

HALOCLINE
COACHING &
CONSULTANCY

Inside the REC

Sophie Welch

A candid look inside the workings of the research ethics committee, and an exploration of the factors likely to inform the outcome of the ethical review process.

Stage 1: Principled

(1) Principled: Does this respect the rights, autonomy, dignity, and wellbeing of the participant? Has the applicant considered these principles? Do they show due respect for the participant? Is there differentiation between consent to treatment and consent to research? In TwiCs design consent is patient centred, but (how) can randomisation without consent respect patient autonomy and dignity? Consider 'pre-consent to randomisation to future unspecified studies' (re: Flory et al, p.6).



Stage 2: Evidence-based

(2) Evidence-based: Do not assume familiarity with the methodology. Is the protocol transparent? Is there a strong (ethical) justification for proposing this methodology? Is there a sound evidence base? Is it in the interests of the participant, the researcher, or the research itself? Is the peer review comprehensive and supportive? Remember: the welfare of participants comes first, and an argument of efficiency requires a strong ethical justification.

Stage 3: Self-referential

(3) Self-referential: Am I familiar with this methodology? Have we considered similar applications? What is my gut feeling? Lay member: how would I feel if I was a participant, and what would I want to know? (Refer to patient engagement, patient preference, TwiCs acceptability surveys.) Expert: would I consider this methodology in my projects? (Refer to precedents).

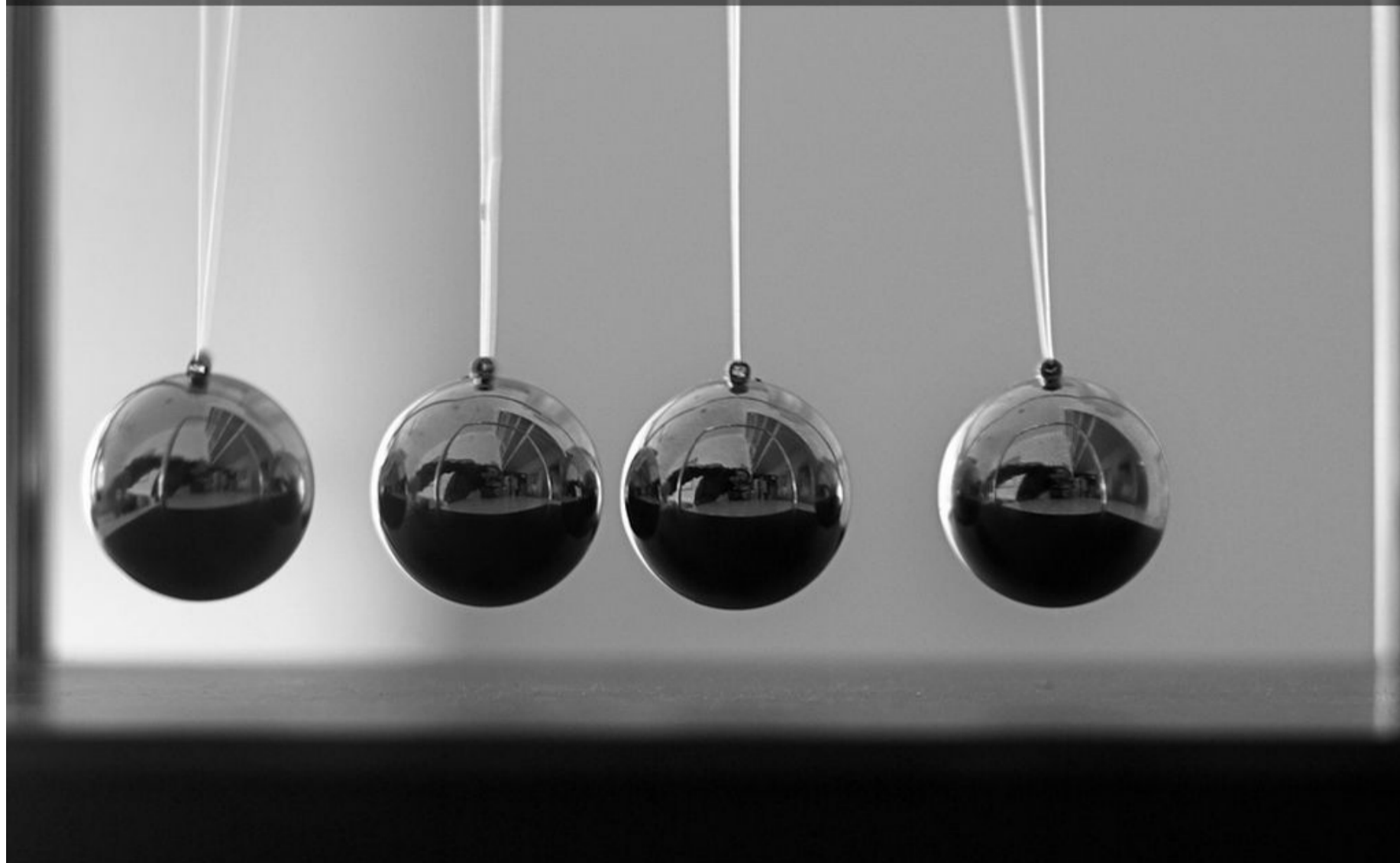
Stage 4: Perspective seeking

(4) Perspective seeking: Is anyone else familiar with this methodology? What are their views? Are they persuasive? Do I trust them? What does the Chair think? What do the EU Clinical Trial Regulations (2004/2014) say? What about HRA, MRC, and NREAP guidance? (Refer to TwiCs Symposium).

Stage 5: Precedent seeking

(5) Precedent seeking: Has a similar project been approved before? In the UK? How long ago? Who was the sponsor? (Reputable?) And the funder? (RCUK?) Is randomisation without consent ever considered ethical? Yes, in emergency research (and cluster randomisation, US) where consent is not feasible...

An invitation to you.



Summary and invitation: It is within your gift to engage proactively with all five of these stages as you prepare your ethics application. RECs exist to facilitate ethical research, and by approaching review from a position of integrity (honesty, rigour, transparency and open communication, care and respect) and collaboration you will be well placed to navigate the ethical review process.

**HALOCLINE
COACHING &
CONSULTANCY**

Questions?

sophie@haloclinecoaching.com