



Office of Research
Integrity and Compliance

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TO: Principal Investigators
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FROM: Annie Muñana 
Director, Office of Research Integrity and Compliance
Children's Memorial Research Center

DATE: September 26, 2007

RE: Policy on Research Involving Human Cell Lines

The following policy is being adopted immediately regarding research involving the use of human cell lines.

Note: *This policy does not apply to human embryonic stem cells.*

Research involving coded and de-identified specimens, such as human cell lines, does not require an exempt determination by the Institutional Review Board (IRB) as it does not constitute research involving human subjects as defined in the Code of Federal Regulations CFR 46.102(f) as put forth by the Department of Health and Human Services (DHHS) and Office for the Protection of Research Subjects (OHRP).

Specimens are considered coded/de-identified when all identifying information, (such as name or social security number), that would enable the investigator to readily ascertain, either directly or indirectly, the identity of the individual to whom the specimens pertain has been removed and replaced by a number, letter, symbol or combination thereof.

Investigators submitting research proposals to the IBC that involve the use of human cell lines must provide assurance that the specimens are coded/de-identified and that the investigator will not obtain, receive or access any identifiable private information relating to the human cell lines.

In order to assist in the implementation of this policy, the Office of Research Integrity and Compliance will revise the current IBC registration form to address this type of research.

Investigators who have questions related to this policy, such as what is considered identifiable information or are unsure of whether or not their research involves human subjects, should contact the IBC or ORIC for guidance.

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