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| Cbbapr2016 |

Faculty of Health Sciences Ethics Office for Research, Training and Support
[www.nwu.ac.za/healthethics](http://www.nwu.ac.za/healthethics)

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| **Estimated environmental impact Category *Version 1.01 (April 2016)*** |
| Research-related activities may have impacts on the environment – either directly or indirectly. The impacts on the environment may depend on the research-related activities as well as the specific area where the research-related activities will be conducted (i.e. wetland, protected area, world heritage site, archaeological areas) and the environmental features that may be impacted on (i.e. threatened and protected species, important animal species).Research-related activities may require the application for authorisations (permits and/or licences) for the transportation of indigenous biological resources, bioprospecting, the use of genetically modified organisms (GMO’s) and the management of collections of biological organisms, etc. It is the duty of the researcher to determine the need to apply for the necessary authorisations. It is recommended that the researcher liaise with the Legal Office of the NWU, should assistance be required.The researcher must use the process flow diagram (below) to determine the actions required based on the environmental impact category. |



Category 0-1 reviewed by the Scientific/proposal Committee and category 2-5 by a REC

**Annexure 1: Environmental impact category descriptors**

|  |  |  |
| --- | --- | --- |
| **Cate-gory** | **Description** | **Select** |
| **0** | **None****Effect on the environment:** Potential for incidental and/or transient changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** No legal implications. No need to apply for any environmental authorisations; **or****Potential impact on reputation of the NWU:** No discernible impact on reputation. | [ ]  |
| **1** | **Mild****Effect on the environment:** Potential for acceptable, short term changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** Complaints from the public and/or regulator. No need to apply for any environmental authorisations; **or****Potential impact on reputation of the NWU:** Potential impact on reputation. | [ ]  |
| **2** | **Medium****Effect on the environment:** Potential for acceptable, longer term changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** Departmental enquiry and correspondence. Environmental authorisation may be required; **or****Potential impact on reputation of the NWU:** Limited, reputation impacted with small number of people. | [ ]  |
| **3** | **Severe****Effect on the environment:** Potential for unacceptable, short term changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** Notification of intent to issue a directive. Environmental authorisation required; **or****Potential impact on reputation of the NWU:** Reputation impacted with some stakeholders. | [ ]  |
| **4** | **Very severe****Effect on the environment:** Potential for unacceptable, longer term changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** Withdrawal of permit. Environmental authorisation required; **or****Potential impact on reputation of the NWU:** Reputation impacted with significant number of key stakeholders. | [ ]  |
| **5** | **Intolerable****Effect on the environment:** Potential for irreversable changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** Referral to the National Prosecuting Authority. Potential investigation by authority with prosecution and fines. Environmental authorisation required; **or****Potential impact on reputation of the NWU:** Reputation impacted with majority of key stakeholders. | [ ]  |

**Annexure 2: Risk assessment process**

The researcher needs to complete the risk register (Table 1) to determine the raw and residual risk.

To determine risk, the risk matrix (Table 2) must be used.

**Risk = Severity x Likelihood**. The researcher shall first determine severity, and secondly determine the likelihood that the impact would occur at the determined severity.

**Table 1. Risk register for determining raw (pre-mitigated) and residual (post-mitigated) risk. (Johan Nel of Glaudine Roos 994068)**

|  |  |  |  |
| --- | --- | --- | --- |
| **HAZARD (CAUSE) AND EFFECT ANALYSIS** | **PRE-MITIGATION / RAW RISK ESTIMATION(use table 2)** | **CONTROLS (MITIGATION)** | **RESIDUAL RISK ESTIMATION(use table 2)** |
| Hazard sources that threaten people/the environment | What can cause the harm? | When and where can the event occur? | Receptor (Environment/ Researcher(s)/ other people) | What is the consequence, or effect, i.e. what happens or can happen to the receptor? | Severity | Likelihood | Raw risk estimation | List the current controls or combinations of controls that are specifically in place to control or mitigate either the severity of effects, or the likelihood of harm occurring, or both | Severity Y-axis | Likelihood | Residual risk estimation |
| **Examples** |
| Generation and management of waste | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | ?? | ?? | ?? | Click here to enter text. | ?? | ?? | ?? |
| Site access and path clearance | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | ?? | ?? | ?? | Click here to enter text. | ?? | ?? | ?? |
| Failure to obtain relevant authorisations | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | ?? | ?? | ?? | Click here to enter text. | ?? | ?? | ?? |
| Collection of biotic specimens | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | ?? | ?? | ?? | Click here to enter text. | ?? | ?? | ?? |
| Collection of abiotic samples | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | ?? | ?? | ?? | Click here to enter text. | ?? | ?? | ?? |
| Alteration to the environment | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | ?? | ?? | ?? | Click here to enter text. | ?? | ?? | ?? |

**Table 2.** **Risk matrix.**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  | **POTENTIAL IMPACT ON REPUTATION** | **EFFECT ON ENVIRONMENT (E1)** | **LEGAL IMPLICATIONS (L)** |
| **Severity** | **A** | Intolerable | Intolerable | Intolerable | Intolerable | Intolerable | Intolerable | Reputation impacted with majority of key stakeholders. | Potential for irreversable change to valuled flora and fauna, ecosystem processes and structure, including ecosystem services. | Referral to the National Prosecuting Authority. Potential investigation by authority with prosecution and fines. Environmental authorisation required. |
| **B** | ALARP | Intolerable | Intolerable | Intolerable | Intolerable | Intolerable | Reputation impacted with significant number of key stakeholders. | Potential for unacceptable, longer term change to valuled flora and fauna, ecosystem processes and structure, including ecosystem services | Withdrawal of permit. Environmental authorisation required. |
| **C** | ALARP | ALARP | Intolerable | Intolerable | Intolerable | Intolerable | Reputation impacted with some stakeholders. | Potential for unacceptable, short term change to valued flora and fauna, ecosystem processes and structure, including ecosystem services. | Notification of intent to issue a directive. Environmental authorisation required. |
| **D** | Maintain | Maintain | ALARP | ALARP | Intolerable | Intolerable | Limited, reputation impacted with small number of people. | Potential for acceptable, longer term change to valued flora and fauna, ecosystem processes and structure, including ecosystem services. | Departmental enquiry and correspondence. Environmental authorisation may be required. |
| **E** | Maintain | Maintain | Maintain | ALARP | ALARP | ALARP | Potential impact on reputation. | Potential for acceptable, short term change to valued flora and fauna, ecosystem processes and structure, including ecosystem services | Complaints for the public and/or regulator. No need to apply for any environmental authorisations |
| **F** | Maintain | Maintain | Maintain | Maintain | Maintain | Maintain | No discernible impact on reputation. | Potential for incidental and/or transient changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services. | No legal implications. No need to apply for any environmental authorisations. |
|  |   | **G** | **H** | **I** | **J** | **K** | **L** |  |  |  |
|  | **Likelihood** | **Colour** | **Descriptor** | **Action** |
|  |  | Highly unlikely | Rare | Unlikely | Possible | Likely | Regular |   | Intolerable | Immediate action |
|  |   | ALARP (as low as reasonably practicable) | Heightened action |
|  |   | Maintain | Ensure levels of control |
|  |  | <0,1% | 0.1-4% | 5-14% | 15-49% | 50-74% | Almost Certain |  |  |  |
|  | Descriptor | Practically impossible, not foreseen to occur | Conceivable under exceptional circumstances | Only remotely possible (has happened somewhere) | Unusual but possible (can happen) | Quite possible  | Is it very likely and expected to happen (has and foresee it to happen again) |  |  |  |

**Annexure 3: Environmental management plan (example)**

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| **Environmental management plan** |
| **Objectives** | **Targets** | **What needs to be done? (Tasks)** | **Who is responsible to do it?** | **Completion date and schedule** | **Resources** |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Completion date: Click here to enter a date.Schedule: Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Completion date: Click here to enter a date.Schedule: Click here to enter text. | Click here to enter text. |
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| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Completion date: Click here to enter a date.Schedule: Click here to enter text. | Click here to enter text. |

**Annexure 4: Guidance for determining the need to apply for an environmental authorisation(s)**

| **Does your survey/sampling/research include one of the following:** |
| --- |
|  | **Yes/No** |  | **Yes/No** |
| **Transportation of indigenous biological resources** | Choose | **If so, is/are the following in place:** | Choose |
| **Bio-prospecting permit and/or an export permit if the sample is exported outside of South Africa?** |
| **Description:*** When used in relation to bio-prospecting, the term indigenous biological resources means any living or dead animal, plant or other organism of an indigenous species; any derivative of such an animal, plant or other organism; or any genetic material of such an animal, plant or other organism, whether gathered from the wild or accessed from any other source, including any animals, plants or other organisms of an indigenous species cultivated, bred or kept in captivity or cultivated or altered in any way by means of biotechnology; any cultivar, variety, strain, derivative, hybrid or fertile version of any indigenous species or of any animals, plants or other organisms; and any exotic animals, plants or other organisms, whether gathered from the wild or accessed from any other source which, through the use of biotechnology, have been altered with any genetic material or chemical compound found in any indigenous species or any animals, plants or other organisms; but excluding genetic material of human origin; any exotic animals, plants or other organisms, other than exotic animals, plants or other organisms; and indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture; or,
* when used in relation to any other matter, the term means any resource consisting of any living or dead animal, plant or other organism of an indigenous species; any derivative of such an animal, plant or other organism; or any genetic material of such animal, plant or other organism
 | **Description:** The National Environmental Management: Biodiversity Act (NEM:BA) (10 of 2004), requires that * no person may, without a (bio-prospecting/export) permit issued in terms of Chapter 7 of the NEM:BA, transport or export from the Republic any indigenous biological resources for the purpose of bio-prospecting or any other kind of research;
* indigenous biological resources may be exported for a research purpose other than bio-prospecting only with an export permit;
* if a stakeholder (a person, including any organ of state or community providing or giving access to the indigenous biological resources to which the application relates) has an interest, an issuing authority may issue a permit only if the applicant and the stakeholder have entered into a material transfer agreement that regulates the provision of or access to such resources;
* if the applicant for a bio-prospecting permit intends exporting the indigenous biological resources to which the application relates, the applicant must apply for an integrated export and bio-prospecting permit
 |

| **Does your survey/sampling/research include one of the following:** |
| --- |
|  | **Yes/No** |  | **Yes/No** |
| **Bio-prospecting** | Choose | **If so, is/are the following in place:** | Choose |
| **Bio-prospecting/export permit?** |
| **Description:**In relation to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes—(a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application;(b) the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities; or(c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation | **Description:** Collecting specimens are regulated in terms of the legal requirements for bio-prospecting in the National Environmental Management: Biodiversity Act (NEM:BA) (10 of 2004), which regulates the systematic search, collection or gathering of indigenous biological resources (see the definition above) or the making of extractions from such resources for the purposes of research, development or application; the utilisation of any information regarding any traditional uses of indigenous biological resources by indigenous communities for the purposes of such research or development; or research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation.The Regulations on Bio-prospecting, Access and Benefit-Sharing (GN R 138 in GG 30739 of 8 February 2008) further define “any other kind of research" as research other than bio-prospecting that includes the systematic collection, study or investigation of indigenous biological resources, conducted under the auspices of a bona fide research institute or organisation to generate scientific knowledge; but excluding incidental surveys and searches. |
| **Using Genetically Modified Material (GMO)** | Choose | **If so, is/are the following in place:** | Choose |
| **Permit and environmental authorisation?** |
| **Description:** Permit in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997).EA in terms of Chapter 5 of the National Environmental Management Act.GNR 506: NEMBA No 10 of 2004. Alien and Invasive Species Regulations (Including Risk Assessment) |

| **Does your survey/sampling/research include one of the following:** |
| --- |
|  | **Yes/No** |  | **Yes/No** |
| **Management of collections of biological organisms** | Choose | **If so, is/are the following in place:** | Choose |
| **Bio-prospecting/export permit?** |
| **Description:** Collections are regulated in terms of the legal requirements for bio-prospecting in the National Environmental Management: Biodiversity Act (NEM:BA) (10 of 2004), which regulates the systematic search, collection or gathering of indigenous biological resources (see the definition above) or the making of extractions from such resources for the purposes of research, development or application; the utilisation of any information regarding any traditional uses of indigenous biological resources by indigenous communities for the purposes of such research or development; or research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation.The Regulations on Bio-prospecting, Access and Benefit-Sharing (GN R 138 in GG 30739 of 8 February 2008) further define “any other kind of research" as research other than bio-prospecting that includes the systematic collection, study or investigation of indigenous biological resources, conducted under the auspices of a bona fide research institute or organisation to generate scientific knowledge; but excluding incidental surveys and searches. |
| **Activities involving specimens of a listed, threatened or protected species** | Choose | **If so, is/are the following in place:** | Choose |
| **Permit?** |
| **Description:**Restricted activities in relation to a specimen of a listed, threatened or protected species include: gathering, collecting or plucking any specimen of a listed, threatened or protected species; picking parts of, or cutting, chopping off, uprooting, damaging or destroying, any specimen of a listed, threatened or protected species; having in possession or exercising physical control over any specimen of a listed, threatened or protected species; growing, breeding or in any other way propagating any specimen of a listed, threatened or protected species, or causing it to multiply; conveying, moving or otherwise translocating any specimen of a listed, threatened or protected species; and selling or otherwise trading in, buying, receiving, giving, donating or accepting as a gift, or in any way acquiring or disposing of any specimen of a listed, threatened or protected species.TOPS Regulations: GNR 389 of 2013 | **Description:** The National Environmental Management: Biodiversity Act (NEM:BA) (10 of 2004) requires that a person may not carry out a restricted activity involving a specimen of a listed, threatened or protected species without a permit issued in terms of Chapter 7 |

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