**School of Natural Sciences (SNS) Research Ethics Policy**

**School of Natural Sciences, Trinity College Dublin**

In line with Trinity College Dublin’s Policy on Good Research Practice, all research in the School of Natural Sciences (SNS) should be conducted according to the overarching ethical principles of “respect for the individual subject or population, beneficence and the absence of maleficence (research should have the maximum benefit with minimal harm) and justice.”

All individuals involved in research should facilitate and ensure research is conducted ethically. Ethical conduct in research is a shared responsibility. Primary responsibility rests with the Principal Investigator(s). Ethical responsibilities and legal obligations may overlap. All staff and students conducting research are required to ensure that their research is carried out in compliance with this policy. Ethical review is required before any studies involving human subjects, other living organisms and/or the natural environment, encompassing biosphere, geosphere, hydrosphere and atmosphere, commence. This requirement applies to staff, postgraduate and undergraduate students and volunteers/interns. Field- and laboratory work cannot commence until ethical review has been completed and approval has been gained. Staff or students planning to undertake research should complete the Research Ethics Application (Appendix 2).

Projects involving researchers from other Schools or institutions which have ethical approval from those bodies do not need further ethical approval, but evidence of the approval must be submitted to the SNS REC.

The process for applying for ethical approval is outlined in the following steps:

**1. Read the Trinity College Dublin** [**Policy on Good Research Practice**](http://www.tcd.ie/about/policies/assets/pdf/TCDGoodResearchPractice.pdf)

**2. Complete the** [**SNS Research Ethics Application**](https://naturalscience.tcd.ie/assets/doc/ethics/SNSRECpresentation-08-february-2017.pptx)**.** Applications should be sent to the Chair of the Research Ethics Committee, [Stephen Waldren](mailto:Stephen.Waldren@tcd.ie). **Deadlines** for ethical approval submission are on the **15th of each month**, and the School of Natural Sciences Research Ethics Committee will aim to respond by the **1st of the following month**.

All researchers must complete the **Section 1** ‘Applicant Details’ and **Section 2** ‘Initial Research Ethics Checklist’. If the study is desk-based or does not include interaction with live organisms, including humans as research models, nor does it involve working in natural or human-made outdoor habitats, then it is deemed not to require ethical approval, and the study can proceed without the approval of an ethics committee, but the completed and signed (Section 5) form should be submitted to the REC. If the study is deemed to require ethical approval, then the applicant should complete **Section 3** ‘Checklist for School REC suitability’ to determine if the application is suitable for consideration by the School REC. Checklists for student projects must be endorsed by their supervisor.If the study is suitable for consideration by a Level 1 committee (ie none of section 3 questions were answered “Yes” without the possibility of mitigation to reduce ethical risk), the researcher should complete **Section 4** ‘Ethical Approval Application’. Students should ensure that this is approved by the project supervisor before being sent to the Chair of the REC (as indicated on the form). *All researchers must complete* ***Section 5*** *‘Declaration’*.

If any of the answers to the checklist in Section 3 are yes, and suitable mitigation cannot be applied, the study requires the approval of a Level 2 committee. The applicant should then download the application and procedures for the appropriate Level 2 REC ([the Faculty of Engineering, Mathematics and Science REC](mailto:fems-ethics@tcd.ie), or the [Animal REC](mailto:parthasl@tcd.ie) for vertebrate research).

All animal (vertebrate) research must be ultimately approved by the Animal REC; research involving vertebrates in their natural habitats will be assessed by the SNS REC initially and then the decisions will be overseen by the AREC, but any research involving vertebrates in a laboratory setting needs to be submitted directly to the AREC. Please see HPRA [guidelines](https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/aut-g0119-guide-to-practices-outside-the-scope-of-scientific-animal-protection-legislation-v4.pdf?sfvrsn=10).

**3. Submit participant information and informed consent forms where applicable (Appendix 2).**

**4.** The ethics application will be reviewed by two members of the SNS Research Ethics Committee and returned to the applicant by the 1st of the month following submission.

**5. Respond** if necessaryto any requests for further information, or clarification, that the committee mightmake in relation to the approval request. Discuss these with your supervisor where necessary. Both student and supervisor will be given notice when REC decision is made.

**6. For projects of more than one year duration,** if there are changes to the project details which may have a bearing on ethical considerations, then applicants must submit an [**annual report**](https://naturalscience.tcd.ie/assets/doc/ethics/Annual%20Research%20Ethics%20Report%20Template.docx) (**Appendix 3**). **All applicants must submit an** [**end of project report**](https://naturalscience.tcd.ie/assets/doc/ethics/End%20of%20Project%20Ethics%20Report%20Template.docx) **upon completion of the study (Appendix 4).**

# Appendix 1

SNS REC Project Reference Number (to be completed by REC):

**Research Ethics Application**

**School of Natural Sciences, Trinity College Dublin**

**Section 1: Applicant Details**

|  |  |
| --- | --- |
| **Name** (Student/lead researcher) |  |
| **Staff/Student Number** |  |
| **Applicant E-mail Address** |  |
| **Name(s) of Additional Researcher(s)** | *Collaborators, third parties involved in the research if applicable* |
| **Name of Supervisor** (for students) |  |
| **Supervisor E-mail Address** | *Please ensure this is correct. The REC’s decision will be copied to this address* |
| **What School/Discipline are you affiliated to?** |  |
| **Title of Project** |  |
| **Brief description of the project (max 200 words)** | *Include brief rationale for research, data collection methods (including experimental design, sampling methods, how sites/samples will be selected, sample size, fate of specimens used in study, whether rare/ threatened species/habitats/geological structures/geographical features are involved etc[[1]](#footnote-1).). If the research involves human participants, give details of the population to be studied, sampling procedures, incentives/compensation to be offered to participants, recruitment process, and sample informed consent forms (see appendix 2).* |
| **Highlight the category that best describes the research** | Undergraduate project / Taught MSc project  Full-time postgraduate research project  Staff research project |
| **Has this application been submitted to another TCD Ethics Committee for approval?[[2]](#footnote-2)** | *If so, which, and what was the outcome?* |
| **Has ethical approval for this project been sought from outside TCD? What was the outcome?** | *Provide back-up documents where applicable.**If ethical approval has been granted from another body, approval from SNS REC may be fast-tracked.* |

**Section 2: Initial Research Ethics Checklist**

DOES YOUR RESEARCH PROJECT FALL CLEARLY UNDER ANY OF THE FOLLOWING CATEGORIES?

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| 1. Quality assurance study (e.g. assessment of teaching practice)[[3]](#footnote-3) |  |  |
| 2. Audits of standard practice (not involving identifiable records) |  |  |
| 3. Research on existing publically available information, documents or data (i.e. already gathered and in the public domain) |  |  |

**If you have answered YES to one or more of the above questions**, your research project can proceed without the need for ethical approval from the School Research Ethics Committee (REC). Please be aware that all researchers have a responsibility to follow TCD’s Policy on Good Research Practice, (available [here](https://www.tcd.ie/about/policies/assets/pdf/TCDGoodResearchPractice.pdf)) as well as any academic or professional code of practice or guidelines relevant to the specific research project. Even if you answer YES to one of the above question, **please return a signed (Section 5) copy of this form to the Chair of the SNS REC** as a record must be kept of all projects.

**If you have answered NO to all of the above questions**, proceed to Section 3 to determine whether your application is suitable for consideration for the School REC or if the application needs to be evaluated by a Level 2 committee.

**Section 3: Checklist for School REC suitability**

This checklist needs to be completed in order to determine whether your application is considered “low risk” and is therefore suitable for consideration by the School REC[[4]](#footnote-4).

Please indicate if your application falls into any of the categories below (categories from TCD “Criteria for Research Ethics Committees” [document](https://medicine.tcd.ie/assets/pdf/Criteria-for-Research-Ethics-Committees-Final.pdf), Jan 2014). Answer “NO” if your work does not involve the scenario. Answer “YES” if it does and ethical risks cannot be mitigated. Answer “YES but see…” if ethical risks can be mitigated by appropriate actions such as designing the study to minimize the chances of potentially endangering people, populations of study organisms and/or the environment (and list these in Section 4).

|  |  |  |  |
| --- | --- | --- | --- |
|  | NO | YES | YES but see mitigation strategy in Section 4 |
| **1.** Surveys asking questions of a sensitive or private nature |  |  |  |
| **2.** Questionnaires or observational studies involving children or vulnerable adults. |  |  |  |
| **3.** Research where there is a risk of a participant feeling undue pressure to participate by virtue of his/her relationship with the researcher (e.g. student/supervisor; patient/clinician). |  |  |  |
| **4.** Projects involving a justifiable degree of deception. |  |  |  |
| **5.** Analysis of archival irrevocably anonymised human tissue samples for which consent for research was not originally given, and was not acquired in the course of clinical treatment. (Archived samples taken for a previous research study must always get new ethical approval). |  |  |  |
| **6.** Research involving invasive procedures on humans (other than those listed above). |  |  |  |
| **7.** Research other questionnaires or observational studies involving vulnerable persons[[5]](#footnote-5). |  |  |  |
| **8.** Research where identifiable information obtained may have legal, economic or social consequences for research subjects. |  |  |  |
| **9.** Research that may identify illegal activity on the part of the participant. |  |  |  |
| **10.** Projects where each subject is paid (over and above token gestures). |  |  |  |
| **11.** Research that may potentially cause irrevocable damage to[[6]](#footnote-6) the population of subjects, and/or researchers, and/or 3rd parties, and/or the environment. **See note below.** |  |  |  |
| **12.** Research involving the collection of human tissue. |  |  |  |
| **13.** Research that may have a direct military application. |  |  |  |
| **14.** Potentially harmful research involving humans conducted outside Ireland[[7]](#footnote-7). |  |  |  |
| **15.** Research involving psychological intervention. |  |  |  |

*Official Approval/licensed research:* Research involving elements that may cause harm to the environment, to invertebrate animals or plants; or deal with endangered fauna and/or flora and/or protected areas; or involve the use of elements that may cause harm to humans, including research staff; may need formal approval/licensing by outside body, and such approval for the research (e.g. from the relevant Government Department) must be attached to this application. If formal approval for the work has been granted please give details in the box below:

|  |  |
| --- | --- |
| Approval for work granted by: | *Give Government Department or relevant authority who has granted approval* |
| Licences held relating to research activities | *Give Government Department or relevant authority who has granted licence* |
| Details of approval: | *Describe how work may potentially endanger environment and how this will be minimised, and what the formal approval covers* |

**If you have answered YES to any of the above questions and cannot mitigate ethical risks**, then the application is deemed to be of moderate or high risk (*i.e. risk or discomfort is greater than that usually encountered during normal daily life*) and should be submitted to the appropriate Level 2 Ethics Committee. The applicant should download the application and procedures for the appropriate Level 2 REC ([the Faculty of Engineering, Mathematics and Science REC](mailto:fems-ethics@tcd.ie), or the [Animal REC](mailto:parthasl@tcd.ie) for vertebrate research).

**If you** **have not answered YES** to any question in Section 3, your application can be submitted for consideration by the SNS REC after completion of Section 4.

**Section 4: Ethical Approval Application Form for School of Natural Sciences Level 1 REC**

All student applications should be reviewed and approved by the project supervisor prior to submission.

**Project Description**

|  |  |
| --- | --- |
| **Title of research project** |  |
| **Start date of research project** |  |
| **End date of research project** |  |
| **Potential ethical issues** | |
| *Are there ethical issues or problems which may arise with the proposed study, and what steps will be taken to address these? Are there potentially adverse outcomes to the environment (e.g. destruction of individuals, populations, habitats, physical structures)? Will the environment be altered by the experiment (e.g. through alteration of biological, geological or chemical systems)?* | |
| **Ethical considerations, reducing potential risks and mitigating impacts** | |
| *Where potential risks to participants or the environment may be present, explain any steps that will be taken to mitigate against and minimize these and any additional support services that might be used should the need arise.* | |
| **Data storage** | |
| *Provide an explanation of any measures that will be put in place to preserve confidentiality and anonymity of human participants, including an explicit explanation of secure data storage and disposal plans. Provide details of where data will be stored at the end of the project. Note that there may be a need to store data for a period after completion of the project.* | |
| **Published ethical guidelines to be followed** | |
| *Identify professional code(s) of practice and/or ethical guidelines relevant to the research.* | |

**Section 5: Declaration**

|  |  |
| --- | --- |
| **Signature of applicant**  *I declare that the information given herein is accurate. I have read the TCD Ethics Policy and will follow the guidelines therein. I have read and understood the* [*TCD Data Protection Policy*](https://www.tcd.ie/about/policies/data_protection.php)*.* | **Signature:**  **Date:** |
| **Signature of Supervisor (in case of students)**  *I declare that the information given herein is accurate. I have read the Ethics Policy and will follow the guidelines therein.* | **Signature:**  **Date:** |

To be completed following REC review:

|  |  |
| --- | --- |
| **Approval by the School’s Ethics Committee**  *Based on the information available on this form, the SNS REC believes the ethical risks in this project are negligible and will be appropriately mitigated during the course of the research[[8]](#footnote-8).* | **Sign/Stamp:**  **Date:** |

# Appendix 2

**Template for Participant Information Form**

**School of Natural Sciences, Trinity College Dublin**

Where applicable, a Participant Information Leaflet and Consent Form must be submitted to the committee. The leaflet should be written in clear non-technical English and aimed at the potential subjects in the project, not at the REC. All the headings should be included. For several of the headings, recommended wording is provided in *italics* and should be used if appropriate for the particular study.

1. **Title of study:**

**2. Details:** Name of principal investigator and research assistants; name of organisation; name of sponsor; name of project

**3. Introduction:** Provide a brief description of the research project, stating the purpose of the study, the question being tested, and the extent of the participant’s involvement, e.g. time span of participation, expected number of interviews etc.

**4. Procedures:** List the criteria for selection for participation in the study. Then detail the nature of the participant’s involvement, e.g. the number of interviews, how long they should take etc.

**5. Benefits:** List any benefits to participants in the study. The study may have no direct benefit to the individual participant but the results may benefit others.

**6. Risks:** List any risks involved in participating in the study. If the risks are unknown this should be stated.

**7. Exclusion from participation:**List the criteria excluding an individual from participating in the study.

**8. Confidentiality:** *Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study.*

**9. Voluntary Participation:** *You have volunteered to participate in this study. You may quit at any time. If you decide not to participate, or if you quit, you will not be penalised and will not give up any benefits which you had before entering the study.*

**10. Reimbursements***:* Provide details of any planned reimbursements to participants such as travel costs. Confirm that additional incentives are not available.

**11. Stopping the study:** *You understand that the researcher may stop your participation in the study at any time without your consent.*

**12. Permission:** State that the study has School of Natural Sciences Research Ethics Committee approval. Also include any additional organisational or national research ethics committee approvals.

**13. Access to data:** Tell the participant that they can access their own data at any time under [the Freedom of Information Act 2014](http://www.irishstatutebook.ie/2014/en/act/pub/0030/index.html).

**14. Sharing the results:** Confirm that the research results will be shared with the participants and community before publication (this is now common practice for participatory research projects).

**15. Further information:** *You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Dr….........who can be telephoned at …............*

**Template for Informed Consent Form**

**School of Natural Sciences, Trinity College Dublin**

**Title of research study:**

This study and this consent form have been explained to me. I believe I understand what will happen if I agree to be part of this study.

I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement and I understand that, if there is a sponsoring company, a signed copy will be sent to that sponsor.

**Name of sponsor**:

**PARTICIPANT’S NAME:**

**PARTICIPANT’S SIGNATURE:**

**Date:**

**Date on which the participant was first furnished with this form:**

**Participants with literacy difficulties:**

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely and understands that they have the right to refuse or withdraw from the study at any time.

**Print name of witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date (Day/month/year) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Thumbprint of participant:**

**Statement of investigator’s responsibility:** I have explained the nature, purpose, procedures, benefits, risks of, or alternatives to, this research study. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

**Researcher’s signature: Date:**

(Keep the original of this form in the project records, give one copy to the participant, and send one copy to the sponsor (if there is a sponsor).

# Appendix 3

**Annual Research Ethics Report Template**

**School of Natural Sciences, Trinity College Dublin**

|  |  |
| --- | --- |
| **Name** |  |
| **Staff/Student Number** |  |
| **E-mail Address** |  |
| **Title of Project** |  |
| **SNS REC Project Reference Number** |  |
| **Date** DD/MM/YY |  |

|  |  |  |
| --- | --- | --- |
| **Questions:** | **YES/NO** | **Details:** |
| Is the study continuing? If YES, please provide the anticipated date of completion. |  |  |
| Have there been any modifications to the study for which Ethical approval was granted? If YES, please provide details (only give details that are relevant to ethical approval) |  |  |
| Have there been any adverse outcomes associated with the conduct of the research? If YES, please provide details. |  |  |
| Are all data being stored in accordance with Trinity’s data storage policy, in adherence to the Freedom of Information Act, and in compliance with the requirements of the Data Protection Commissioner? See <https://www.tcd.ie/about/policies/data_protection.php> |  |  |

# Appendix 4

**Research Ethics End of Project Report Template**

**School of Natural Sciences, Trinity College Dublin**

|  |  |
| --- | --- |
| **Name** |  |
| **Staff/Student Number** |  |
| **E-mail Address** |  |
| **Title of Project** |  |
| **SNS REC Project Reference Number** |  |
| **Date** DD/MM/YY |  |

|  |  |  |
| --- | --- | --- |
| **Questions:** | **YES/NO** | **Details:** |
| Are the results of the study published? If YES, where (give details of thesis, paper, report etc.) |  |  |
| Were there any modifications to the study for which Ethical approval was granted? If YES, please provide details (only give details that are relevant to ethical approval) |  |  |
| Were there any adverse outcomes associated with the conduct of the research? If YES, please provide details. |  |  |
| Are all data being stored in accordance with Trinity’s data storage policy, in adherence to the Freedom of Information Act, and in compliance with the requirements of the Data Protection Commissioner? See <https://www.tcd.ie/about/policies/data_protection.php> |  |  |

1. Include details on whether collection permits are needed (even if they are not required, these may be desirable); ensure that collection of organisms does not harm natural populations of the taxa, and that the study has minimal impacts on the habitat; state whether the taxa studied are threatened (e.g. IUCN threat status) - if so, special measures should be in place to ensure the study does not further endanger the species: this applies to collecting samples of the taxa, and disturbance of their habitat; ensure that study of potentially invasive species will not lead to their release outside of their natural range; ensure that the locality information of sensitive species (threatened species, those of potential or actual economic value) are not made widely available (if necessary, advice should be sought from relevant conservation agencies in the state where the study takes place); determine whether there are other, non-target species (including vertebrates) that may not be the subject of the study, but may utilise the same habitat and be disturbed or impacted by the field work - due care needs to be taken to ensure minimal impacts on non-target species. [↑](#footnote-ref-1)
2. All research involving animals (vertebrates) must ultimately be approved by the Animal Research Ethics Committee (AREC); research involving vertebrates in their natural habitats will be assessed by the SNS REC initially and then the decisions will be overseen by the AREC, but any research involving vertebrates in a laboratory setting needs to be submitted directly to the AREC. [↑](#footnote-ref-2)
3. Quality assurance and audit studies do not routinely require ethical approval. However, if following the study there is scope to publish the findings of a study, an REC may grant a letter of approval if required. [↑](#footnote-ref-3)
4. In situations where research ethics approval has been granted by an appropriate body outside TCD, approval must also be sought from an appropriate TCD REC, although, at the discretion of the REC chair, the submission may qualify for fast-tracked approval. [↑](#footnote-ref-4)
5. Vulnerable persons: Certain individuals who face excessive risk of being enrolled in research include those with limitations in their ability to provide informed consent to research because of factors such as immaturity or cognitive impairment. Vulnerability can also stem from individuals’ relationships with others, and it is imperative that coercive situations are avoided. Such cases may occur when an employee/student/dependent is asked to participate in research being conducted by a supervisor/mentor. Additional social factors, such as poverty and lack of access to health care, can also make individuals vulnerable to coercion, exploitation or other risks and need to be considered and appropriately mitigated for. [↑](#footnote-ref-5)
6. Relevant Health and Safety Risk Assessment forms must be completed before work can be undertaken. [↑](#footnote-ref-6)
7. Does not apply to material publically available in another jurisdiction. Note that the same ethical standards will apply to research carried out by SNS researchers within and outside of Ireland. Work must comply with legal requirements of the State in which it is carried out. [↑](#footnote-ref-7)
8. Primary responsibility for ensuring ethical conduct in research rests with the Principal Investigator(s). [↑](#footnote-ref-8)