IRB Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Please ensure that all applicable materials listed below are submitted to the IRB office. The IRB will not put the protocol on an agenda until all applicable materials listed below are received.**

**\_\_\_\_\_\_\_\_ Continuing Review Submission Form**

**\_\_\_\_\_\_\_\_ Most recent version of protocol**

**\_\_\_\_\_\_\_\_ Most recent version of investigator’s brochure or Instructions for Use**

**\_\_\_\_\_\_\_\_ Currently approved version of the informed consent document**

**\_\_\_\_\_\_\_\_ Brief project summary including current status**

**\_\_\_\_\_\_\_\_ Summary of any Unanticipated Problems**

**\_\_\_\_\_\_\_\_ Copies of the signed consent forms from the last three patients enrolled**

**\_\_\_\_\_\_\_\_ Data collection form**

**\_\_\_\_\_\_\_\_ Any approved IRB materials (surveys, flyers, other patient recruitment materials, etc.)**

**\_\_\_\_\_\_\_\_ Copy of last monitoring report and statement from Principal Investigator indicating how any findings were resolved**

SLHS INSTITUTIONAL REVIEW BOARD

CONTINUING REVIEW SUBMISSION

**Goals of IRB continuing review**

1. Verify that the research still meets the IRB approval criteria:

* Risks to subjects are minimized;
* Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result;
* Selection of subjects is equitable;
* Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, and appropriately documented;
* Where appropriate, the research plan adequately provides for monitoring the data collected to ensure the safety of subjects;
* Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
* Appropriate additional safeguards are included to protect vulnerable subjects; and
* Where the study involves children, the research complies with 21 CFR Part 50 Subpart D and/or 45 CFR Part 46 Subpart D.

1. Ensure the rights, safety and welfare of the research subjects are protected.

To meet these goals, please fill out this form and attach all applicable documents and information listed on page 1.

1. **Administrative and Study Information**

|  |  |
| --- | --- |
| Principal Investigator: |  |
| Email address: |  |
| Phone Number: |  |
| Number of studies principal investigator is currently conducting: |  |

|  |  |
| --- | --- |
| Sub-Investigator(s): |  |
| Email address: |  |
| Phone Number: |  |
| Sub-Investigator(s): |  |
| Email address: |  |
| Phone Number: |  |
| Sub-Investigator(s): |  |
| Email address: |  |
| Phone Number: |  |
| Sub-Investigator(s): |  |
| Email address: |  |
| Phone Number: |  |
| Sub-Investigator(s): |  |
| Email address: |  |
| Phone Number: |  |

|  |  |
| --- | --- |
| Lead Study Coordinator: |  |
| Email Address: |  |
| Phone Number: |  |

|  |  |
| --- | --- |
| Other Study Staff: |  |
|  |
|  |
|  |
|  |

|  |  |
| --- | --- |
| Other Study information:  Date of initial IRB approval:  Date of prior IRB continuing review, if any:  Interval of time of IRB approval prior to requiring next IRB continuing review (e.g., 1 year):  Date of current IRB Continuing Review Expiration |  |
|  |
|  |
|  |
|  |

|  |  |
| --- | --- |
| Single site study: | YES |
| NO |
| Multi-site study: | YES |
| NO |
|  |

Source of Funding:

|  |
| --- |
| Industry Sponsored Name of Sponsor: |
| Federally funded |
| Investigator Initiated Source of funding (if applicable): |
| Other |

1. **Subject Selection**
2. Total number of subjects enrolled at SLHS sites: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Total number of subjects enrolled since last review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Subjects in screening: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. Screening failures: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. Subjects consented for primary research: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
7. Subject withdrawals (including deaths): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
8. Subjects whose research participation was terminated by investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
9. Subjects completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
10. Number of subjects accrued study-wide, if available: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
11. Summary of the reasons for subject withdrawal:  N/A

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Summary of any complaints about the research from subjects enrolled at the local site:  N/A

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Have any subjects been removed by the investigator? If yes, please provide an explanation.

Yes  No

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1. Have any subjects been lost to follow up? If yes, please provide an explanation.

Yes  No

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1. Check all that apply to the human subjects that have been enrolled in this study:

Pregnant Women  Neonates

Children (18 yrs or less)  Cognitively impaired

Prisoners  Wards of the state/children in court custody Patients with active psychiatric disease

People unable to read, speak or understand English

1. Have any non English speaking subjects been enrolled since the last IRB review?

Yes  No

1. Have any minors been enrolled since the last IRB review?

Yes  No

1. **Status of Study**

Please check all that apply

Study is active and currently enrolling patients

Study is active but closed to enrollment – Date closed to enrollment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

All subjects have completed all research related interventions and interactions

The remaining activities are limited to long term follow up of subjects

The remaining activities are limited to analysis of data

1. **Review of Study**
2. Is there any new risk or benefit information related to this study that has not previously been reported to the IRB? If yes, please explain.

Yes  No

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Is there any other new and relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research?

Yes  No

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Is there a safety monitoring report available?

Yes, it is provided to the IRB with this submission

Yes, it was previously provided to the IRB

No (please provide explanation) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Have there been any changes to the protocol, consent or study materials not previously reported to the IRB? If yes, please complete a separate amendment form describing the changes.

Yes  No

1. **Unanticipated Problems Involving Risks to Subjects or Others/Adverse Events**
2. Since the last IRB review, has any new information become available or have unanticipated problems been discovered? If yes, please explain.

Yes  No

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Please submit a summary of both unanticipated problems and adverse events since the last IRB review. Please provide enough detail for the IRB to understand the nature of the report. Please also ensure that the summary includes the PI’s assessment of whether the problems or adverse events warrant changes to the protocol, consent process or the risk/benefit ration.***

Adverse events that would be considered an unanticipated problem include:

* Any adverse experience that, even without detailed analysis, represents a serious unexpected adverse event that is rare in the absence of drug exposure;
* A series of adverse events that, on analysis, is both unanticipated and a problem for the study (a safety signal not just isolated occurrences and are significant to the rights, safety and welfare of subjects);
* An adverse event that is described or addressed in the investigator’s brochure, protocol, or informed consent documents, or expected to occur in study subjects at an anticipated rate, but that occurs at a greater frequency or at a greater severity than expected.
* The key questions regarding whether a particular adverse event is an unanticipated problem is if the answer to the following three questions is affirmative:
  + Is the adverse event unexpected?
  + Is the adverse event related or possibly related to participation in the research?
  + Does the adverse event suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized?
* Any other significant information related to subject risks, such as the most recent report, if any, from data monitoring committees or other monitoring entity:
* Aggregate information about relevant regulatory actions occurring since the last review that could affect safety and risk assessments (e.g., withdrawal or suspension from marketing in any country on the basis of safety, reports of recalls):

1. **Other relevant information**
2. Changes in the principal or sub-investigators’ situation or qualifications, with accompanying explanation (e.g., suspension of hospital privileges, medical license, increase in research supervisory responsibilities):  N/A

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Current investigations or charges involving the principal or sub-investigators, with accompanying explanation: N/A

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Changes in the acceptability of the research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable state and local law, or standards of professional conduct or practice, with accompanying explanation:  N/A

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Reports from third party observation of the research, if any (such as an IRB member’s observation of the informed consent process):  N/A

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Monitoring**
2. Has the study been the subject of any monitoring visits since the last IRB review?

Yes\*\*

No

\*\*If you answered yes to the above question, please provide copies of the monitoring report to the IRB.

1. Has the study been audited by FDA or OHRP since prior approval of the research? If so, please provide date and explanation of audit below.

Yes\*\* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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No

\*\*If you answered yes to the above question, please provide copies of the audit report to the IRB.

1. **Informed Consent**

Please check all that apply

Signed informed consent has been obtained from every subject or the subject’s legally authorized representative

The IRB previously granted a waiver or alteration of the informed consent process

The IRB previously granted a waiver of documentation of informed consent

Assent procedures were followed and documented, per protocol or IRB determination, if applicable

1. **Conflict of Interest**

*Prior to IRB re-approval, all personnel listed on the study must complete an updated financial conflict of interest disclosure if there have been any changes to the reported information or if the previous disclosure has expired. The questions below apply to the study on this application. The questions below apply to all members of the study team.*

1. Do any members of the study team or their immediate family members have a financial interest in the sponsoring company? *(This includes honoraria, income, stock/stock options)*

YES

NO

1. Do any members of the study team or their immediate family members have any consulting agreements, advisory positions or management responsibilities with the sponsoring company? *(this includes both paid and unpaid positions)*

YES

NO

1. Do any members of the study team or their immediate family members receive gift funds, educational grants or any other remuneration from the sponsoring company?

YES

NO

1. Do any members of the study team or their immediate family have any ownership or royalty interest in the intellectual property utilized in this study?

YES

NO

1. Have any members of the study team or their immediate family been reimbursed by this company for travel?

YES

NO

If you answered yes to any of the questions above, details must be provided to the IRB office prior to consideration of the submission.

Signature of principal investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*We suggest you keep a copy of the completed submission for your records.*