NIHR | Manchester Biomedical Research Centre

Micrima

MANCHESTER 1824 The University of Manchester

Breast Density Community Project

Information Sheet Summary

We are looking at new ways to measure breast density in younger women. Breast density helps to understand if someone is at a higher risk of breast cancer.

WOMEN AGED 30–49

1 VISIT LOCAL COMMUNITY CENTRE OR GP

- You will meet a female healthcare professional
- You can bring a family member or friend with you
- You will be in a private space for your visit

2 THE HEALTHCARE PROFESSIONAL WILL:

- Ask for your age, date of birth and bra size

3 THE HEALTHCARE PROFESSIONAL WILL:

- Measure your height and weight

4 REMOVE YOUR T-SHIRT/TOP AND BRA

5 THE HEALTHCARE PROFESSIONAL WILL USE MI~SCAN® TO MEASURE YOUR BREAST DENSITY

- The Mi~Scan® device is safe to use
- The Mi~Scan® device gently touches the breast
- There is **no** chance you will be told you have cancer

6 COMPLETE A SURVEY ABOUT YOUR VISIT

- You can also sign up for an optional group discussion at a later date

7 WE GIVE YOU A £12.50 GIFT VOUCHER

- The visit will take less than 30 minutes

Please read the full participant information sheet for more details.
Use this link to book your visit: https://tinyurl.com/2rcprvw7
You can contact the study teem on 07818 975 073 or email molly.parfett@manchester.ac.uk if you have any questions

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Breast Density Community Project

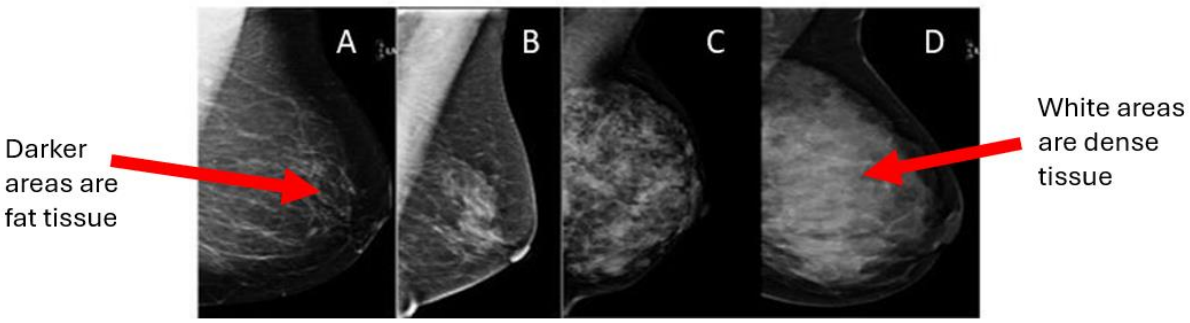
Participant Information Sheet

You are being invited to take part in a research project to find out what women in your community think about an experimental device that scans breasts to measure breast density. Before you decide to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

What is the purpose of the project?

In the UK, **breast cancer affects 1 in every 7 women** and is the top cause of death in women aged 35 to 49 years old. Cancer researchers are working to identify young women who are more likely to develop breast cancer as early as possible. Health professionals can then offer early breast screening and prevention measures to reduce women's cancer risk and help diagnose cancer early, when treatments are most effective.

The four pictures below are mammograms from four different women with low to high breast density from left to right (A to D). Women with more dense breasts (type D) have a higher risk of breast cancer than women with less dense breasts (type A).



Women can be put off going for mammogram scans, because they can cause discomfort, use a small dose of radiation and may not be available close to home. Because of this, researchers want to test new ways to measure breast density.

We are working with a company called Micrima, who have created a new desktop scanning device to measure breast density. The device is called Mi~Scan® and it uses radiofrequency waves not ionising radiation. Radiofrequency waves are also used by your mobile phone and are completely safe. Women can have Mi~Scan® in their local community instead of having to travel to a hospital.

To help us learn more about this experimental device, we want to find out what women in your community think about it, including how comfortable the scan is and where people would like to receive the scan, for instance at their GP surgery or in a community setting such as a Church Hall or Community Centre.

It is important to note that Mi~Scan® is not a test for cancer and there is no chance that you will be told you have breast cancer if you take part. By taking part, you will not find out your breast density score as this project is focusing on what women think about the Mi~Scan® device. The device is not a diagnostic test for breast cancer and studies to confirm how well it assesses breast density are ongoing. The Mi~Scan® device does not replace screening mammograms. You will still receive your first invitation to breast screening between the ages of 50 and 53 if you are registered with a GP.

In the future, researchers hope that Mi~Scan® will help identify women who are more at risk of breast cancer when they are young, so these younger women can be offered preventative medicines and breast screening.

Why have I been invited to take part?

We are inviting **women aged 30 – 49 years** in Manchester.

If you were **approached by your GP**, you are invited to attend an appointment at the Manchester Integrative Medical GP Practice.

If you saw us promoting the project **in your community**, you are invited to attend an appointment at a community venue.

Whilst we are keen for women from **all ethnicities** to take part, we are particularly interested in hearing from women with **Black African or Black Caribbean heritage**. This is because research has found that young Black women are more likely to get breast cancers that grow and spread quickly. We want to make sure that Black women can take part in this project to ensure this research is meaningful and valuable to the Black African and Black Caribbean community. However, we do not

want to exclude women from any other ethnic groups as we believe Mi~Scan® should be useful for all.

We hope that 240 women agree to take part in this project.

Who is not able to take part?

You will not be able to join the project if:

- You have previously been diagnosed with breast cancer
- You have had both of your breasts removed (a double mastectomy)
- You are currently pregnant or breast feeding
- You are under follow up in a breast cancer history clinic or have known mutation in a high-risk cancer gene such as BRCA1 or BRCA
- You have any implantable electronic devices (e.g., a pacemaker)
- You have non-removeable nipple piercings
- You have had breast implants or augmentation surgery
- You have areas of broken skin on the breast or armpit
- You have conductive or electronic (tech) tattoos
- You were not born female
- You cannot understand written and verbal English

Do I have to take part?

No, it is up to you to decide to take part or not. Before you decide we ask you to read this information leaflet and get in touch with the research team if you have any questions.

You can take part in the breast density scan without taking part in the follow up focus group discussion.

What will I need to do if I take part?

If you decide to take part, we will ask you to do the following:

1) You will need to attend an appointment to have the breast density scan. You will be able to choose a date/time that suits you. The location of your appointment will depend on how you were invited to take part in the project:
    a. **If approached via your GP,** you will need attend a local GP practice at the time and date you booked online
    b. **If you signed up at a community setting,** you will need to attend the community setting at the time and date you booked online
2) The health professional conducting the scan will check that you are eligible to take part in the project by asking you about the questions from '*Who is not able to take part?'* section above.
3) If, after reading this information sheet and speaking to the health professional, you decide to take part in this project, we will ask you to read and sign the consent form.

4) The health professional will ask for your date of birth and measure your height (in metres), weight (in kg) and bra size.
5) The health professional will then measure your height and weight.
6) You will then be asked to take off your top and bra to have the Mi~Scan®. Please note - **the health professional doing your scan will be a woman.**
7) **The scan will be done as follows:**
    a. You will be asked to remove any jewellery or tie up long hair which may get caught up during the scan process and then undress to the waist (removing your top and bra so your breasts are exposed).
    b. You will sit in a chair, facing the health professional performing the scan.
    c. The health professional will lightly touch the two small pads of the Mi~Scan® device onto the skin surface of your breast and obtain a measurement. The position of the pads will then be moved, and another reading will be taken.
    d. A total of 12 measurements will be taken on one breast and then the whole process will be repeated on your other breast.
    e. This will be the end of the Mi~Scan® and you will be asked to put your clothes back on.
8) After the scan, you will be asked to complete a short questionnaire. The health professional can help you read or complete the questions if you would like. The questionnaire will take about 5 minutes and will have three sections:
    a. Your opinions about having the scan
    b. How satisfied you were with the information you received
    c. Questions about you and your background
9) You will receive a **£12.50 Love2Shop voucher** to say thank you for your time taking part in the project.
10) If you would like, you can take part in a **focus group** to discuss your views further with a group of women. If you are interested, you will be asked to provide your contact details on the consent form.

The entire process of having the scan and completing the questionnaires should take around 15 minutes. **You will not be told your breast density or your risk of breast cancer if you take part** because this project is just finding out what women think about the Mi~Scan® device.

If you present with an abnormality in your breast at the appointment, the healthcare professional will discuss this with you. If it is a new concern that has not received medical attention and you would like to seek further investigation, we will contact your GP by letter to request further examination and onward referral if needed. The healthcare professional conducting your scan will not be qualified to examine the breast and will not be able to advise on any symptoms you are experiencing.

What will I need to do if I take part in the optional focus group?

1) If you indicate that you are interested in taking part in an optional focus group on the consent form, the research team will contact you to ask which days or times

you are available. The research team will then confirm with you by phone or email when the focus group will take place.

2) You will have the option to attend an in-person focus group at a community venue or online (via Teams). If you attend an online focus group, we will encourage you to turn your camera on to make the session as engaging as possible.
3) You can expect the group to be with approximately 7 other women and the discussion will last around 60 minutes.
4) Before the focus group starts, you will have the chance to ask any questions about what will happen during the session. If you are still happy to take part, you will give informed consent to the research team. If you attend in-person, you can complete a written form and if you attend online, you can call a phone number to speak to a member of the research team.
5) A member of the research team, known as a moderator, will lead the discussion. The moderator will ask the group about things such as what you thought about how you were invited to the project and how you found the scan. There will be another researcher, known as a mediator, taking notes. **There are no right or wrong answers in a discussion of this kind – we are simply interested in your opinions.**
6) At the end of the focus group, you will receive a **£25 Love2Shop voucher** to say thank you for taking part. If you attend the meeting in person and you bring receipts, we will be able to cover reasonable expenses such as travel or childcare costs.
7) The focus groups will be recorded to make sure everyone's views and ideas are captured. The recordings will be stored securely at the university.
8) If you would like us to, we can update you about the results from the project and provide you with information on other studies you might like to take part in.
9) We will share the results of the project at an in-person event, which all the research team and participants will be invited to.

What are the possible benefits of taking part?

If you take part, you will be contributing to research aimed at identifying women who are most at risk of developing breast cancer, before it happens. The results of this research project may help women in your community so that more women survive breast cancer in the future.

What are the possible disadvantages and risks of taking part?

The scan

As you will be undressed to the waist for the procedure, you may feel embarrassed. However, the person taking the measurements will be a woman and will be a qualified health professional with lots of experience working with women.

The focus group

If you know anyone who has been impacted by breast cancer, you may find some of the topics discussed slightly distressing. You will be able to take a break or leave the focus group at any point you wish to. We will also share information on organisations in Manchester that can offer you support.

Is the Mi~Scan® device safe and how does it work?

The Mi~Scan® device has been independently tested to ensure it is safe to use. The device uses radiofrequency waves to measure breast density. By taking the 12 measurements of each breast the Mi~Scan® builds up a measurement of the density in your breast, similar to the one created from a mammogram image. Radiofrequency waves are the same waves used by your mobile phone and are completely safe. The device was submitted for CE marking under the Europe Union Medical Device Regulations in August of 2024. The CE Medical Device Regulations are a set of European Union (EU) regulations that govern the safety and performance of medical devices. The regulations require that medical devices have a CE (Conformité Européenne) mark before they can be sold in the EU (including the UK). This process can take over twelve months to complete. To enable the device to be submitted for CE marking review it first required safety testing, by independent test laboratories to meet all the applicable state-of-the-art international safety standards. In order for the device to be used in clinical trials, ahead of receipt of this CE mark, the device has been reviewed and approved for use in clinical trials by the UK Medicines and Healthcare products Regulatory Agency (MHRA) that regulates medical devices. The Mi~Scan® device has been used in clinical trials since June 2024 with no adverse events. However, like any other device which is attached to mains electricity it comes with a very small theoretical risk of electrocution or fire if not used according to the instructions for use.

How do I withdraw from the project?

The scan

If you sign up to the project but then decide that you no longer want to be part of it, please let the research team know. If you withdraw, any data which has already been gathered will be retained in order to protect the validity of the research. Please note the data you share in the optional EDI questionnaire will be stored anonymously so that it is not possible for anyone, even members of the research team, to identify you.

The focus group

If you sign up to the focus group but then decide that you no longer want to be part of it, please let the research team know. You can withdraw from the focus group at any point before the focus group begins, without giving a reason and without your legal or medical rights being affected. It will not be possible to withdraw from the focus group once the focus group has begun. You will be reminded before the focus

group starts that once the discussion begins, your input and contributions in the focus group cannot be removed.

What will happen to the results of the project?

- We will share the results of the project at an in-person event, which all the research team and participants will be invited to.
- Fully anonymised questionnaire data and fully anonymised transcripts of the focus groups, whereby any identifiable information is removed, will be deposited in an open data repository at the end of the project.
- The results of the project will be published in medical journals. Please note **you will not be identified in any reports or publications**.
- If you would like a general summary of the results of the project when they are available, please indicate this on the consent form or contact the research team.

What information will you collect about me?

In order to participate in this research project, we will need to collect information that could identify you called “personal identifiable information”. Specifically, we need to collect information about you such as your name, age, ethnicity, postcode and record of consent. We will use a questionnaire to find out more about your experience of the breast density scan. We will collect your breast density data to check that the Mi~Scan® device worked as expected.

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

How will we use information about you?

We will need to use information from you for this research project. This information will include:

- Name
- Preferred contact details
- Date of birth
- Your weight, height and bra size
- Questionnaire responses, including about you and your background
- Breast density data
- Anonymised data from the focus groups, if you choose to participate in this part of the project.

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Manchester Research Governance Ethics and Integrity Office is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Storing your information in a pseudonymised form
- Ensuring that only the research team have access to study documents
- Storing all physical documents in a locked cabinet in a locked university office
- Ensuring all online documents are password protected
- Storing the Mi~Scan device and the laptop connected to it in a locked room
- Following the University of Manchester's Research Data Management Policy

The purpose of the study is to explore whether the scans are acceptable to both the women who take part, and the healthcare professionals who are conducting the scans. For this reason, the healthcare professional will perform the scan using the live Micrima software to collect breast density data. Your breast density data will be shared with the company Micrima in a pseudo-anonymised form. This means that your breast density data will be stored using a unique ID number to ensure your confidentiality. The University of Manchester will be able to link your ID number to your identity using a linkage document but Micrima will not have access to the linkage document so they will not be able to identify you or link the breast density data back to you. The company will analyse all the breast density data from the project to confirm that the device worked as expected. As soon as the company has successfully completed their analysis, the company will delete the breast density data from the device. The results of the breast density data analysis will be archived in the University's Research Data Storage for 5 years after the study results have been published.

Your responses to the optional Equality, Diversity and Inclusion (EDI) questionnaire will be kept and managed separately from any other information that you provide to us. We may use this data to give a report of the demographics of this project, but no individual information will be identified. We may share this EDI data with others at the university and it may be included in reports or published in the context of understanding inclusion, but this is likely to be as part of a wider set of data. We will retain this data for at least 15 years. There is a chance that this data will be merged with other, larger data sets, and may be kept in this form for longer than 15 years e.g., as part of monitoring Division inclusion annually over time.

If you choose to take part in a focus group, we will record the discussion using an encrypted device. If you participate in a face-to-face focus group this will be an audio recording. If you participate in an online focus group, the recording will record the

video and audio. At the end of the project we will deposit a fully anonymised dataset, including de-identified interview transcripts, in an open data repository where it will be permanently stored. We will use Figshare at the University of Manchester Library. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

Recordings will be uploaded to the University's Research Storage server (Isilon), password protected and encrypted. The researcher will listen to the recording to check the upload and will then permanently delete the recording off the device. Recordings will be stored on Isilon until the final analysis of results have taken place. The recording files will be deleted once they have been transcribed and papers written up for publication. Anonymised transcripts will be archived in the University's Research Data Storage for 10 years after the study results have been published.

Recordings will be transcribed by 1st Class Secretarial, a University approved transcription service under a confidentiality agreement. Recordings will be uploaded to a personal encrypted folder on 1st Class Secretarial's secure server. 1st Class Secretarial will upload completed work to this folder after an internal check for errors has been performed. All files are transferred using 256-bit SSL encryption and stored using 256-bit AES encryption. The research assistant will download the transcripts from the folder onto a University password protected computer. Transcripts will be stored as password protected files on Isilon. The research assistant will proofread all transcripts whilst listening to the recording to assure accuracy of the data. The production and storage of recordings and transcripts will be carried out in accordance with the University's Standard Operating Procedure for secure handling of recordings and transcriptions.

The data collected during this research may, in future, be used for secondary analysis in combined anonymised form. This means that your data is gathered together with everyone else's, with all personal identifiers removed to ensure your privacy and confidentiality. This work could support further research projects or educational activities (including training and capacity building), conducted by our research team or by others who have received our permission to use the data for their projects.

International transfers

Your data will not be shared outside the UK.

Will my information be kept confidential?

Yes. We will follow ethical, legal and data protection practices and all information collected about you during the research will be kept strictly confidential. In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means we are responsible for making sure your personal information is kept secure, confidential, and only used in the way you have been told it will be used. Your personal details will be removed before we analyse any data. For analysis your questionnaire information will be given a code that

cannot be linked with your records. Only the research team will be able to identify you.

We **will not** share any personal information about you with the company Micrima. We will share the results of the analysis with Micrima where no personal information will be included. We will share the breast density data with the company Micrima in a pseudo-anonymised form, where it will not be possible for the company to identify you. This means that your breast density data will be stored using a unique ID number to ensure your confidentiality. The University of Manchester will be able to link your ID number to your identity using a linkage document. However, Micrima will not have access to the linkage document so they will not be able to identify you or link the breast density data back to you.

Please note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this project to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in monitoring the project will have a strict duty of confidentiality to you as a research participant.

After the project is completed, your data will be stored in secure storage and in password protected files at the University of Manchester for 5-10 years after which your data will be destroyed. We stored your data for this length of time in order to address any questions about the project, for example, to evaluate how the project has been conducted.

If you choose to take part in a focus group online, your participation in this research will be recorded using Microsoft Teams and your personal data will be processed by Microsoft. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place.

These recordings will be removed from Teams and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. A fully anonymised transcript, whereby any identifiable information is redacted, will be deposited in an open data

repository at the end of the project. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- Our leaflet: http://documents.manchester.ac.uk/display.aspx?DocID=37095
- HRA leaflet: http://www.hra.nhs.uk/patientdataandresearch
- By sending an email to molly.parfett@manchester.ac.uk

What if there is a problem?

You can report any concerns you have about any part of the project to the research team using the contact details at the end of this leaflet.

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information at https://ico.org.uk/make-a-complaint/ or phoning the helpline 0303 123 1113.

What if something goes wrong?

The University of Manchester will arrange insurance for research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students, subject to policy terms and conditions.

In the event that something does go wrong, and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Manchester, but you may have to pay your legal costs.

Who is organising and funding the research?

The project is being run by the University of Manchester.

Researchers from the University of Manchester worked together with public contributors, a GP (Manchester Integrative Medical Practice) and the company Micrima to design this project.

The breast density device (Mi~Scan®) was developed by the company Micrima.

To make sure the project is meaningful and appropriate for the people it aims to serve, two public advisors worked as part of the research team. The team also worked with Cancer Care Diaspora to consult with twelve local women through a discussion group.

The project is funded by a grant from Greater Manchester Cancer Alliance.

The project management work was funded by the Manchester Biomedical Research Centre.

The public involvement work to help design the project was funded by The Sarah Harding Appeal.

Who has reviewed the project?

All research in the NHS is approved by the Health Research Authority (HRA) and reviewed by an independent group of people called a Research Ethics Committee (REC). The Research Ethics Committee is made up of experts, non-experts and members of the general public. Together they review research applications to ensure your safety, rights, wellbeing and dignity are protected at all times. This project has been reviewed and given favourable opinion by the West of Scotland Research Ethics Committee 4 (REC Reference 25/WS/0016). The MHRA have also reviewed the application.

Where can I find out more about breast cancer?

Cancer Care Diaspora **Website:** https://cancercarediaspora.org/ **Phone:** +(44) 788 573 2781 **Email:** info@cancercarediaspora.org This organisation provides practical, culturally sensitive support and information to those affected by cancer. It is based in Central Manchester.	**CAN-Survive UK** **Website:** https://can-survive.org.uk/ **Telephone:** 0161 232 1286 **Mobile:** 07496089310 **Email:** info@can-survive.org.uk Can-Survive UK provides culturally sensitive support and information to people living with and beyond cancer, their families and carers.
Prevent Breast Cancer **Website:** https://preventbreastcancer.org.uk/ **Telephone:** 0161 291 440 This charity is based in Manchester and promotes breast health awareness. They have information about breast cancer, cancer risk and early detection on their website.	**Maggie's Manchester** **Website:** https://www.maggies.org/our-centres/maggies-manchester/ **Telephone:** 0161 641 4848 **Email:** manchester@maggies.org Maggie's offers support free to anyone with cancer and their families.
Breast Cancer Now **Website:** https://breastcancernow.org/ **Telephone:** 0808 800 6000 (free confidential helpline) This national charity supports people affected by breast cancer, raises awareness of breast cancer and funds new research.	**CoppaFeel!** **Website:** https://coppafeel.org/ This national charity raises awareness of breast cancer and shares information on how to check your breasts. You can text 'CHECK' to 82228 to receive free monthly reminders to check your breasts.
MacMillan **Website:** https://www.macmillan.org.uk/ **Telephone:** 0808 808 00 00 (confidential support for people living with cancer and their loved ones) MacMillan is a national charity which provides support to anyone impacted by cancer.	**Cancer Research UK** **Website:** https://www.cancerresearchuk.org/ **Telephone:** 0808 800 4040 (confidential free helpline to speak to nurses) This national charity shares information on cancer, influences better policy to improve cancer detection and treatment and funds new research.

Research team contact details

For further information about the project please contact: Molly Parfett, Research Assistant

Address: Manchester Centre of Health Psychology
School of Health Sciences
University of Manchester
Coupland 1 Building
Oxford Road
Manchester
M13 9PL

Telephone: 07818 975 073

Email: molly.parfett@manchester.ac.uk

Thank you for taking the time to read this information sheet