RDS – Clinical Governance Workflow

Author: Suzy Wignall, Clinical Governance Advisor

## Study Progress Reporting

If the study has received NHS REC approval, then an Annual Progress Report (APR) should be submitted annually, with the first being submitted 12 months after the date of the favourable opinion.

For *non-interventional studies* - complete the APR on the appropriate NRES APR form, found on the HRA website – www.hra.nhs.uk and submit to the REC that granted the FO, in hard copy or email.

Forward the APR to the Sponsor and NHS R&D departments that have granted their Trust agreement.

With regard to interventional projects, the CI should forward the draft APR to the Sponsor for review and comment, at least two weeks before the submission date.

The REC will acknowledge within 30 days or receipt and may invite the CI to meet to discuss study progress. They may write to the CI to request further information.

File the APR and correspondence in the TMF. If an APR is not received by the REC in time, they will issue a reminder. If not submitted within a month, then study termination may be considered.

If a CTIMP, then a Development Safety Update Report (DSUR) should be submitted to the MHRA and NHS REC. They are submitted annually, with the first being due 12 months after the date the CTA was granted. Submit within 60 days.

In completing a DSUR, the SmPC/SPC and/or the IB should be reviewed to ensure that the safety profile does not require updating. The DSUR should be forwarded to the Sponsor at least two weeks before the submission date for review and comment.

Submit the DSUR via http://cesp.hma.eu/Home and send to the NHS REC that granted the FO, along with a completed CTIMP safety report – template from the HRA website.

File all reports and correspondence in the TMF.