (IKS): Given South Africa's and Africa's history of exploitation, asset stripping, and challenges to ways of doing things and understanding the world, researchers need to be particularly careful of the risks involved in gathering data for research where the research might lead to the exploitation (again) of the indigenous community that provided the data. IKS can therefore be seen as a combination of cultural concerns (design and music influences, for example), IP concerns (the case of the *Hoodia Gordonii* plant is a case in point, but the current investigation of traditional medicine into the combatting of the Corona Virus is another), and the rights of the individual and (a particular, exploited or previously disadvantaged) community (relocations, ethnic cleansing and the like).

Risks here might range from a mild undermining of dignity but might proceed to the entire annihilation or exploitation of the community (the Tuskegee experiment is a case in point). In a number of cases in Africa medical trials have been carried out on communities by exploiting IKS systems of power at play in that community (for example, if the chief says we must take this, then we must take this). In this latter case the researcher is caught between the universal rights of each individual to decide to take part in the research, and the IKS right of community and culture to practice their own cultural rights.

³ This is the reason why most institutions that carry out research have Research Ethics Committees or Institutional Review Boards. These committees assess the risk to the institution that is supporting the research. It is also the reason why such institutions have Insurance policies.

The Educational: In research that engages with formal education practices there are a number of areas that need consideration. Overarchingly it must be accepted that, by law, no person under the age of 18 may give consent to engage in research – permission from legal guardians is required.⁴

The first area of concern is around *possible coercion by the teacher or lecturer* (made more troubling if this is the researcher himself or herself) to take part in the research⁵. This might occur through mark manipulation, failing students, disciplinary action and so forth. The key here is to accept that human rights apply to the student or pupil as well, even if they do not have the right to give consent, they have the right to refuse contribution without potential repercussions. A second area is around *the effect that contribution might have on their educational pathways*. Thus, for example, if a new approach is being tested, and the end result is a failure, the student or pupil has the right to be brought up to the same level as those who did not go through the new approach. A third area of risk resonates with the *notions of the physical, the emotional/psychological and cultural*, as outlined above, and should be considered. A fourth area is where the research with pupils and students might make the teachers or lecturers (or the institution) vulnerable. Here a difference needs to be made between gathering data for research purposes and gathering data as part of quality assurance.

The domains of risk in the educational world are great, yet research in this domain is vital. Critically, the “risk continuum” outlined above can be extremely useful in determining the mitigating and controlling factors that need to be in place when research in the education domain is undertaken.

The environment (the research is about intervening in the environment): In this approach, the environment, and potential changes to the environment, forms the central concern of the research. Here the insertion into the environment and the effects that such invasiveness might have on the environment are the very core of the research. This might consist of minimal risk matters such as driving across a field with cows grazing in it to get to a polluted stream that needs analysis, to *in situ* attempts to gauge the effect of Agent Orange or radioactive discharges on a pine plantation. The research might range from simply being in the environment for observation purposes (nightly observations of owls, for example), to massive changes to the environment through construction, mining or dumping.

In all of these cases the attempt should be made to return the environment to the same or better condition than when the research intervention took place.

The environment (the research requires an enabling environment): In this approach, the research requires an environment for the research to take place. On the risk continuum one might consider a computer laboratory at one end of the continuum (where there is very little risk beyond the normal running of the laboratory⁶) and the other end where one is engaged

⁴ Child headed households present a very particular dilemma that will not be engaged with here.

⁵ There is a burgeoning branch of research known as SOTL or the Scholarship Of Teaching and Learning. SOTL provides particular risks in the domains of education.

⁶ Here one is talking about the operations of the laboratory, and not the type of research that requires the computer facilities. Thus, accessing the “dark web” or manipulating the stock exchange would be risky, but

with nuclear fission/fusion laboratories, chemical and biological warfare development or different types of accelerators, for example.

In all of these cases it is expected that each enabling environment will have sets of Standard Operating Procedures (SOPs) for the environment to safely offer the enabling that is required. A declaration of knowledge of these SOPs becomes necessary to avoid the risk or the potential for Serious Adverse Events to occur. It needs also to be borne in mind that adherence to the SOPs not only reduces the risk factor and enhances, therefore, the safety of working in the enabling environment, but it also enhances the trustworthiness of the data that comes from the research – it can be seen as the equivalent of following the correct research method and design.

The researcher team: Much literature is devoted to determining risk to those domains that provide the data for the research, seldom is there any attention actually paid to those that gather the data – the researchers, the research assistants, the laboratory assistants, the collators, and so on. Much of this is covered, in particular environments, by SOPs, in terms of the use of PPEs, following predetermined procedures, adhering to standardised methods and designs, and so forth, but particularly in research that gathers data from humans (and animals) such risks to the researchers are seldom considered.

Although there is no formal reason for including this risk assessment in the various documents, it is an important set of considerations. Such risks to the research team might range from emotional and psychological trauma, through physical danger (including threats, attacks, transport, exhaustion and the like), and might include having to engage with the law in the reporting of criminal activity. Preparation for, and protection against, such possible eventualities is important.

(One area that has created some interest here is where an autoethnographic methodology is employed because, in this case, the researcher and the researched are one and the same person.)

A RISK-CHARTING TABLE

The table below summarises what has gone before and is offered as a method to determine the level or severity of risk involved in the data collection. ***It must be remembered the primary concern is determining the risk to that which (or who) is to provide the data or the sources of the data.***

In what follows one of the cardinal concerns will be around the amount of effort that will be required to control the possible effects of the risk.

The other cardinal concern will deal with the potential benefits.

would not fall under this particular ‘enabling environment’ consideration, unless such work had the potential to disable the entire facility (through the spread of a virus, for example).

As such, in charting the risk on the table, there three concerns of **RISK, CONTROL** and **BENEFIT** form guiding considerations.

Definitions:

No Risk: This implies that no data is being collected beyond that which is freely available in the public domain. Fundamentally, this would include texts, social media, and databases that are available to everyone to access, free of charge. Only plagiarism matters apply. (The one grey area is around using ‘observation’ as a method of data capture – here the test would be whether that which is observed and reported on might be placed in a vulnerable position should it be clearly identified).

Minimal Risk: The VUT Research Ethics policy and the SOPs broadly define minimal risk research as research where participants would not experience more risk than they would in their normal daily activities. Driving a car or drinking hot coffee is always risky but it occurs as part of daily activities and therefore, would be seen as minimal risk.

Potent Risk: This risk can be determined by the amount of intervention that will be required to mitigate and control the risk. Basically, when the effort to control the risk is the same as the effort to carry out the research, but there is a fair amount of benefit that will accrue from the research, one is in the domain of potent risk.

Dangerous Risk: For research to fall into this category, the potential for dangerous activities is high, the control of the risk is more than the effort for the research to be carried out, and the potential benefits have to be very large and very well argued and justified.

Extreme Risk: This is where the research might lead to death, destruction of lives and property, the complete collapse of companies and institutions, wars or sectional annihilation. To get to this stage, the benefit of the research that produces this level of risk must also be extreme and is almost too difficult to contemplate (although the development of the atomic bomb during World War II might be an example).

DOMAIN	No risk 0	Minimal risk 1	Potent risk 2	Dangerous risk 3	Extreme risk 4
<i>Physical</i>					
<i>Emotional</i> <i>Psychological</i>					
<i>Economic/</i> <i>Personal</i>					
<i>Economic/</i> <i>Business</i>					
<i>Cultural</i>					
<i>Intellectual</i>					

Property					
IKS					
Education					
Environment/ Laboratory					
Environment/ In Situ					
Researcher team					

BENEFIT AND BENEFICIATION

Having established the potential risks that the research (that is to say the gathering and interpreting of data) might hold, and then beginning to plan how to mitigate or control the risks, it becomes necessary to turn to whether the research endeavour will in fact be worth the effort. We turn now to consider matters of Benefit and Beneficiation, as research that does not achieve any benefit at all is a waste of time and resources and therefore unethical.

It is important to state at the beginning of this section that determining benefit falls into two basic categories: benefits of the research and benefits to the data-providers.

Benefits of the Research. On the one hand one has a determination of how society, the world, the discipline, industry, science and so forth will benefit from the findings of the research. In other words, to what extent does the successful completion of the research project, with the conclusions it reaches, be of some benefit to others besides the researcher, who might achieve a qualification, promotion or appointment following the research, but there will be no other benefit. (This does not include the ‘data sharers’ who are in the midst of the research project - these will be dealt with in the next section). This is often difficult to determine, especially when one is dealing with so-called “blue sky” research, or foundational or fundamental research where basic principles are being set or established (or discovered). In most cases the benefits here will be clear to the subject specialists, who will determine the potential “use value” of the conclusions. Nevertheless, such a benefit must at least be effectively speculated upon.

Of course, different disciplines will engage in different types of research beneficiation. As such, it is perhaps useful to revisit the Risk table, above, to determine at least the domains in which the beneficiation might take place. However, such a table does allow one to attempt to speculate on the ‘size and complexity’ of the benefits that might/must accrue from the research. Thus, one can begin to see the correlation between the potential risk and the potential benefit. Again, working on a sliding scale or benefit continuum of “no benefit” on the one hand - a situation not acceptable for research but that might be acceptable to data-providers - to “massive, earth-shattering and discipline revolutionary benefit (paradigm changing, for example)” one can begin to grasp that, if the risk is at level 2, for example, the benefit needs to be far beyond that.

As one engages with the benefits of the research one notices that the justification for the research project itself, often to be found in the proposal under the section usually called “*Background and Rationale/Motivation*”, will need to convince of the benefits of the project. In this one might encounter three types of benefits:

- **Promised benefits:** these are speculative in nature but suggest that, should the research work, then such-and-such will be the benefits. Exploratory research for example, might suggest promised benefits.
- **Actual benefits:** These are where the problem is clearly defined and the solution to the problem, which will arise from the research, is clearly indicated.
- **Quality benefits:** In this case the benefits are to be found in the refinement and improvement of what already exists.

Benefits accruing to the “data-providers”: It is inevitable that those who do something for the researcher might require something in return. In the case of the human aspect this is obvious, but in the case of the ‘non-human’ this is less obvious. In this latter case, perhaps the key concern is that at least any changes to the non-human situation are beneficial to the situation, ranging from restorative processes (returning the environment at least to its original condition) to improvements in that environment (the combatting of erosion, for example). The rest of this section on data-providers will be devoted to the human condition.

The fundamental position is to determine what might make it “worth their while” to be part of the research. Put another way, are they convinced that the benefits that might accrue from participation in the research outweigh the potential risks (coupled with the control over invasiveness and vulnerability). In this one can see the importance of the Information Leaflet that leads to the Informed Consent documents. Thus, participants need to weigh up risk, benefit, and protection.

Such benefits are also wide. Perhaps it is important to start with what may NOT be used for benefits. This is where the participant is paid directly, financially, for the data. In other words, a data-for-money exchange is not acceptable. With that out of the way, beneficence may range from a sense of altruism (a feel good factor for contributing in some small way to the enhancement of knowledge) but might include benefits that are connected to the research (receiving a copy of the report so that the findings can be implemented in the company, for example, free medical or dental consultations, a basket of the first products that come from the research), but they might also be of another nature: a T-shirt or cap, for example, and so on. What is important is that, should the participant in any way be out of pocket because of the participation, such refunding is allowable. Often beneficence includes a meal or a gift basket or food voucher, if these are appropriate. (Two interesting ones have been a parcel of PPEs for waste pickers, and an invitation as guests of honour to the opening of an exhibition of art work based on the data provided by the participants).

One needs to see this type of beneficence as a way of expressing gratitude for the contributions made, and not necessarily as an incentivisation to take part. It is accepted that the two concepts are occasionally difficult to separate. Nevertheless, one can begin to realise that the greater the risk, the greater the beneficence might need to be.

In summary one might ask the following questions as ways of determining whether beneficitation has taken place, or should take place, and in what way. The questions are applicable both for research beneficitation as well as data-provider beneficitation. The questions themselves are 'self-prompting' and therefore are not expanded upon:

- **What** will benefit?
- **Who** will benefit?
- **How** will they benefit?
- **When** will they benefit?

The table below might assist in pinpointing where the benefits and the beneficitation needs to be considered, and in what ways. If course, read against the Risks table, above, only certain domains will be relevant and these are the ones that need to be considered. Nevertheless, it is worth considering all of the domains and benefits, simply to consider whether one has left anything out.

	BENEFIT	Science	Society	What	Who	How	When
DOMAIN							
Physical							
Emotional Psychological							
Economic/ Personal							
Economic/ Business							
Cultural							
Intellectual Property							
IKS							
Education							
Environment/ Laboratory							
Environment/ In Situ							
Researcher team							

CONCLUSION:

Determining the risk-to-benefit ratio is vital for research to be conducted ethically. There are two categories of determining this.

- Firstly, the greater the risk, the more society needs potentially to benefit from the research.
- Secondly, the greater the risk, the more the data-providers need to benefit from taking part or contributing.

And in both cases, the greater the risk, the greater the contribution that needs to be made to controlling, reducing and mitigating the risk.

