Imperial College London

ATLAS

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TRUST LOGO

Informed Consent Form for a study called IP9 - ATLAS

Study Title:	**Full Study Title:** A randomised controlled trial of regular MRI scans compared to standard care in patients with prostate cancer managed using active surveillance. **Short Study title / Acronym:** Imperial Prostate 9 – ATLAS (**A**pproaches **T**o **L**ong-Term **A**ctive **S**urveillance)
Study Number:	IRAS Number: 328263 Sponsor reference number: 22CX7971 REC number: 23/WA/0323
Subject Number:	
Study Site:	
Name of Principal Investigator:	

Patient statement	*Please **initial** all boxes below if you agree*
1. I confirm that I have read and understand the participant information sheet version ..... dated ..... for IP9-ATLAS (**A**pproaches **T**o **L**ong-Term **A**ctive **S**urveillance) and have had the opportunity to ask questions which have been answered fully.	
2. I understand that my participation is entirely voluntary and that I am free to withdraw from the study at any time without giving a reason and without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from Imperial College London and/or their authorised representatives, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records which will identify me by name.	
4. I understand that imaging data from my MRI will be used for research in this study. This will only occur only after the relevant NHS clinical reporting has been completed. The MRI images will be transferred to Imperial with my personal identifiable information through the National Image Exchange Portal for sharing of images. The MRI scans will be anonymised at Imperial and then stored. I understand that these stored images and derived data from analyses on these images might be shared with both academic and commercial partners for this purpose.	
5. I agree to donate the imaging data from my MRI for future academic and commercial research projects. These will be anonymised. I understand that donating these images is a gift for this research, that it is entirely voluntary and that I am free to withdraw my approval for the use of the images at any time without giving a reason and that my medical treatment or legal rights will not be affected by this voluntary donation.	

6. I understand that some of this research could generate information that academic groups and medical companies may use in future for commercial gain and that I will not benefit financially from this.	
7. I give my permission for the study team to contact my GP to inform them of my participation in the IP9-ATLAS Study and also advise them of any medically relevant events during the study as well as any clinically relevant study results.	
8. I give my permission for the central research team at Imperial College London to hold my full name and contact details so that the health status questionnaires can be posted or emailed to me on a regular basis.	
9. I consent to take part in IP9-ATLAS (**A**pproaches **T**o **L**ong-Term **A**ctive **S**urveillance).	

Optional Consent ***If you do not wish to give permission to any of the below, do not initial – you can still participate in the study.***	*Please **initial** box below if you agree*
1. I would like to be sent a copy of the lay summary of the study results once the study has ended	
2. I give permission for the study team to contact my GP for my medical information in the future if we cannot obtain this from your hospital records.	
3. I give my permission for the IP9-ATLAS research team to hold identifiable information such as my name, address, date of birth and NHS number. I understand this will be used to collect healthcare information directly from me and, in future, on me from national records, such as the Office for National Statistics, NHS Digital, Office for Health Improvement & Disparities, and other applicable NHS information system, or national database.	
4. I give consent for anonymised information collected about me to be used to support other research in the future, including those outside of the EEA.	
5. I give consent for prostate tissues samples collected at the time of my diagnostic biopsy before my participation in this study, and prostate tissue samples collected during this study, to be used in future research in an anonymised form. I give permission for my samples to be sent to other organisations, including these outside of the EEA.	
6. I give permission for my name and NHS number to be used as linkage to obtain information about my health status from records held by the NHS and maintained by the NHS Information Centre and the NHS Central Register or any applicable NHS information system (including linkage to routine hospital admission data). I give this consent solely so that researchers may follow up on my health status for 10 years after my participation in the study.	
7. I give permission to be contacted directly by a member of the central / local study research team within 10 years of signing the informed consent form after the study has ended to complete a questionnaire about my health status and quality of life. A member of the study research team may send this request to my home address.	

8. I give consent for anonymised information collected about me to be used to support other research or in the development of a new treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure).	
9. I give consent to being contacted to potentially taking part in other research studies.	

Patient signature		
Your signature confirms that you have had an opportunity to ask questions and that all of your questions have been answered. [You will be given a signed and dated copy of this consent form]		
Patient name (print): _____	Patient Signature: _____	Date signed: _____

Investigator Statement and Signature ***To be completed by the investigator or designee taking consent***		
I have discussed this research study with the patient and/or his authorised representative using a language that is understandable and appropriate. I believe that I have fully informed the participant of the nature of this study and the possible benefits and risks of taking part. I believe the participant has understood this explanation.		
Investigator name (print): _____	Investigator signature: _____	Date signed: _____

When completed one copy should be given to participant and one to be kept in medical notes; the original should be kept in the researcher site file.
To ensure confidence in the process and minimise risk of loss, all consent forms must be printed, presented and stored in double sided format