

## **LESSONS LEARNED FOR HIGH RISK APPLICATIONS TO THE UCL REC.**

1. There is an advantage to getting applications in earlier than the deadline.
  - The ethics officers often do a 'pre-screen' before the committee meets. The earlier you get your application to them, the earlier you will receive comments from the pre-screen, giving you more time to revise, a better chance of being seen and evaluated favourably in the next ethics committee meeting.
2. **RESPOND** to feedback from your local ethics chair.
3. If this links to a previous proposal, you can help the REC by highlighting: **WHAT** the similarities were, **WHAT** the ethical issues were, **HOW** you responded to them, including how you responded to any previous issues raised.
  - Simply stating "This is similar to application no: xxxx, which was previously approved" will not help, as the REC want to 'check', and won't have the time to do so. Make it easy for them...
4. If you want to submit an amendment to a 'low risk' element of your 'high risk' ethics, you should send it first to your departmental ethics chair, who will forward it to the REC with a cover letter stating if they advise approval. This will expediate amendments.
5. Durations of studies (how long each session will be for a participant) should be clearly indicated. Where studies form part of a program application, the upper time duration permitted for any individual study should be indicated.
6. Program applications should be explicit in their 'exclusionary criteria' – that is, when a study would cease to be covered under this program ethics.
7. Program applications for high risk projects should not be too broad. If in doubt, better to split applications into separate applications. In all instances where local ethics chairs have recommended 'splitting', this has been aligned with the feedback from the central UCL REC (see point 2!).