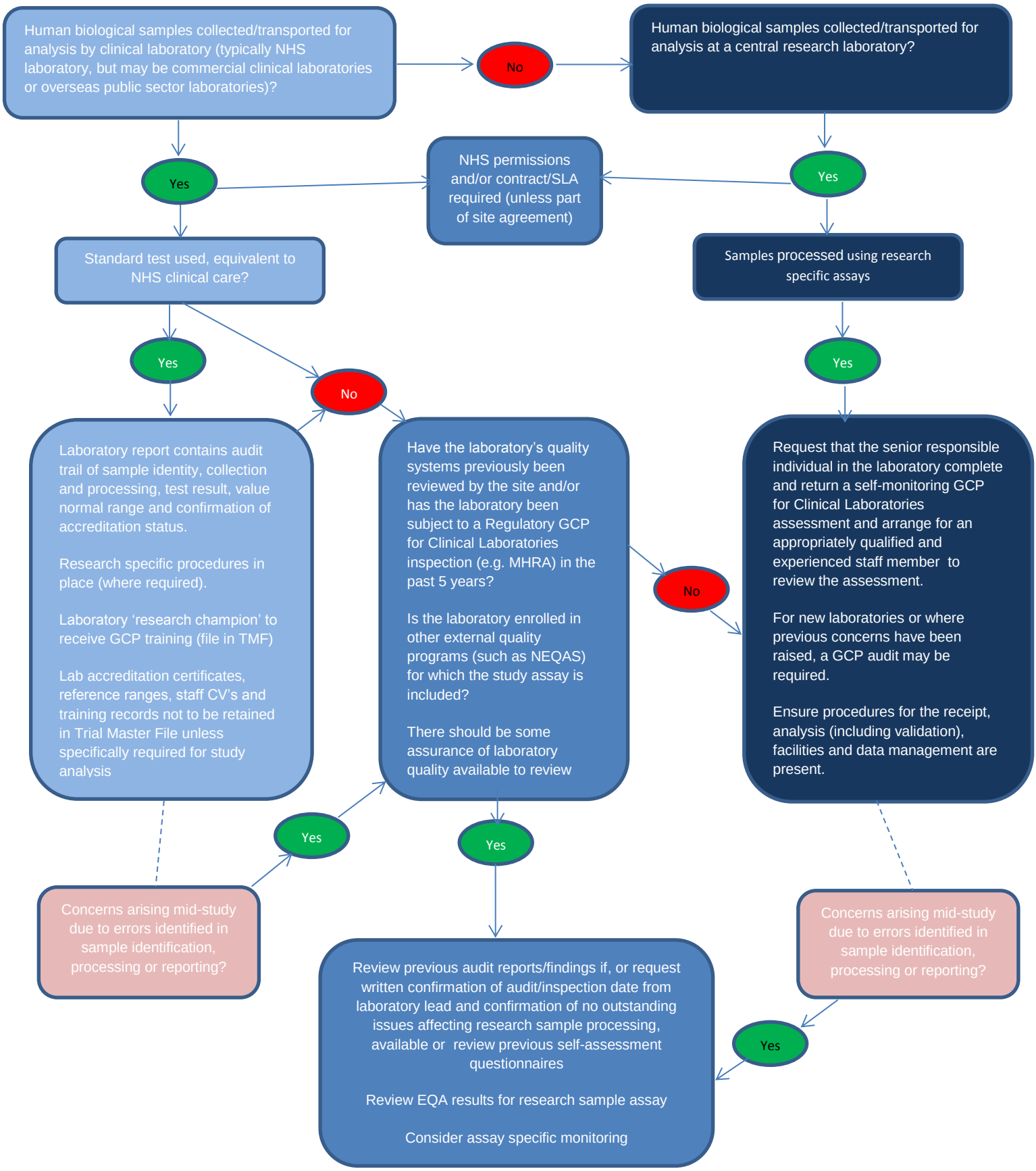
UKCRC
Registered
Clinical
Trials Units

# Flowchart for Oversight of Laboratories by CTUs

UK CLINICAL RESEARCH COLLABORATION

igniting our potential




**If concerns persist or may constitute a potential serious breach**

Consider commissioning a GCP for Clinical Laboratories audit of the facility on behalf of the study sponsor.

The study Trial Management Group (TMG) should consider consulting the Trial Steering Committee (TSC), Data Monitoring Committee (DMC) and/or any other trial oversight committees available when recommending this course of action, to confirm it is a necessary measure. If not represented on the TSC, the sponsor may be consulted separately.

Any audit should be conducted by an appropriately qualified and independent laboratory auditor. Cost implications may need to be discussed with study funder and/or sponsor where no budget is available to conduct such an audit.

UKCRC CRN Flowchart for oversight of laboratories by CTUs v1.0