University of British Columbia – Children's & Women's Research Ethics Board

UBC C&W Research Ethics Board
Room A2-141A
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RESEARCH ETHICS ARTIFICIAL INTELLIGENCE / MACHINE LEARNING APPLICATION SUBMISSION CHECKLIST

The purpose of this checklist is to highlight key items in the evaluation of the ethical acceptability and privacy-related information of a research application which involves the use and/or development of AI/ML algorithms. **Please address each topic described below, either within this document or a separate one, and upload the document to Section 9.8 of the RISe Application. If any of these categories are not applicable to your specific AI/ML application, please indicate this with "N/A" and a brief explanation.**

*****Please note: The REB may send the application to the PHSA AI working group for review, prior to REB review.***

PURPOSE AND CONTEXT OF ALGORITHM

Please describe:

- The specific clinical function of the algorithm (i.e., Treatment response, diagnostics, improved efficiency).
- The target population and clinical setting.
- The intended method of clinical implementation.
- Is this application for the development of a new algorithm or will a previously developed algorithm be used?

QUALITY OF DATA USED FOR ALGORITHM TRAINING

Please describe:

- The population used in the training dataset and any bias this dataset may contain, such as underrepresented demographics in the training or evaluation datasets (dataset bias must be addressed by the study team).
- The degree of missing data in the training dataset and how this was/will be handled.
- How accessible the training dataset is (i.e., open access/restriced use data).
- The interoperability of the algorithm between different technological platforms.
- If the training dataset is able to be stored and reused.
- How reliable the labeling of the training data was or is expected to be.

MODEL PERFORMANCE

- Please describe the internal validation and external validation steps and performance assessment values that were or will be used in this algorithm.
- In the event of the algorithm failing, how will this impact the various groups involved (i.e., patient, clinician, hospital, etc.).
    - Please provide confusion matrix results, if relevant and available.

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CLINICAL INTERPRETABILITY OF MODEL OUTPUTS

- Please clearly list the labels and predictors of the dataset.
- Please explicitly state if an explanation exists for how the predictions were generated, and if the model decision process is transparent, or if a black box model will be used.
- Please describe how model predictions were/will be generated. Please state if this application describes the use of supervised, unsupervised, semi-supervised algorithms.
- Have the features important in driving model predictions been assessed in both general and individual cases (i.e., SHAP values).

MODELS WHERE CLINICAL INTEGRATION IS WITHIN SCOPE OF USE: FIT OF ALGORITHM INTO CURRENT WORKFLOWS

- Please describe how the algorithm is expected to fit and complement the current clinical workflow, including when the algorithm would be applied and the degree of training of clinical staff needed for implementation.
- Please describe how easy it is to use the algorithm in the recommended way and also the consequences of using it in an unintended or wrong way. Please include details on the recommended use (i.e., one piece of evidence in a more holistic assessment or a definite decision tool to automate a process).

MODELS WHERE CLINICAL INTEGRATION IS WITHIN SCOPE OF USE: MODEL TRANSFERRABILITY TO CLINICAL SETTING

- Please describe how the algorithm is expected to perform in different clinical settings, such as varying population characteristics, different medical equipment, etc. and any efforts to adapt it to new settings.

EVIDENCE FOR IMPROVED PATIENT CARE AND OUTCOMES FROM USE OF THE ALGORITHM

- Please describe if this algorithm has been previously used, and if so, its effect on clinical care.

DETRIMENTAL PREDICTIONS OF AN ALGORITHM

- Please consider all potential detrimental effects in use of the algorithm in the context described in this application and describe the efforts that will be taken to avoid outdated or corrupted datasets or harmful predictions.
- Please comment on how the algorithm would be updated and reviewed after deployment and how difficult this will be to perform.

ETHICAL, LEGAL OR SOCIAL CONCERNS OF ALGORITHM

Please indicate the following:

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- Have participants specifically consented to their data being used for this application, or is a waiver of consent being requested? Please comment on how **participant consent** of the corresponding data will be considered during the development of the algorithm.
- Who takes **responsibility for post-implementation monitoring** of the safety and efficacy of the algorithm.
- **Potential material incidental findings** resulting from use of the algorithm and the plan to address these.
- How the various groups involved would be impacted if the **algorithm is failing.**

PRIVACY AND SECURITY CONCERNS

Please indicate the following:

- Is this project being conducted with **partners outside of PHSA**? If so, please decribe the data or products shared with these partners, and if TDO have been notified about the potential need for an agreement.
- Please clearly state **who will have stewardship of the data** used in the algorithm and if any ownership claims of the data are anticipated.
- Who will **own the intellectual property** pertaining to the algorithm.
- Will this research be **conducted internally** within a pre-vetted PHSA environment? Please describe how the data will be accessed, describe the environment and platform. Note that new platforms, environments, or activities that have not been vetted for security and privacy compliance and/or aim to connect with Health Authority systems will require a Privacy Impact Assessment (PIA) and security review.
- How **privacy** will be preserved while using the algorithm. Note that Google Collaboratory is not appropriate to use for sensitive data.
- Does each **study site have the resources/equipment** needed to implement this algorithm for the specific target population, or are there any potential concerns regarding including different institutions with implementation and use of this algorithm.