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Sent: Thursday, June 14, 2018 3:22 PM
To: 'UKORI-IRB-L@lsv.uky.edu'
Subject: General Announcement: NIH Certificate of Confidentiality (CoC) and Participant Payment

National Institutes of Health (NIH) Certificate of Confidentiality (CoC) and Participant Payment

NIH funded studies that were ongoing or started after December 13, 2016 that collect "identifiable, sensitive information" from subjects, are deemed to have a Certificate of Confidentiality. The following information is provided to clarify the implications of an NIH issued CoC.

1) If research subjects are paid $100 or less per occasion for study participation and cumulative payments do not exceed $600 in a calendar year, subjects ID or name is the only required data for payment via Business Procedures Manual E 9-1 Compensation to Research Subjects. Most research investigators with a CoC fall into this category.

2) If research subjects with a reportable condition are paid $100 or less per occasion for study participation, subjects can still be paid under provision 1) listed above. The condition, however, is reportable per state law by a health professional if a reportable disease or by the researcher for other reportable events. For reference, see the ORI summary of Kentucky reporting requirements.

3) If payment(s) to a subject total $600 or more/year, the income has to be reported for tax purposes. The following verbiage, which can be found in the UK ORI/IRB informed consent template, shall be included to inform subjects of this fact: "*With a few exceptions, study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year*"

4) At the request of a PI, ORI also consulted with an NIH CoC coordinator regarding entering research information protected by CoC into the medical records. NIH stated the following in response:*Per the new CoC statute, identifiable research information can only be disclosed to those not involved in the research if it is required by other federal, state or local laws (except for legal proceedings), or for other research in compliance with federal human subjects regulations, or with the consent of the subjects. Generally, placing research information protected by a CoC in a subject's medical record would require the subject's consent.*

5) UK ORI will only provide a CoC certificate of acknowledgement for NIH CoC issued studies where subjects need additional protection for payment purposes.

6) The UK ORI/IRB informed consent template contains NIH issued CoC language to be included in the consent form to inform subjects of the protections of the CoC.

7) If a PI is using a non UK IRB, the PI is required to abide by the UK policies and procedures in regards to CoC and payment to research subjects (as well as local IRB requirements).

Additional information about NIH CoC is available at the NIH CoC Frequently Asked Questions website.