UNIVERSITY COLLEGE DUBLIN

UCD Internal Audit

Research Ethics Compliance Review (Humans)
Internal Control Questionnaire

Version 2.0

No.	Audit Objective	Audit Test Questions / Procedures	Response / Result / Finding (Attach documentation if relevant)
1.	**Awareness of Policies and Guidelines (Q3)** Audit Objective is to confirm that staff and students have informed themselves of the relevant HREC Policies and Guidelines.	Have you read: HREC 1 – 8 Guidelines and Policies for Ethical Approval of Research involving Human Subjects UCD Data Protection Policy Data Protection Guidelines on Research in the Health Sector	

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2.	**Insurance Cover (Q2)** Audit Objective is to ensure that confirmation of insurance has been obtained from the University Safety Office.	Discuss with team leader and obtain copy of confirmation from Safety Office or check directly with Safety Office records.	

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3.	**Changes following Ethical Approval (Q1, Q4 – Q7)** Audit Objective is to confirm the HREC has been informed of changes following ethical approval. These changes should be notified to HREC on Form HREC10.	Discuss with team leader to ascertain: Have there been any changes in the research team since the original ethical approval was received from HREC? Obtain a copy of the original ethical approval and compare to current team membership. Obtain a copy of any notification to HREC re changes in team membership. Have any ethical issues not previously identified in the initial application arisen in the course of the study? Was the HREC informed? Obtain copy. Have there been any changes in the inclusion and exclusion criteria of the participants recruited into the study since receiving ethical approval for the study, and if so, has the HREC been informed.	

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		Obtain copy. Have there been any changes in the method of recruitment since receiving ethical approval for the study, and if so, has the HREC been informed? Obtain copy. Has the information leaflet been altered since receiving ethical approval for the study and if so has the revised information leaflet received approval from the HREC? Obtain copy.	

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4.	**Data Protection (Q8 – Q17)** Audit Objective is to confirm that records are maintained in compliance with data protection requirements.	Discuss with team leader to ascertain: In the course of the study were participants apportioned codes, or were they de-identified, for the purpose of collecting personal data? If coded: Where are the records linking codes to participants stored? Where are individual signed consent forms stored? What arrangements are in place to ensure that the identity of each participant remains confidential? Have participants withdrawn from the	

		study? If so, was their personal data identified and destroyed? How was the data destroyed? Who is responsible for the management of the records, including the security of participants' personal data? Has this person been replaced since receiving ethical approval for the study, and if so has the HREC been informed? Where/how are paper/electronic records containing personal data stored? What is the method of destruction of the data at the conclusion of the approved retention period? Where PCs/laptops are used, are they password protected/encrypted (encryption is compulsory when using laptops)?	

		Have any of the following recording devices been used for the collection of personal data during the research study? a. Audio/Sound recorder (tape/cds) ☐Yes ☐No b. Photography(incl. digital cameras/phones) ☐Yes ☐No c. Film/Video/DVD recorder ☐Yes ☐No d. Other ☐Yes ☐No If yes Where/how is this data stored? What is the method of destruction of the data at the conclusion of the approved retention period?	

		Please confirm that the data are used and stored in compliance with Data Protection guidelines (i.e. UCD Policy, DPC Guidelines). *See Audit Objective 1 above.* Where a study has ceased or is complete, has the data been deleted/destroyed? What was the method of destruction?	

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5.	**End of Study Report (Q18)** Audit Objective is to ensure that a HREC End of Study Report has been submitted to HREC on completion of each study.	Discuss with team and leader and obtain copies of any End of Study Reports submitted to HREC.	

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6.	**Reporting of Adverse Events (Q19)** Audit Objective is to ensure that any adverse events in the course of the study have been reported to HREC.	Discuss with team leader to ascertain if there have been any adverse events and, if so, whether these adverse events were reported to HREC. Obtain copy of any correspondence with HREC in relation to adverse events.	