National School of Healthcare Science

NHS England

IACC 2023 Case-based discussion (CBD) scenario

Specialty:	Respiratory and Sleep Science

CBD Scenario

CBD Scenario Title	How can the ethical approval process differ between producing an audit and conducting an investigative research project?								
CBD Scenario Aim	To assess the trainees understanding of the ethical approval process and how research ethics apply differently to audit, service evaluation, and research.								
CBD Focus (please provide the codes of the module(s) this scenario addresses)	*STP Project (SC3)*								
GSP Domains covered (enter X to indicate all that apply)	**GSP 1**		**GSP 2**		**GSP 3**		**GSP 4** ✓		**GSP 5**
CBD Scenario description	You have been asked to acquire and analyse some data within your department as part of a service development project. You have been informed it involves prospectively capturing data from patients that are not typically gathered in standard practice. Does this project require ethical approval? What different types of ethics approval processes should you consider and how do these pathways differ?								
CBD Scenario model answer/ assessor guidance Detailed guidance that will be available for the assessors. Include guidance on what kinds of behaviours, actions, comments should secure a pass. What should the assessor expect to see? Assessors will be asked	The trainee will be asked to perform what would be considered a research project guised as a service evaluation. The aim is to allow them to discuss the differences between service evaluation and research. The student will be able to demonstrate that they understand the difference in the ethical and research governance pathways for different types of research and understand that it is governed by law. They should describe the following:								

to plan questions in advance including links to trainee's IACC submission.	• All forms of research and service evaluation require some degree of approval • They should know to liaise with the hospital R&D department • Demonstrate they understand ethical review bodies depending on the nature of the project • Integrated research application Service (IRAS) filter questions • Which projects require Research Ethics Committee (REC) approval and / or health research approval (HRA) * *in Wales: Health and care research for Wales (HCRW)** Examples requiring REC 1. NHS patients/service users (including potential participants recruited by the patient or user's past or present treatment and NHS patients treated under contracts with private sector institutions) 2. Potential participants identified because of their status as relatives/carers of patients and users of the NHS 3. Access to data (unless anonymised), organs or other bodily material (including DNA extracted from acellular material) of past and present NHS patients 4. Foetal material and IVF involving NHS patients 5. Recently dead in NHS premises 6. Healthy volunteers where a drug or device is being tested within the NHS 7. Research tissue bank Examples requiring HRA but excluding REC 1. Research limited to secondary use of non-identifiable data previously collected during usual care with no intention to use it for research at the time of collection. 2. Research limited to secondary use of non-identified tissue samples previously collected during usual care with consent for research 3. Research limited to use of non-identified acellular material (e.g., plasma, serum) extracted from tissue previously collected during usual care 4. Research involving health or social care services staff, who are recruited by virtue of their professional role (no patient involvement) Fail Criteria The trainee does not demonstrate an understanding of the process, and fail to mention trust R&D, IRAS filter questions and research ethics committee (REC) approval / health research approval HRA.
Trainee instructions Please include any specific information to be provided to the trainee	

as part of the CBD scenario	

Criteria being assessed by this CBD scenario

Aspect	Please indicate if this criterion is being assessed
1. Understands the clinical context of the scenario, including priority setting and testing strategies	
2. Understands scientific principles of scenario	✓
3. Can discuss the relevant procedures involved in the scenario and associated health and safety issues	✓
4. Understands and applies the appropriate test validation, IQC, EQA, relevant professional/clinical guidelines	
5. Understands and applies associated IT/bioinformatics and other appropriate resources	
6. Is able to interpret and report patient results and provide appropriate clinical advice	
7. Can discuss the significance of patient results within the clinical context of the referral	
8. Understands the ethical, legal and social implications of the scenario	✓
9. Is aware of the importance of audit and can use this tool effectively	✓
10. Output meets accepted laboratory/professional standards	
11. Demonstrates awareness of the limits of responsibility and when to seek advice	
12. Consideration of patient/professionalism	
13. Overall ability to perform	