Participant Information Sheet – Focus Groups

Project title: SWARM – **S**mall robots **W**ith collective behaviour as **A**I-driven cancer therapies; building **R**egulations for future nano**M**edicines

Thank you for expressing interest in the SWARM study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and if you have any questions about any aspect of the study, please contact Matimba Swana, Department of Engineering, University of Bristol, Matimba.Swana@bristol.ac.uk. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the purpose of the project?
This project is investigating the ethical and regulatory complexity of the first in-human clinical trial of robotic nanoswarms. The aim is to explore how swarm medicine should be regulated in clinical trials, as well as the attitudes of stakeholders towards this new technology. The results of our study will be analysed and may be used in conference papers and peer-reviewed academic papers.

The project is part of a PhD which aims to develop a regulatory framework for nanoswarms in clinical trials. The project lead is Matimba Swana, a PhD student based at the University of Bristol. Jonathan Ives and Sabine Hauert are the supervisors for this PhD research. Please find their details at the end of this document.

What are nanoswarms and why should we think about the regulations?
With new medical technologies we are always trying to make these technologies better, be more specific and safer so that in the future these technologies can help people who get sick. One day, we could use millions of tiny particles or tiny man-made robots, smaller than a blood cell**.** We can “programme” the behaviour of these **so they can act as a collective and can interact with each other and their environment (nanoswarms)**. Nanoswarms can:

- move through the body in a controlled way;
- create a map to the desired site and gather there, this allows for controlled drug release at the site;
- regulate the shape and size of the group;
- interact with each other while sensing and monitor the environment of the body;
- stick to cancer cells;
- work together to move objects which are too heavy or too large for individuals so they have the capacity to carry higher payloads of drugs.

So what? Well for example, people with cancer currently take a medicine that gets rid of both healthy and cancer cells so they can have side effects that make them sick. The aim of cancer treatment is to achieve a cure, and when a cure is not possible, treatments are needed such as targeted therapy that uses drugs designed to "target" cancer cells without affecting normal cells. These nanoswarms could be used to help someone who has cancer, the nanoswarms would be injected or inserted into a person's body, they then travel to the site of the cancer in the body and deliver medicine to the cancer cell and make the person feel better. In addition the nanoswarms could be personalised, so it would be made for that person and their specific cancer. **Before we do this we need to look at when we want to do this, why we want to do this, how will we do this, what do we need to have in place when this is ready as well as what all the good and bad things that this can cause**.

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We want to hear from you to understand what you think of this, how it makes you feel, if you think it is important and if you should have a say in how this is studied and used.

Why have I been invited to participate?
You have been asked to participate because we believe you are either interested or involved in the development of new drug technologies, you are involved in regulating, prescribing, or influencing new drug technologies, or you are a member of the public who may one day be a user of new drug technologies.

Do I have to take part?
You do not have to take part in this research. It is up to you to decide whether or not you want to be involved. If you do decide to take part, you will be given a copy of this information sheet to keep and will be asked to sign a consent form. If you do decide to take part, you are free to stop and withdraw from the study at any time without giving a reason.

What will happen to me if I take part and what will I have to do?
Participation is voluntary and involves you participating in a focus group discussion with around 4-7 other people. If you agree to take part you will be asked to select a time to participate via a doodle poll. The focus group will be run by Matimba Swana either in person or online. The focus group will last for approximately 60 minutes. The discussion will focus around your experience and opinions on how we should regulate clinical trials of nanoswarms.

You will be presented with a written summary outlining nanoswarm technology that will be sent to you prior to the focus group. We will review this summary, which will be followed by questions/answers on this summary. At the start of the focus group, you will be presented with a draft proposal for how to regulate clinical trials of nanoswarms. We will then facilitate discussion between all the members of the focus group about what you think of the proposal.

The discussion will be audio recorded in full. The audio recording will then be transcribed (written down) and deleted to keep your data anonymised. If you have any questions prior to the focus group, please, do not hesitate to contact Matimba.Swana@bristol.ac.uk.

What are the possible disadvantages and risks involved in taking part in the project?
No risks are anticipated, and you are free to leave the focus group at any time. You will not be pressured in taking about anything you do not want to.

What are the possible benefits of taking part?
There are not significant benefits to taking part. However by taking part in this study you will be helping us to gain a better understanding of the ethics and regulatory requirements for clinical trials of nanoswarms. As a token of thanks for your time, we will offer you a £10 Amazon voucher, or we will make an equivalent value donation to a charity of your choice.

Will my participation in this project be kept confidential?
You will be in a group with other participants, and you will interact with other participants. We will impress upon every member of the focus group the importance of not disclosing who said what during the discussion, but it is not possible for us to enforce this. As such the following applies to what we will do to maintain confidentiality.

We will keep your participation in this project confidential. This means we will not tell anyone that you have taken part in this study, and no identifying information about you will be published or communicated outside the research team. Your input from the focus groups will be used only by the research team to analyse and summarise the outcomes of the study. We will use your words from the focus groups in publications about the project, but we will not publish anything that identifies you.

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Any personal information (e.g. your name, or contact details) we collect about you during the course of the research will be kept strictly confidential and will only be accessible to members of the research team. According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)).

All your personal data will be confidential and will be kept separately from your responses. If you agree to take part, you will be asked to sign a consent form in advance of the interview, which will be stored securely at Bristol University for a period of 10 years, after which time it will be securely destroyed or deleted.

The research team will take several steps to anonymise the data and make sure you cannot be identified from what you say. First, audio recorded data will be transcribed (with any identifying information removed). The audio recordings will be stored securely for the duration of the project and then deleted by April 2025 which is approximately the end of the PhD project. You will be allocated a participant number that will be used to label all your data. The key that links your participant ID, name and consent form will be stored securely and separately from all the research data.

Only members of the research team and responsible members of the University of Bristol may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All these people have a duty to keep your information, as a research participant, strictly confidential.

Consent forms will be completed digitally and stored on the University of Bristol's secure cloud storage. Hard copy material (the consent form) will be kept in a locked and secure setting to which only the researchers will have access in accordance with University policy, the Data Protection Act 2018 and General Data Protection Regulation (GDPR) requirements.

All identifying information we receive from you will be treated in the strictest confidence and all published data will be completely anonymised.

What does it mean for my data to be shared in the online Research Data Repository?
If you agree to data sharing then the anonymised focus group transcript will be deposited on an online data repository managed by the University of Bristol (data.bris). The anonymised transcripts will NOT be destroyed and this data may be shared with other researchers in the future, if they are approved by the University. Other authorised researchers may use anonymised transcripts in publications, reports, web pages, and other research outputs, as long as they have permission from the University of Bristol. Your personal details will never be shared.

What if I change my mind and want to withdraw from the study?
You can withdraw up to the completion of the focus group without giving a reason. After this point, your data would have already been analysed and cannot be removed from the study completely. It will not be possible to withdraw from the study at all once the data has been published. If you decide to withdraw from the study, it may not be possible to withdraw any information you provided at the focus group. The researchers might not be able to distinguish your input from that of others in the group. In all cases any data the researchers use will be anonymised and not attributable to any individual participants.

What will happen to the results of the research project?

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Research findings will be written into a PhD thesis and will be written up for publication in academic journals and presented at conferences.

Who is organising and funding the research?
This is part of a Trustworthy Autonomous Systems Node in Functionality PhD project funded by UK Research and Innovation (UKRI) / the Engineering and Physical Sciences Research Council (EPSRC).

Who has reviewed the study?
The project has been reviewed and approved by University of Bristol Faculty of Engineering Research Ethics Committee, ref 11141. Any comments, questions or complaints about the ethical conduct of this study can be addressed to the Research Ethics Committee. If participants have any concerns related to their participation in this study please direct them to the Faculty of Engineering Research Ethics Committee, via Liam McKervey, Research Governance and Ethics Officer (Tel: 0117 331 7472 email: Liam.McKervey@bristol.ac.uk)

Further information and contact details
Project Supervisors:
Professor Jonathan Ives Jonathan.Ives@bristol.ac.uk
Dr. Sabine Hauert Sabine.Hauert@bristol.ac.uk

If you would like any further information about the research please contact in the first instance:
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Thank you for agreeing to take part in this study. You will be given a copy of this Participant Information Sheet and your signed Consent Form to keep.

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