From: OC GCP Questions
To: [redacted]
Subject: Seek your advice on IEC related cases
Date: Monday, March 28, 2016 7:07:11 AM

Good morning –

Please see FDA's IRB Information Sheet for IRB membership.

Search for FDA Guidance Documents > Institutional Review Boards Frequently Asked Questions - Information Sheet Please see Section II – Membership

Additionally, FDA's regulations on Institutional Review Boards (21 CFR Part 56) specifically 21 CFR 56.107 (IRB Membership) address the qualifications, expertise, diversity, primary concerns, and conflict of interest of IRB members. 21 CFR 56.107 (a) states:

Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

There are two specific regulations which can be seen as more on point to the question you are asking. They are 21 CFR 56.107(d) and 21 CFR 56.107(e) which respectively state:

Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The regulations do not specifically address membership nationality.

I can also point you to FDA's compliance program for IRBs. This document discusses IRB membership as well.

www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133768.pdf

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Saturday, March 26, 2016 2:42 AM
To: OC GCP Questions
Subject: Seek your advice on IEC related cases

Dear Sir,

Good Afternoon...

I am [redacted] working in clinical research field and seek your valuable advice related to IEC Member eligibility on following cases. Request to guide me please.

1. Is it must to have nationality of same country to become member in Ethics Committee? For e.g. Only US Citizen can become IEC/IRB member in US or any nationality person can become IEC Member in US.
2. Can a person with dual nationality become IEC member in both country or any one country?
3. Can HUSBAND and WIFE become member of two different IEC (husband in X IEC and wife in Y IEC), And CRO can take services of that both the IEC?
4. Will USFDA accept protocol approval obtained from IEC whose member was not citizen of particular country. But Was belongs to other country and participated in voting for opinion on protocol (Study conduct outside USA)?

Thanks in advance for your guidance,

Regards,
[redacted]