University of St Andrews

University Teaching and Research Ethics Committee (UTREC)

Ethical Risk Filter Form

This form requires use of Microsoft Word desktop version (available via IT Services)

Interim ethical risk filter form in response to COVID-19

Please complete the ethical risk filter questions - these determine whether your application will undergo full review or proportionate review by your School ethics committee. See the information on the Interim guidance for research involving humans web page.

NOTE: This form refers to ethical risks and should not be confused with the University's travel and fieldwork risk policy or assessment.

Ethical risk filter questions	Yes	No
Will your research involve participants from any of the following groups: • Children aged 16 years or younger (18 in England) • Protected adults • NHS patients or staff • Individuals engaged in criminal activity • Individuals in custody, care homes, or other residential institutions • Individuals impacted by a traumatic event such as war, displacement, acts of terrorism, abuse, discrimination, crime, disasters, life-changing illness or injury, bereavement • Individuals where there is any doubt over their capacity for freely given consent such as through cognitive impairment, language barriers, legal status, terminal illness. • Any other individuals where the researcher or SEC identifies a vulnerability that cannot be satisfactorily mitigated.	☐	☒
Will your research involve sensitive topics such as: • Criminal activity • Traumatic experiences like those detailed above • Self-identity i.e. gender, national, ethnic or racial identity • Body image • Mood or mental health conditions	☐	☒
Will your research involve collection, creation or inference of special category data. Special category data is: • personal data revealing racial or ethnic origin • personal data revealing political opinions • personal data revealing religious or philosophical beliefs • personal data revealing trade union membership • data concerning health • data concerning a person's sex life or sexual orientation • genetic data • biometric data (where this is used for identification)	☒	☐
Will your research involve collection, creation or inference of any other personal, confidential or sensitive data where you feel this might cause distress or that could cause harm should this data be intercepted?	☐	☒
Is there a risk that the research may result in participants becoming distressed? (Consider that this may be harder to monitor remotely and that usual support services may be disrupted)	☐	☒
Will your research involve the use of deception, the withholding of any information about the aims of the research or anything other than total transparency over your role as a researcher?	☐	☒
Will you research involve face-to-face contact between you, or any others associated with the research, and participants? (Note the current restrictions on face-to-face interaction)	☐	☒
If you answered **YES** to **ANY** of the above, your application will undergo full review by your SEC.		
If you answered **NO** to **ALL** of the above, your application will undergo proportionate review by your SEC.		

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Application Form – Cover Sheet

Note: this page contains meta data about your research which is subject to audit and monitoring

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Version 2020_1.1

Researcher Name	Shuen-Jen Chen, Adam Jaamour, Ashay Patel		
Email	sjc29_agj6_ap316@st-andrews.ac.uk	**Date Submitted**	03/06/2020
School/Unit:	School of Computer Science	**Supervisor (if student):**	Dr David Harris-Birtill

Undergraduate	☐	Staff	☐
Postgraduate Research	☐	Postgraduate Taught	☒
Module Co-ordinator on taught module	☐	Module Code	CS5099

Project Title
(If your title is not immediately understandable to a lay audience, be sure it is clearly explained in the project description)

Breast Cancer Detection in Mammograms using Deep Learning Techniques

Project description: Give a concise narrative description without technical terminology of what you are proposing to do; who your participants are (e.g. age, organisation) and how they will be approached/ recruited; where the research will take place (e.g. site, country); what methods you will use, (e.g. survey, interview). *(900 characters for database reasons)* (see exemplars).

This project aims to build on and improve current state of the art deep learning techniques for breast cancer detection using publics dataset of mammograms. All data used has been originally obtained and is now distributed online for further research with the participants' consent. The techniques used are a combination of different deep learning techniques that learn the underlying patterns found in the x-ray pictures of breasts in order to determine the presence tumours, whether they are benign or malignant, and their location in the x-ray. In this project, various deep learning models will be trained, tested and evaluated on the datasets used.

Ethical Considerations: Give an overview of both **the ethical issues raised** by your research and **how you will address** them (see exemplars). This could include: how you will ensure consent is voluntary and informed; confidentiality and how your data will be managed to protect this; potential risks to participants such as distress or reputational harm. NOTE: this should not substantially duplicate the response given in 'Project description' above**.** *(900 character max.)*

The main ethical concern for projects using sensitive medical data (such as medical imagery) is whether it can be traced back to the original patient. In order to ensure that the data cannot be traced back to the patient, the data is fully anonymised by the providers. Furthermore, all data has already been originally obtained and is now distributed online for further research with the participants' consent. The criteria mentioned above will apply to all data used as part of this research and no additional datasets will be published as part of this project. All ethical protocols and data use agreements provided for the datasets will be adhered to. Any work presented as part of this research will contain the anonymised datasets only. There is no way for any participant to be identified along the process.

Has ethical approval for this research already been obtained from an external ethics committee? If YES, do not complete the rest of this form. Instead submit a copy of the external application paperwork and approval, and a copy of this page, to your School Ethics Committee.

In this form there are icons, links and guidance to assist you, hover over them for tips or ctrl+click to follow links:	
	This icon indicates that a supporting document may be required - see Appendix 1. DOCUMENT CHECKLIST
	This icon indicates that you may need to provide an explanation or more information in Q31
	This icon indicates there is guidance on how to answer (hover the pointer over the icon)
	This icon follows 'skip to question X' statements - Ctrl+Click the icon to skip to that part of the document
Link	**This formatting indicates a link to relevant documents or webpages**

RESEARCH INFORMATION		
	1. Estimated start date of research activities	1St June 2020
	LOCATION AND EXTERNAL APPROVALS	
	2. Location of the research	University of St Andrews (remote)
	3. If applicable, have you obtained permission to access the site of research? If YES please state agency/authority etc. and provide documentation. If NO please indicate why in Q31	**NOT APPLICABLE**
	FUNDING	
	4. Is this research funded by any external sponsor or agency?	**NO**
	If **YES**, please provide the name of the funder:	
	5. Does the funder appear on the automatically approved list of ethical funders? If NO, you must complete an ethical funder application and attach the approval to your application	**NOT APPLICABLE**
	COLLABORATION & ROLES	
	6. **a**. Does this research entail collaboration with researchers from other institutions and/or across other University Schools/Units? If YES state name and affiliations below:	**NO**

Name	Affiliation

	b. If the research is collaborative, has a framework been devised to ensure that all collaborators, are given appropriate recognition in any outputs?	**NO**
	7. Where projects raise ethical considerations to do with roles in research, intellectual property, publication strategies/authorship, responsibilities to funders, research with policy or other implications etc., have you taken appropriate steps to address these issues?	**YES**

RESEARCH PARTICIPANTS		
	8. Are you using **only** library or archival sources; media publications; secondary data (with appropriate licenses and permissions) or data in the public domain? If **YES**, but the project has other ethical considerations, skip to Q31 and detail these ⏭ If **YES,** and the project has no other ethical considerations, skip to 'Declarations' ⏭ If **NO**, continue with the rest of the form	**YES**
	9. Who are your participants?	
	10. Describe below how you will identify, approach and recruit participants	
	11. Estimated duration of participant involvement	
	12. Do participants fall into any of the following vulnerable groups? (Check all that apply)	
	Children (under the age of 16 in Scotland or 18 in England and Wales)	☐
	Protected adult, receiving care or welfare services	☐
	People with learning or communication difficulties	☐
	Residents/Carers in a specific location e.g. Care Home	☐
	NHS patients or staff	☐
	People in custody	☐
	People engaged in illegal activities (e.g. drug taking)	☐

ETHICAL RISK CHECKLIST		
	If you answer 'NO' to any of the following please provide a full explanation in Q31	
	13. Will you tell participants that their participation is voluntary and that they can decline to participate with no disbenefit?	**Click to select**
	14. Will you describe the main project/experimental procedures to participants in advance so that they can make an informed decision about whether or not to participate?	**Click to select**
	15. Will you tell participants that they may withdraw from the research within the time specified in the PIS and for any reason, without having to give an explanation, and with no disbenefit?	**Click to select**
	16. Will you obtain appropriate consent from participants?	**Click to select**
	17. If the research is photographed or videoed or taped or observational, will you ask participants for their consent to being photographed, videoed, taped or observed?	**Click to select**
	18. Will participants be free to continue in the study if they reject the use of research methods such as audio-visual recorders and photography?	**Click to select**
	19. Will you tell participants that their data will be treated with full confidentiality and that if published or shared, it will not be identifiable as theirs? (see DATA MANAGEMENT Q30)	**Click to select**
	20. Will participants be clearly informed of how the data will be stored, who will have access to it, and when the data will be destroyed? (see DATA MANAGEMENT Q30)	**Click to select**
	21. Will you give participants a debrief explanation in writing of the study after participant involvement explaining where participants can find out about the results of the project and access sources of support, if appropriate?	**Click to select**
	22. With questionnaires and/or interviews, will you give participants the option of omitting questions they do not want to answer?	**Click to select**
	If you answer YES to any of the following please provide a full explanation in Q31	
	23. Is there any significant risk (inc. physical/psychological harm or distress) to the researcher and / or any participants, field assistants, students, collaborators involved in the project?	**Click to select**
	24. Will your project involve deliberately misleading participants in any way?	**Click to select**
	25. Will any financial inducement, other than expenses, be offered to participants?	**Click to select**
	26. Are any of the participants in a dependent relationship with the investigator? i.e. family members, patients, students	**Click to select**

RISK ASSESSMENTS & INSURANCE		
	27. Does your research require a risk assessment as per University policy ? (if YES, include this with your application, or if it is still being processed, indicate this in Q31)	**Click to select**
	28. For fieldwork and travel abroad, have you checked that you are covered by University travel insurance ?	**Click to select**

DATA MANAGEMENT

Collection, storage and destruction of data should be undertaken in accordance with University guidance and policies plus data protection law. For queries on data protection, contact dataprot@st-andrews.ac.uk ; on research data management, contact research-data@st-andrews.ac.uk. Additional training is available.

In this section, the following definitions are used:

- **Personal data -** information relating to natural persons who: can be identified directly from the information in question; or who can be indirectly identified from that information in combination with other information. NOTE: consent forms are not considered personal data (copies must be securely retained for the lifetime of the research)
- **Special category data** - personal data relating to race, ethnic origin, politics, religion, trade union membership, genetics, biometrics (where used for ID purposes), health, sex life, or sexual orientation
- **Fully identifiable data** - personal data that can be directly linked to an individual
- **Pseudonymised data** - personal data that can be indirectly linked to an individual using a 'key'
- **Anonymised data -** data that cannot be linked to an individual using any reasonable means, is NOT personal data.

29. Given the definitions above - at the point of collection, will data collected by your research include:	
a. personal data?	**Click to select**
b. special category data?	**Click to select**

30. Data Lifecycle

Describe how you will ensure the confidentiality of personal data over the full lifecycle (see exemplars).

You should include in each of these sections:

- What form the data will take, particularly if and how it will be anonymised or pseudonymised or if it will remain identifiable
- Who will have access to the data, e.g. John Doe and Professor X or me and my supervisor/co-researcher(s)
- Secure locations where data is stored, e.g. encrypted file on secure University Server, locked filing cabinet
- Consideration of the requirements of data protection law and Open Access requirements of funders

The information you provide in these sections should reflect the contents of your participant documents

a. Collection and Transfer

Describe what data you will be collecting (ensuring it is the minimum amount necessary for your purposes), including how/when you will collect it, and how you will ensure its safe transfer into storage

b. Storage, Backup and Access

Describe how the data will be securely stored, backed up and accessed

c. Sharing and Publication

Describe if, where and in what form the data will be shared. Researchers should consider institutional, funder and publisher policies before deciding on their approach to sharing data arising from their study. It is crucial that researchers anticipate their potential future data sharing and/or publication requirements.

Some examples of sharing data include:

- depositing the data (raw or edited) in a research data repository
- including data files with a publication, dissertation or other research output
- including excerpts of data like tables, figures or quotes in a publication, dissertation or other research output

If your data will be shared or published in an IDENTIFIABLE form, provide a rationale and further explanation in Q31

d. Retention and Destruction

Describe how long the data will be retained for and if or when the data will be destroyed (see University guidance).
This may be a fixed date, relative to an event such as study completion, or could be indefinite.
Include here if and how the data will change form (i.e. pseudonymised data becoming anonymised for long term retention).

ETHICAL ISSUES

31. Please provide a clear, concise description of your research design and methodology, the ethical issues raised and how you will address them (see exemplars). You should also include:

- Details of how you will obtain consent
- Description and rationale for adjustments made to the template participant documents
- Detailed responses for questions marked ✎, if required.

Use sub-headings for structure where appropriate. If necessary, continue on a separate sheet.

This project aims to build on and improve current state of the art detection and segmentation techniques for breast cancer. We will not be collecting additional data, but we will be using sensitive medical data from the following datasets:

- CBIS-DDSM Cancer Imaging Archive dataset (https://wiki.cancerimagingarchive.net/display/Public/CBIS-DDSM#5e40bd1f79d64f04b40cac57ceca9272).
- DDSM Cancer Imaging Archive dataset (http://www.eng.usf.edu/cvprg/Mammography/Database.html).
- mini-MIAS database of mammograms dataset (http://peipa.essex.ac.uk/info/mias.html).

These datasets contain fully anonymised mammograms that have been originally obtained and are now distributed online for further research with the participants' consent. In this project various algorithms will be trained, tested and evaluated on the datasets used.

The main ethical concern for projects using sensitive medical data (such as medical imagery) is whether this data can be traced back to the patient. The anonymised nature of the datasets ensure that the data cannot be traced back to the patient. Furthermore, all data has been originally obtained and now distributed for further research with the participants' consent. The criteria mentioned above will apply to all data used as part of this research and no additional datasets will be published as part of this project. All ethical protocols and data use agreements provided for the datasets will be adhered to. Any work presented and analysed as part of this research (and future publications) will contain the anonymised datasets only. There is no way for any participant to be identified along the process. The data presented and analysed may be further published in conference/journal articles, where the data will remain anonymised.

[If you answered questions:
3. If applicable, have you obtained permission to access the site of research?

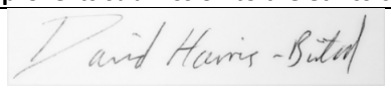
If YES please state agency/authority etc. and provide documentation.
If NO please indicate why in Q31
8. Are you using only library or archival sources; media publications; secondary data (with appropriate licenses and permissions) or data in the public domain?
If YES, but the project has other ethical considerations, skip to Q31 and detail these ⏭
If YES, AND the project has no other ethical considerations, skip to 'Declarations' ⏭
If **NO**, continue with the rest of the form13-22. If you answer 'NO' to any of the following please provide a full **explanation**
23-26. If you answer YES to any of the following please provide a full **explanation**
30c. If your data will be shared or published in an IDENTIFIABLE form, provide a rationale and further explanation
Appendix 1. DOCUMENT CHECKLISTif your application is made prior to obtaining any required external approvals or documents, describe how you will ensure that these are in place before your research commences
TIP: You can Ctrl+Click on the question text above to go to that question] Delete/overtype this guidance as required.

DECLARATIONS	
○ I am aware of, understand and will enact my responsibilities as a researcher as detailed in: ○ The University's Principles of Good Research Conduct policy and ethical guidelines ○ Any relevant professional guidelines (e.g. BPS, MRC, ASA) ○ The University's Policy and guidance on Data Management and Protection	☒ ☒ ☒
○ I am aware of the conditions of any funding associated with my work and will ensure that information given to my research participants is in line with those conditions.	☒
○ I understand that I must store the final completed copy of this form as part of my research project paperwork.	☒

Researcher signature		**Date**	03/06/2020

ADDITIONAL SECTION FOR STUDENT RESEARCHERS

Student researchers must not submit an ethical amendment application without first discussing it with their Supervisor, and the Supervisor reading and signing this form. Applications submitted without the below section completed by the Supervisor will be returned to the applicant.

Supervisor Comment			
I confirm that I have discussed the ethical implications of this project with the student applicant, that I have read this application, and that I approve its submission to the ethics committee for consideration			
Supervisor signature		**Date**	03/06/2020

Submission guidance:

To submit your application, it must be sent to your School Ethics contact:

- Electronic form (.doc, .docx, .pdf) is the preferred submission format for Ethics Applications, as it allows for easy transferral of text to the database
- If you submit a scanned copy of a handwritten or typed form, or a hardcopy, please email your School Ethics contact an electronic form version of the Cover Sheet (first page).

Signing the form:

- Creating an electronic signature is straightforward – sign a piece of blank paper, take a photo i.e. with a smartphone, copy and paste the image into the signature box and resize it as necessary
- If you or your supervisor wish to physically sign a hardcopy, please follow the guidance above on submission requirements
- If you/your supervisor choose to type a signature:
  - staff: email the form to your School Ethics administrator from your @st-andrews.ac.uk email address to confirm your identity.
  - students - email the form to your supervisor from your @st-andrews.ac.uk email address.
    - supervisor: add your name/ signature to the form and then forward it to the School Ethics administrator from your @st-andrews.ac.uk email address

Under **no circumstances** should this form, or supplementary documents, contain identifiable information about your participants i.e. completed consent forms.

APPENDIX 1. DOCUMENT CHECKLIST

Please ensure **all relevant documents** are attached to your application.

You should indicate in Q31 if your research will require any additional documents/approvals. If you have approvals in hand when submitting this form, you should append these to the application and indicate this below. Some School Ethics Committees may require all documents/approvals to be fully obtained before you seek ethical approval.

For online research, such as surveys, you may include relevant screenshots or excerpts of text instead of forms.

Templates are available for some documents, follow the links. Preferably, template participant documents should be used as given. You may adjust the content to suit your project, but you MUST document a rationale for the changes in Q31 of the application form

Application document(s)	**Attached?**	**When to include this**	
Participant Information Sheet	**NOT APPLICABLE**	Research involves human participants	
Participant Consent Form	**NOT APPLICABLE**	Research involves human participants	ⓘ
Participant Debrief	**NOT APPLICABLE**	Research involves human participants	ⓘ
All advertisements	**NOT APPLICABLE**	Participants will be recruited using adverts	ⓘ
Questionnaire / Online Survey Screenshots	**NOT APPLICABLE**	Research includes questionnaires or surveys	ⓘ
Interview questions/Focus Group guide	**NOT APPLICABLE**	Research includes interviews or focus groups	
Copies of letters to parents/ guardians/children	**NOT APPLICABLE**	Research involves children or educational establishments	ⓘ
External approvals/documents	**Attached?**	**When to include this**	
Data Management Plan (DMP)	**NOT APPLICABLE**	ONLY if you already have a DMP (e.g. due to funder requirements). If YES, also email a copy to research-data@st-andrews.ac.uk.	ⓘ
Ethical funder approval letter	**NOT APPLICABLE**	The research is funded by an organisation not on the approved funders list	ⓘ
Risk assessment	**NOT APPLICABLE**	Research involves fieldwork risk, such as travel abroad or lone working	ⓘ
Insurance documents	**NOT APPLICABLE**	May be required for fieldwork or travel abroad	ⓘ
DBS / PVG documents	**NOT APPLICABLE**	Research involves vulnerable participants: • Children (under 16 in Scotland/18 in England) • Vulnerable adults	ⓘ
External permission forms / emails	**NOT APPLICABLE**	Research requires permission for access to sites, data, participants or other aspects.	ⓘ
Security sensitive research declaration	**NOT APPLICABLE**	Research involves contact with individuals, data or material linked to terrorist or extremist activity	ⓘ
External ethical application/approval documents	**Attached?**	**When to include this**	
NHS ethical approval documents - in full	**NOT APPLICABLE**	Research involves: • NHS data, patients, sites or staff • Participants who are in custody Participants who are in care	ⓘ

Ethical approval documents (in full) from an external review body	**NOT APPLICABLE**	Your research has already been reviewed and approved by another institution or organisation	

Please list below any other documents that are included in your application: