Research Ethics Committee (CONFIRMED Minutes)

Wed 02 March 2022, 14:00 - 15:30

Online

Attendees

Board members

John Stevens (Independent Chair), Donald Gobbett (Independent Deputy Chair), Chris Chapleo (Academic Staff Member), Tanya Le Roux (Academic Staff Member), Joseph McMullen (PGR Representative), Andy Mercer (Academic Staff Member), Jonathan Parker (Chair, Social Sciences & Humanities REP), Sam Porter (Chair, Science, Technology & Health REP), Natalie Stewart (Doctoral College Representative), Liam Wignall (Academic Staff Member), Suzy Wignall (Clinical Governance Adviser), Sarah Bell (Secretary)

Absent: Zulfiqar Khan (Academic Staff Member), Jamie Matthews (Academic Staff Member)

Meeting minutes

1. Welcome & Apologies

Information
John Stevens

Members were welcomed and apologies from absent members noted.

2. Minutes of last Meeting (November 2021)

John Stevens

It was agreed that the minutes were an accurate account of the last meeting.

3. Conflicts of Interest

John Stevens

No conflicts of interest were reported.

4. Update on Actions

Information
Sarah Bell

Online Ethics Modules (Epigeum) had been renewed for another 3 years.

S Bell to conduct a scoping exercise into the possibility of BU producing its own bespoke training modules.

5. STH REP Report

Discussion
Sam Porter

The Chair reported the following:

Discussion times at live panels have incrementally increased of late, to the point where the efficiency of the panel was in danger of being compromised. The Chair had taken a liberal approach to enable all members of the panel to contribute to the extent that they see fit. In response to some disquiet about the extended and repetitive nature of some discussions, the panel is now engaged on an experiment with two alternatives. The first, which was used in February and will be used again in March, involves allowing each member of the panel to raise a single point initially. After all panel members have had the opportunity to raise a point, then any allotted time remaining is opened to all. This worked well in February, with the additional benefit of facilitating all to contribute. The second alternative is to adopt the system of first and second Reviewers. This approach will be applied in April. Panel will then decide which alternative is preferable.

The second issue involves a managerial decision to halt a trial that was part of a PhD project. The trial had a Favourable Opinion following an ethics review by an ethics champion following identification of the study as low risk by the supervisors involved. An adverse incident was subsequently reported and investigated with the involvement of the Ethics panel Chair. While it was deemed that the incident was not indicative of significantly increased risk, the manager of the research institute where the research was conducted did not feel it appropriate to allow the study to continue in its present form. The issue of when it is appropriate to gain ethical permission via the appropriate BU ethics review process and when NHS IRAS is required is one that needs further exploration.

Action: RDS Governance Team to conduct a random audit of low risk PGR checklists approved by Ethics Champion.

6. SSH REP Report

Discussion
Jonathan Parker

One main concern for discussion:

The Chair raised a discussion point on how ethical scrutiny might work more smoothly in matters of evaluation (organisational projects), where the work may not need to be subject to the usual strict research ethics scrutiny and the later requests for permissions to publish from the data – an ethically appropriate aspiration – have been undertaken within panel.

After discussion, it was agreed that a light touch approach to a review was appropriate under these circumstances.

7. Clinical Governance Update

Discussion
Suzy Wignall

Monitoring of NHS REC projects continue (both in person and online). Over the next couple of months, a number of PhD clinical projects will be closing and therefore final monitoring/closing visits will be undertaken.

An update on the Compliance and Licenced Activity Committee (CLAC). CLAC have met twice (agreeing Terms of Reference). The Terms of Reference for the sub committees (which will report to CLAC) such as the Human Tissue Working Group have now been agreed.

Juan Campos-Perez (Clinical Research Coordinator) presented a flow chart for regulated activities. The RDS Governance Team would support projects through a risk analysis and advise on appropriate pathway (sub committee).

CLAC also discussed with the Human Tissue Working Group suitable IT solutions, to enable progression with the licence to continue.

8. Clinical SOP updates

Decision
Suzy Wignall

Minor changes to the following SOPs were considered and ratified by the Committee:

- BU RDS SOP 017 - Sponsorship Role v2
- Information Document - Types of Clinical Studies v2

9. Safety Reporting (non clinical research)

Discussion
All

To centralise the process for reporting adverse events, it was recommended to introduce an adverse event standard operating procedure.

Following discussions it was agreed to ratify the SOP following minor amendments with changes to the Ethics Code of Practice to highlight the centralised approached to safety reporting.

The ethics checklist will also have an additional question added which covers adverse events (data collection activity section).

10. Ethics review process for Organisational Projects

Discussion
Jonathan Parker

This had been discussed as part of the SSH REP Chairs Report.

11. Matters Arising

John Stevens

No further matters were raised by members

12. Any other Business

John Stevens

The matter was raised in relation to the transfer of projects and ethics. The current research ethics code of practice (RECP) is silent on the point of ethics and what should happen in the event an active research grant is transferred to BU. The Committee agreed that this should be added to the RECP.

Action: S Bell to add to the RECP 'ethics and transfer of research grant' to Section 7 Researchers Responsibilities.

13. Date of next meeting - 6 July 2022 Information