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To: [REDACTED]
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Date: H1 YgXhzt >Ubi Ufm&+2 &S% %& &). \$\$ DA

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67. Several comments stated that FDA should allow meetings to take place by conference calls. These comments argued that effective dialogue can occur between IRB members on conference calls without forcing the members to be physically present in one room.

Although FDA, like HHS, encourages meetings to take place with members physically present in the room, FDA also recognizes that in some cases time and commuting expense would favor conference calls. As long as each IRB member can actively participate in any discussion of a protocol and has all pertinent material before the call, FDA has no objection to allowing meetings to occur in such a fashion and will consider meetings that take place by conference call to be "convened" meetings. These meetings must follow the same requirements (minutes, etc.) as meetings with members physically present.

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14. When IRB members cannot attend a convened meeting, may they send someone from their department to vote for them?

No. Alternates who are formally appointed and listed in the membership roster may substitute, but ad hoc substitutes are not permissible as members of an IRB. However, a member who is unable to be present at the convened meeting may participate by video-conference or conference telephone call, when the member has received a copy of the documents that are to be reviewed at the meeting. Such members may vote and be counted as part of the quorum. [emphasis added] If allowed by IRB procedures, ad hoc substitutes may attend as consultants and gather information for the absent member, but they may not be counted toward the quorum or participate in either deliberation or voting with the board. The IRB may, of course, ask questions of this representative just as they could of any non-member consultant. Opinions of the absent members that are transmitted by mail, telephone, telefax or e-mail may be considered by the attending IRB members but may not be counted as votes or the quorum for convened meetings.

HF C r gto ku KTD o go dgt r ctvlekr cvklp kp c eqpxgpgf o ggvlpi xlc vgrjr j qpg qt xlf gqeqphgtgpeklpi cu npi cu gcej KTD o go dgt ecp cevkgm{ r ctvlekr cvg kp cp{ f kuewukp qhc r tqvqncpf j cu cmr gtlvpgpvo cvgtkndghgtg vj g o ggvlpi 0 [qwuuj qwrf eqpukf gt lpenf lpi kphqto cvklp kp vj g KTD y tkwgr r tqegf wgu cdqwj qy vj g KTD eqpxgpgu vj g o go dgtu qh vj g KTD hqt c o ggvlpi cpf y j cvkur gto kwgf tgi ctf lpi cwpgf cpeg cvc eqpxgpgf o ggvlpi *g0 0 kp r gtuqp. xlc vgrgqphgtgpeklpi . xlf gqeqphgtgpeklpi . qt qvj gt o gej cpluo +0 Cnuj. vj g o kpwgu qh vj g KTD o ggvlpi uj qwrf o cng engct y j lej o go dgtu. khcp{. r ctvlekr cvgf kp vj g eqpxgpgf o ggvlpi xlc cp cngtgcwkg o gej cpluo . uvej cu vgrjr j qpg qt xlf gqeqphgtgpeklpi 0

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From: [REDACTED]
Sent: Monday, January 26, 2015 3:29 PM
To: OC GCP Questions
Subject: IRB Convened meetings

I am wanting more information regarding IRB meetings convened via telephone or video conference call. Most of our members are physically present at the meetings but there may be circumstances in which a member(s) is not able to be physically present. Of note, all members receive the same information to be reviewed electronically prior to each meeting. I found a letter from DHHS dated March 28, 2000 that references this however I am unable to locate any documentation that is more recent. Can you please advise?

Thanks,
[REDACTED]