STANDARD APPLICATION FORM

For the Ethical Review of Health-Related Research Studies, which are not Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM
IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study:_____

Principal Investigator:_____

Applicant's Signature:_____

For Official Use Only – Date Stamp of Receipt by REC:

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This Application Form is divided into Sections.

Sections A, B, C, D, E, J, K, L are **Mandatory.**

Sections F, G, H, and I are optional. Please delete Sections F, G, H, and I if these sections do not apply to the application being submitted for review.

IMPORTANT NOTE: Please refer to **Section I** within the form before any attempt to complete the Standard Application Form. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

SECTION A GENERAL INFORMATION

SECTION A IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

A1 Title of the Research Study:

Answer

A2 Principal Investigator(s):
Title: Dr. / Ms. / Mr. / Prof. **Name:**
Qualifications:
Position:
Dept:
Organisation:
Address:
Tel: **E-mail:**

A3 (a) Is this a multi-site study? Yes / No

A3 (b) Please name each site where this study is proposed to take place and state the lead investigator for each site:

Site:	Lead Investigator:

A3 (c) For any of the sites listed above, have you got an outcome from the research ethics committee (where applicable)?

Answer

A4. Co-Investigators:

Name of site

Answer

Title: Dr. / Ms. / Mr. / Prof. **Name:**
Qualifications:
Position:
Organisation:
Address:
Role in Research:

A5. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.

Title: Dr. / Ms. / Mr. / Prof. **Name:**
Address:
Tel (work): **Tel (mob.):**
E-mail:

A6. Please provide a lay description of the study.

Answer

A7 (a) Is this study being undertaken as part of an academic qualification? Yes / No

A7 (b) If yes, please complete the following:
Student Name: **Course:**
Institution: **Academic Supervisor:**

SECTION B STUDY DESCRIPTORS

SECTION B IS MANDATORY

B1. Provide information on the study background.

Answer

B2. List the study aims and objectives.

Answer

B3. List the study endpoints (if applicable).

Answer

B4. Provide information on the study design.

Answer

B5. Provide information on the study methodology.

Answer

B6. What is the anticipated start date of this study?

Answer

B7. What is the anticipated duration of this study?

Answer

B8 (a) How many research participants are to be recruited in total?

Answer

B8 (b) Provide information on the statistical approach to be used (if appropriate) / source of any statistical advice.

Answer

B8 (c) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).

Answer

B8 (d) Where sample size calculation is impossible (e.g. It is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.

Answer

SECTION C STUDY PARTICIPANTS

SECTION C IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

SECTION C1 PARTICIPANTS – SELECTION AND RECRUITMENT

C1. 1 How many research participants are to be recruited? At each site (if applicable)? And in each treatment group of the study (if applicable)?

Name of site:	**Names of Treatment Group (if applicable)**		
	Insert name of group:	**Insert name of group:**	**Insert name of group:**
(Insert rows as required)			

C1.2 How will the participants in the study be selected?

Answer

C1.3 How will the participants in the study be recruited?

Answer

C1.4 What are the main inclusion criteria for research participants? (please justify)

Answer

C1.5 What are the main exclusion criteria for research participants? (please justify)

Answer

C1.6 Will any participants recruited to this research study be simultaneously involved in any other research project?
Yes / No / Not to my knowledge

SECTION C2 PARTICIPANTS – INFORMED CONSENT

C2.1 (a) Will informed consent be obtained? Yes / No

C2.1 (b) If no, please justify.

Answer

C2.1 (c) If yes, how will informed consent be obtained and by whom?

Answer

C2.1 (d) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study?

Yes/No

C2.1 (e) If no, please justify.

Answer

C2.1 (f) Will there be a time interval between giving information and seeking consent? Yes / No

C2.1 (g) If yes, please elaborate.

Answer

C2.1 (h) If no, please justify.

Answer

SECTION C3 ADULT PARTICIPANTS - CAPACITY

C3.1 (a) Will all adult research participants have the capacity to give informed consent? Yes / No / Non-Applicable

C3.1 (b) If no, please elaborate.

Answer

C3.1 (c) If no, is this research of such a nature that it can only be carried out on adults without capacity? Yes / No

C3.1 (d) What arrangements are in place for research participants who may regain their capacity?

Answer

SECTION C4 PARTICIPANTS UNDER THE AGE OF 18

C4.1 (a) Will any research participants be under the age of 18 i.e. Children?
Yes / No

C4.1 (b) If yes, please specify:
Persons < 16 Yes / No
Persons aged 16 – 18 Yes / No
Children in care Yes / No

C4.2 Is this research of such a nature that it can only be carried out on children? Yes / No

C4.3 Please comment on what will occur if the researcher discovers that a child is at risk during the course of this study?

Answer

C4.4 Will each child receive information according to his/her capacity of understanding regarding the risks and benefits of the study? Please elaborate and provide copies.

Answer

C4.5 Will the explicit wish of the child who is capable of forming an opinion and assessing information to refuse to participate or to be withdrawn from the study be considered by the lead investigators, co-investigators and principal investigator? Please elaborate.

Answer

C4.6 Please comment on the involvement (if any) of parents / legal guardians of the child in the consent process.

Answer

C4.7 Please explain your approach to reviewing assent where research subjects reache the age of 18 during the course of the study.

Answer

SECTION C5 PARTICIPANTS - CHECKLIST

Please confirm if any of the following groups will participate in this study. This is a quick checklist for research ethics committee members <u>and it is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity.</u>

C5.1 Patients Yes / No
C5.2 Unconscious patients Yes / No
C5.3 Current psychiatric in-patients Yes / No
C5.4 Patients in an emergency medical setting Yes / No
C5.5 Relatives / Carers of patients Yes / No
C5.6 Healthy Volunteers Yes / No
C5.7 Students Yes / No
C5.8 Employees / staff members Yes / No
C5.9 Prisoners Yes / No
C5.10 Residents of nursing homes Yes / No
C5.11 Pregnant women Yes / No
C5.12 Women of child bearing potential Yes / No
C5.13 Breastfeeding mothers Yes / No
C5.14 Persons with an acquired brain injury Yes / No
C5.15 Intellectually impaired persons Yes / No
C5.16 Persons aged > 65 years Yes / No

C5.17 If yes to any of the above, what special arrangements have been made to deal with issues of consent and assent (if any)?

Answer

SECTION D RESEARCH PROCEDURES

SECTION D IS MANDATORY

<u>IMPORTANT NOTE:</u> This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

D1. What research procedures or interventions (over and above those clinically indicated and/or over and above those which are part of routine care) will research participants undergo whilst participating in this study?

Answer

D2. If there are any potential harms resulting from any of the above listed procedures, provide details below:

Answer

D3. What is the potential benefit that may occur as a result of this study?

Answer

D4 (a) Will the study involve the withholding of treatment?
Yes / No / Non-applicable

D4 (b) Will there be any harms that could result from withholding treatment? Yes / No

D4 (c) If yes, please elaborate.

Answer

D5. How will the health of participants be monitored during and after the study?

Answer

D6 (a) Will the interventions provided during the study be available if needed after the termination of the study? Yes / No

D6 (b) If yes, please state the intervention you are referring to and state who will bear the cost of provision of this intervention?

Answer

D7. Please comment on how individual results will be managed.

Answer

D8. Please comment on how aggregated study results will be made available.

Answer

D9. Will the research participant's general practitioner be informed the research participant is taking part in the study (if appropriate)?
Yes / No / Non-applicable

D10. Will the research participant's hospital consultant be informed the research participant is taking part in the study (if appropriate)?
Yes / No / Non-applicable

SECTION E DATA PROTECTION

SECTION E IS MANDATORY

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

SECTION E1 DATA PROCESSING - CONSENT

E1.1 (a) Will consent be sought for the processing of data? Yes / No

E1.1 (b) If no, please elaborate.

Answer

SECTION E2 DATA PROCESSING - GENERAL

E2.1 Who will have access to the data which is collected?

Answer

E2.2 What media of data will be collected?

Answer

E2.3 (a) Would you class the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data?

Answer

E2.3 (b) If 'coded', please confirm who will retain the 'key' to re-identify the data?

Answer

E2.4 Where will data which is collected be stored?

Answer

E2.5 Please comment on security measures which have been put in place to ensure the security of collected data.

Answer

E2.6 (a) Will data collected be at any stage leaving the site of origin? Yes / No

E2.6 (b) If yes, please elaborate.

Answer

E2.7 Where will data analysis take place and who will perform data analysis (if known)?

Answer

E2.8 (a) After data analysis has taken place, will data be destroyed or retained?

Answer

E2.8 (b) Please elaborate.

Answer

E2.8 (c) If destroyed, how, when and by whom will it be destroyed?

Answer

E2.8 (d) If retained, for how long, for what purpose, and where will it be retained?

Answer

E2.9 Please comment on the confidentiality of collected data.

Answer

E2.10 (a) Will any of the interview data collected consist of audio recordings / video recordings? Yes / No

E2.10 (b) If yes, will participants be given the opportunity to review and amend transcripts of the tapes?

Answer

E2.11 (a) Will any of the study data collected consist of photographs/ video recordings? Yes / No

E2.11 (b) If yes, please elaborate.

Answer

SECTION E3 ACCESS TO HEALTHCARE RECORDS

E3.1 (a) Does the study involve access to healthcare records (hard copy / electronic)? Yes / No

E3.1 (b) If yes, please elaborate.

Answer

E3.1 (c) Who will access these healthcare records?

Answer

E3.1 (d) Will consent be sought from patients for research team members to access their healthcare records? Yes / No

E3.2 (a) Who or what legal entity is the data controller in respect of the healthcare records?

Answer

E3.2 (b) What measures have been put in place by the data controller which may make access to healthcare records permissible without consent?

Answer

SECTION F HUMAN BIOLOGICAL MATERIAL

F1 BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL

F1 1 (a) Does this study involve human biological material? Yes / No

If answer is No. Please delete following questions in Section F.

F2 BODILY TISSUE / BODILY FLUID SAMPLES PROSPECTIVELY COLLECTED

F2.1 Does this study involve the prospective collection of human biological material? Yes / No

F2.2 Please state the type of human biological material which is being prospectively collected.

Answer

F2.3 Who or what institution will be the custodian of the prospectively collected human biological material?

Answer

F2.4 (a) Will the human biological material be collected as part of routine clinical care? Yes / No

F2.4 (b) Will the human biological material be collected specifically for the purposes of this research study? Yes / No

F2.4 (c) With reference to your responses to question F2.4 (a), F2.4 (b), please provide more detail, in particular, in relation to whether participants will be consented to the taking of a sample or to the use of a sample (or part of a sample) which will be taken anyway for clinical reasons.

Answer

F2.5 (a) With respect to human biological material which it is proposed to prospectively collect for the purposes of this research study, after the laboratory analysis which this research study involves, will any human biological material remain? Yes / No

F2.5 (b) If yes, will this remaining biological material be retained?
Yes / No

F2.5 (c) If yes, for how long and where will samples be retained?

Answer

F2.5 (d) If yes, for what purpose will samples be retained?

Answer

F2.5 (e) If yes, please comment on consent for retention of biological material.

Answer

F2.5 (f) If yes, will this human biological material and/or any data derived from it be used for any other purpose (including future research projects)? Yes / No

F2.5 (g) If yes, please comment on consent for future use of human biological material.

Answer

F2.6 (a) Will the human biological material be collected specifically for the purposes of depositing this human biological material in a biobank? Yes / No

F2.6 (b) If yes, please provide specific information in relation to this proposed biobank.

Answer

F2.6 (c) If yes, will research participants be informed in all information leaflets and consent forms that this is a biobank?

Answer

F3 BODILY TISSUE / BODILY FLUID SAMPLES RETROSPECTIVELY COLLECTED

F3.1 Does this study involve accessing retrospectively collected human biological material? Yes / No

F3.2 Please state the type of human biological material which is being accessed.

Answer

F3.3 Who will access the material?

Answer

F3.4 Who (or which institution) is the current custodian of the material?

Answer

F3.5 Please state for what purpose the human biological material was originally collected and please comment on the nature of consent for the collection of this material.

Answer

F3.6 (a) Do you intend to contact patients to seek their consent to use stored human biological material? Yes / No

F3.6 (b) If no, please justify why you consider existing consent to cover this project, or that a waiver of consent from the research ethics committee is warranted.

Answer

F4 BODILY TISSUE / BODILY FLUID SAMPLES – SAMPLE MOVEMENT

F4.1 (a) Will human biological material at any stage leave the institution of origin? Yes / No

F4.1 (b) If yes, for what purpose?

Answer

F4.1 (c) If yes, please state where samples will be sent?

Answer

F4.1 (d) If yes, please state if the samples leaving the institution of origin will be anonymous, irreversibly anonymised, pseudonymised, coded, identifiable etc?

Answer

E4.1 (e) If 'coded' please confirm who will retain the 'key' to re-identify the samples?

Answer

F4.1 (f) Does a memorandum of understanding (or agreement / contract) exist between the institution of origin and the institution to which the samples will be sent? Please elaborate.

Answer

F5 GENETIC TESTING

F5.1 (a) Does this research study involve 'genetic testing'? Yes / No

F5.1 (b) If yes, please specify the nature of the genetic testing.

Answer

F6 COMMERCIAL VALUE

F6.1 (a) Will the human biological material in this research study or the data derived from the analysis of the human biological material be commercially valuable or is there the possibility that it will become commercially valuable? Yes / No

F6.1 (b) If yes, please elaborate.

Answer

SECTION G RADIOACTIVE MATERIAL / DIAGNOSTIC OR THERAPEUTIC IONISING RADIATION

G1 RADIOACTIVE MATERIAL / DIAGNOSTIC OR THERAPEUTIC IONISING RADIATION - GENERAL

G1.1 (a) Does this study/trial involve exposure to radioactive materials or does this study/trial involve other diagnostic or therapeutic ionising radiation? Yes / No

If the answer to question G1.1(a) is No, please delete the following questions in this Section.

G1.1 (b) If yes, please specify:
Exposure to radioactive materials Yes / No

Therapeutic ionising radiation Yes / No

Diagnostic ionising radiation Yes / No

G1.2 (a) Does this study / trial involve additional radiation exposure to radioactive materials or diagnostic or therapeutic ionising radiation other than normally received as part of standard care? Yes / No

G1.2 (b) If yes, please elaborate

Answer

G1.3. Is this an application to conduct research involving radioactive materials or diagnostic or therapeutic radiation at a radiation oncology unit? Yes / No

SECTION G2 RADIOTHERAPY TRIALS

G2.1 Does the study/trial involve patients? Yes / No

G2.2 If yes, will the patient receive radiotherapy? Yes / No

G2.3 Is the radiotherapy part of standard treatment or is it experimental?
Standard treatment / experimental

G2.4 <u>In relation to the radiotherapy please provide the following information:</u>

G2.4 (a) Volume of interest (tumour related volume and organs at risk)

Answer

G2.4 (b) (i) Technique to be used, e.g. 3-DCRT (3-dimensional conformal radiation therapy, IMRT (intensity modulated radiation therapy)

Answer

G2.4 (b) (ii) Technique to be used, e.g. IGRT (image guided radiation therapy), etc.

Answer

G2.4 (c) <u>Radiation schedule:</u>

(i) total dose

Answer

(ii) dose per fraction

Answer

(iii) number of fractions per day

Answer

G2.4 (d) Dose volume constraints (DVCs) for organs at risk

Answer

G2.4 (e) Expected spectrum of acute and long-term radio-induced side effects

Answer

G2.4 (f) Details of patient positioning/immobilisation

Answer

G2.4 (g) Details of radiotherapy plan evaluation parameters (i.e. planning target volume [PTV] coverage)

Answer

G2.4 (h) What toxicity scoring criteria are to be used?

Answer

G2.5 For experimental radiotherapy, please provide the following information:

(a) Standard alternatives

Answer

(b) Potential risks associated with the experimental

Answer

G2.6 (a) Radiotherapy quality assurance at delivery: please describe the quality assurance programme i.e. physics quality assurance (beam and dose)

Answer

G2.6 (b) Radiotherapy quality assurance at delivery: please describe the quality assurance programme i.e. clinical quality assurance

Answer

G2.7 Clinical monitoring during radiotherapy and supportive care: please provide a detailed summary of the clinical monitoring of patients included in the study / trial

Answer

SECTION G3 RADIONUCLIDES

Please complete the tables below for <u>each radionuclide</u> to be administered

G3.1 (a) Will any of the study/trial participants be patients? Yes / No

Details of patients to be studied				
Number (whole study)	**Age range**	**Sex**	**Clinical condition**	**Total effective or target tissue dose per individual**

G3.1 (b) Will any of the study/trial participants be healthy volunteers? Yes / No

Details of healthy volunteers to be studied			
Number (whole study)	**Age range**	**Sex**	**Total effective dose per individual**

G3.2 Dose and Risk Assessment

G3.2 (a) What is the total research protocol dose from the exposure in G2 (if any) and what component of this is the additional dose over and above standard practice? What are the risks associated with this dose?

Answer

G3.2 (b) DECLARATION BY MEDICAL PHYSICIST

I am satisfied that the information in sub-section G3.1 and the assessment in sub-section G3.2 provide a reasonable estimate of the ionising radiation exposure planned in this research and the associated risks

Signature: _____ Date: _____

Please Print Name: _____

SECTION G4 CLINICAL ASSESSMENT

G4.1 Will the exposure exceed the exposure that might be received as part of normal care? Yes / No

G4.2 Assessment of additional exposure

G4.2 (a) Please explain how the planned exposure compares with normal practice and assess whether it is appropriate, using language comprehensible to a lay person. Consideration should be given to the specific objectives of the exposure, the characteristics of participants, the potential diagnostic or therapeutic benefits to the participant, the potential benefits to society, the risk to the participant and the availability of alternative techniques involving less, or no, ionising radiation.

Answer

G4.2 (b) If pregnant or breastfeeding mothers are to be studied give reasons and details of special radiation protection measures to be taken

Answer

G4. 3 DECLARATION BY RADIATION ONCOLOGIST

I am satisfied that the exposure to ionising radiation planned in this research study (as defined in sub-section G2 and/or G3) is reasonable

and that the risks are adequately described in the participant information sheet for the study.

Signature: _____ Date: _____

Please Print Name: _____

SECTION H MEDICAL DEVICES

H1 (a) Is the focus of this study/trial to investigate/evaluate a medical device? Yes / No

If the answer to question H1 (a) is No, please delete the following questions in this Section.

H1 (b) If yes, what is the name of the medical device or device nomenclature (system of naming the medical device)?

Answer

H1 (c) If yes, please provide a general description of the medical device.

Answer

H2 (a) Does the device have a CE mark?

Yes / No	
H2 (b) If the device has a CE mark, is it proposed to use the device within the terms of its CE mark or outside the terms of its CE mark? Within / Outside	**H2 (e) If the device does not have a CE mark, is this study being undertaken for the purposes of obtaining a CE mark?** Yes / No
H2 (c) If outside, please elaborate:	
Answer	
H2 (d) CE mark number:	
Answer	

H3. If an application to conduct a clinical investigation of a medical device, will the medical devices section of the Irish Medicines Board be reviewing this clinical investigation of a medical device?

Yes / No / Non applicable

SECTION I MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS

Section I is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product. Section I is optional. Please delete if this section does not apply.

SECTION I.1 NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

I1.1 (a) Does this study involve a medicinal product? Yes / No

If the answer to question I1.1 (a) is No, please delete the following questions in this Section.

I1.1 (b) If yes, please state:

I. The trade name of the medicinal product:

Answer

II. The name of the active substance:

Answer

III. The formulation:

Answer

IV. The authorisation / product number:

Answer

I1.2 (a) Is this an application to conduct a non-interventional trial of a medicinal product? Yes/No

I1.2 (b) Is this trial a post-authorisation safety study? Yes / No

SECTION I.2 COSMETICS

I2.1 (a) Does this study involve a cosmetic? Yes / No

If the answer to question I 2.1 (a) is No, please delete the following questions in Sub-Section I 2.

I2.1 (b) If yes, please state:

I. The trade name of the cosmetic:

Answer

II. The ingredients/composition:

Answer

SECTION I.3 FOOD AND FOOD SUPPLEMENTS

I3.1 (a) Does this study involve food or food supplements? Yes / No

If the answer to question I 3.1 (a) is No, please delete the following question in Sub-Section I 3.

I3.2 (b) If yes, please elaborate:

Answer

SECTION J INDEMNITY

SECTION J IS MANDATORY

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J1 (a) Is each site in which this study is to take place covered by the Clinical Indemnity Scheme (CIS)? Yes / No

J1 (b) If the answer is 'no' for any site, what other arrangements are in place in terms of indemnity / insurance?

Answer

J2 (a) Is each member of the investigative team covered by the Clinical Indemnity Scheme (CIS)? Yes / No

J2 (b) If no, do members of the investigative team not covered by the Clinical Indemnity Scheme (CIS) have either current individual medical malpractice insurance (applies to medical practitioners) or current professional liability insurance either individually or as provided by their hosting/employing institution (generally applies to allied healthcare professionals, university employees, scientists engineers etc.)?

Answer

J3 (a) Who or what legal entity is the sponsor of this research study?

Answer

J3 (b) What additional indemnity arrangements has the sponsor put in place for this research study in case of harm being caused to a research participant (if any)?

Answer

SECTION K COST AND RESOURCE IMPLICATIONS AND FUNDING

SECTION K IS MANDATORY

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K1 (a) Are there any cost / resource implications related to this study? Yes / No

K1 (b) If yes, please elaborate.

Answer

K2 (a) Is funding in place to conduct this study? Yes / No
K2 (b) If no, has funding been sought to conduct this study? Yes / No

K2 (c) Please state the source of funding (industry, grant or other) and the amount of funding.

Answer

K2 (d) Is the study being funded by an external agency? Yes / No
K2 (e) Is the external agency a 'for profit' organisation? Yes / No
K2 (f) Do any conflicts of interest exist in relation to funding? Please elaborate.

Answer

K2 (g) Please provide additional details in relation to management of funds.

Answer

K3. Please provide details of any payments (monetary or otherwise) to investigators.

Answer

K4. Please provide details of any payments (monetary or otherwise) to participants.

Answer

SECTION L ETHICAL ISSUES

SECTION L IS MANDATORY

L1. Please identify any particular additional ethical issues that this project raises and discuss how you have addressed them.

Answer

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.