NUFFIELD DEPARTMENT OF
PRIMARY CARE
HEALTH SCIENCES

UNIVERSITY OF OXFORD

Audit Reporting Obligations
Standard Operating Procedure

Version	1.0
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1. Purpose and Scope

The University of Oxford - Nuffield Department of Primary Care Health Sciences (the Department) has established the procedures outlined in this *Standard Operating Procedure* (SOP) for reporting audits to which the Department is subject.

2. Introduction

This SOP applies to any audit and/or review (collectively, referred to as "Audits") conducted by internal and external auditors ("Auditors").

a) Internal Audit

An "internal" Audit generally refers to those which the University and/or the Department conducts to monitor compliance with data protection or other requirements, including those set forth in University and Department Policies and SOPs. Examples include: Audits by teams from within the University, such as Information Security, Information Compliance, Research Governance, Ethics & Assurance Team, etc. as well the Department IT/IG.

b) External Audit

An "external" Audit generally refers to one which an organization outside the University conducts to monitor compliance with data protection and related research requirements. Examples include, but are not limited to, the following:

• NHS Digital -Standards from DSPT toolkit) • NHS Digital - terms from data sharing agreement for datasets hosted by the Department; • Information Commissioners Office/Data Sharing Code of Practice • UK Statistics Authority/Office for Statistics Regulation - Code of Practice for Statistics • MHRA - Good Clinical Practice (GCP) and other inspections	• UK DHSC - Guide to Good Practice for Digital/Data-driven Health Technologies • NHS - Code of Conduct for Artificial Intelligence (AI) systems • UK Medicines for Human Use (Clinical Trials) Regulations 2004 • eCRF compliance for CTUs • Study / Trial Sponsors

3. Required Procedures

The Senior Manager or designee of the research area subject to the Audit must notify the Department SIRO, Head of IT/G and IG Manager (for the latter via the IG mailbox: datasecurity@phc.ox.ac.uk) within two (2) business days of receipt. The notice from the Senior Manager or designee will include the following information: (i) the scope of the Audit; (ii) when it will occur; (iii) due dates for any required documentation as well as (iv) the documentation provided by the Auditor.

The IG Manager will provide the IG Committee with updates on Audit outcomes and action plans.

Refer also to the IG109 Incident Reporting and Management Policy for more information on Incident referrals.

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Review History: Reviewed on 19/10/2021 by IGC Chair, SIRO, IT/G Head and IGM. Approved with recommendation for adoption as proposed.