Audit Template/ Audit response template for HTA licenced premises

Corresponding Audit No:	**Study Title:**
HTA license No:	**Ethics Clearance Code:**
Designated Individual: Karen Coopman	**Audit Date**
Audit Personnel:	**Response Date:**
Member of staff taking consent:	**Audit Location:**
Feedback presented to:	
***Responses presented by:**	
***Responses should be presented by the Principal Investigator, the Associate Dean for Research or the Head of School. Representatives may be nominated to act on behalf of the afore mentioned persons, only in the instance of provision of a counter signature.**	

Audit Summary:

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Names of any additional persons involved in the consenting process. (Fill Horizontally)			
Provide the contact details of persons involved in the consenting process. (Fill Horizontally)			
		Comments/ Suggested Actions. ***To be completed by the auditors**	**Response (and date completed/ intended to be complete if applicable).** ***This is to be completed post audit.**
Environment			
Is the environment suitable? Does the environment balance participant privacy requirement with safeguarding?			
Communication			
Are there copies of the consent form and the participant information sheet available for recap?			

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Is the written information in a format and language that is easy for the participant to understand?			
Is the consenting session conducted in a professional manner, i.e.; no unnecessary interruptions, attention towards the participant?	.		
Is the verbal information conveyed step by step, and in a manner and language that is easy to understand?			
Have the investigators ensured comprehension of the study by asking the participant to confirm what they think the study involves (this is particularly important for children and vulnerable groups)			
Has the participant been given the opportunity and been invited to ask questions?			
Has the participant been asked whether or not they have had the chance to			

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consult others in their decision.			
Has the participant been given the time stated on the ethics as a minimum to consider the information given prior to signing the consent form? (24 hours minimum). Initial dissemination of information MUST not take place at the same time as consent is being obtained.			
Are there any signs of coercion?			
Is the consent form appropriate for the audience, i.e. child assent form used for minors etc.			
Storage			
If enduring consent has been requested, has the meaning of this been made clear to the participant.			
Withdrawal of Consent			

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Has it been vocalised to the participant that they can withdraw their consent?			
Have any limitations on consent withdrawal been made clear? I.e. if the sample has already been analysed / publication already in press?			
Research misconduct			
Has the participant been informed of the research office and how to lodge a complaint if needs be.			

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The Comments/ Actions recorded above, on 22/06/2021 are accurate and correct to the best of my knowledge.

***Signature of Auditor Print Name……**

The responses recorded above, on 22/06/2021 are accurate and will be actioned and complete by the date agreed with the auditors.

Signature of the Designated Individual; …… Print Name

Signature of Investigator……

Date agreed for actions to be complete……

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Date for re-audit (if applicable) ……

Audit Report Template for HTA licenced premises

Corresponding SSEHS Audit No: xxxxx	**Area/Lab audited:**
HTA license No:	**Person Designated:**
Designated Individual:	**Audit Date:**
Audit Personnel:	**Response Date:**
Other personnel present during the audit:	
Feedback presented to:	
Responses presented by:	